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This bulletin should be shared with all health care practitioners and managerial members of the provider staff. Bulletins are available at no cost from our website: http://www.wpsgha.com

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Items of Importance

ALL PROVIDERS ARE EXPECTED TO SUBSCRIBE TO WPS GHA MEDICARE ENEWS - SIGN UP TODAY!

WPS GHA is pleased to offer the convenient services of our WPS GHA Medicare eNews to all providers in our jurisdiction. WPS GHA Medicare eNews is an electronic newsletter sent to you via email. When you subscribe, WPS GHA Medicare eNews will bring the latest Medicare news directly to your email box, free of charge! You may unsubscribe at any time, and, as with all aspects of the WPS GHA publications, we value your privacy and will never disclose, give, sell or transfer any personally identifiable information to third parties.

WPS GHA Medicare eNews announces the posting of the following:

- Time-sensitive national and local Medicare news
- Medicare program changes
- Policy updates, including new, retired, and revised policies
- Training events (including seminars, teleconferences, webinars, and on demand trainings!)
- Communiqué newsletters
- Specialty- and service-specific educational articles
- Much, much more!

It is important to note that the Centers for Medicare & Medicaid Services (CMS) requires Medicare contractors (including WPS GHA) to increase provider subscribership to their eNews every year. In addition, CMS has instructed that every Medicare provider (including physicians, nurses, and billing staff) should be subscribed to eNews. It is a common misconception that only one provider in an office can be subscribed to WPS GHA Medicare eNews; CMS and WPS GHA encourage and expect all Medicare providers to subscribe to eNews.

Sign up today! Visit our website at https://corp-ws.wpsic.com/apps/commercial/unauth/medicareListservUserWelcomeLoadAction.do to subscribe (it only takes a minute). And if you know a co-worker or another Medicare provider who isn't receiving WPS GHA Medicare eNews, let them know that they're missing out on a very informative educational resource and direct them to https://corp-ws.wpsic.com/apps/commercial/unauth/medicareListservUserWelcomeLoadAction.do to sign up as well!

CENTRALIZED BILLING FOR FLU AND PNEUMOCOCCAL (PPV) VACCINATION CLAIMS

Centralized billing is a process in which a provider, who provides mass immunization services for influenza virus and Pneumococcal (PPV) immunizations, can send all claims to a single contractor for payment regardless of the geographic locality in which the vaccination was administered. (This does not include claims for the Railroad Retirement Board, United Mine Workers or Indian Health Services. These claims must continue to go to the appropriate processing entity.) This process is only available for claims for the influenza virus and pneumococcal vaccines and their administration. The administration of the vaccinations is
reimbursed at the assigned rate based on the Medicare physician fee schedule for the appropriate locality. The vaccines are reimbursed at the assigned rate using the Medicare standard method for reimbursement of drugs and biologicals.

Individuals and entities interested in centralized billing must contact CMS central office, in writing, at the following address by June 1 of the year they wish to begin centrally billing.

Centers for Medicare & Medicaid Services  
Division of Practitioner Claims Processing  
Provider Billing and Education Group  
7500 Security Boulevard  
Mail Stop C4-10-07  
Baltimore, Maryland 21244

By agreeing to participate in the centralized billing program, providers agree to abide by the following criteria.

Criteria for Centralized Billing

- To qualify for centralized billing, an individual or entity providing mass immunization services for influenza virus and pneumococcal vaccinations must provide these services in at least three payment localities for which there are at least three different contractors processing claims.
- Individuals and entities providing the vaccine and administration must be properly licensed in the state in which the immunizations are given.
- Centralized billers must agree to accept assignment (i.e., they must agree to accept the amount that Medicare pays for the vaccine and the administration). Since there is no coinsurance or deductible for the influenza virus and pneumococcal benefit, accepting assignment means that Medicare beneficiaries cannot be charged for the vaccination, (i.e., beneficiaries may not incur any out-of-pocket expense). For example, a drugstore may not charge a Medicare beneficiary $10 for an influenza virus vaccination and give the beneficiary a coupon for $10 to be used in the drugstore. **Note:** The practice of requiring a beneficiary to pay for the vaccination upfront and to file their own claim for reimbursement is inappropriate. All Medicare providers are required to file claims on behalf of the beneficiary per §1848(g)(4)(A) of the Social Security Act and centralized billers may not collect any payment.
- The contractor assigned to process the claims for centralized billing is chosen at the discretion of CMS based on such considerations as workload, user-friendly software developed by the contractor for billing claims, and overall performance. The assigned contractor for this year is Novitas.
- The payment rates for the administration of the vaccinations are based on the MPFS for the appropriate year. Payment made through the MPFS is based on geographic locality. Therefore, payments received may vary based on the geographic locality where the service was performed. Payment is made at the assigned rate.
- The payment rates for the vaccines are determined by the standard method used by Medicare for reimbursement of drugs and biologicals. Payment is made at the assigned rate.
- Centralized billers must submit their claims on roster bills in an approved Electronic Media Claims standard format. Paper claims will not be accepted.
Centralized billers must obtain certain information for each beneficiary including name, health insurance number, date of birth, sex, and signature. Novitas must be contacted prior to the season for exact requirements. The responsibility lies with the centralized biller to submit correct beneficiary Medicare information (including the beneficiary’s Medicare HICN) as the contractor will not be able to process incomplete or incorrect claims.

Centralized billers must obtain an address for each beneficiary so that an MSN can be sent to the beneficiary by the contractor. Beneficiaries are sometimes confused when they receive an MSN from a contractor other than the contractor that normally processes their claims which results in unnecessary beneficiary inquiries to the Medicare contractor. Therefore, centralized billers must provide every beneficiary receiving an influenza virus or pneumococcal vaccination with the name of the processing contractor. This notification must be in writing, in the form of a brochure or handout, and must be provided to each beneficiary at the time he or she receives the vaccination.

Centralized billers must retain roster bills with beneficiary signatures at their permanent location for a time period consistent with Medicare regulations. Novitas can provide this information.

Though centralized billers may already have a Medicare provider number, for purposes of centralized billing, they must also obtain a provider number from Novitas. This can be done by completing the Form CMS-855 (Provider Enrollment Application), which can be obtained from Novitas.

If an individual or entity’s request for centralized billing is approved, the approval is limited to the 12-month period from September 1 through August 31 of the following year. It is the responsibility of the centralized biller to reapply to CMS CO for approval each year by June 1. Claims will not be processed for any centralized biller without permission from CMS.

Each year the centralized biller must contact Novitas to verify understanding of the coverage policy for the administration of the pneumococcal vaccine, and for a copy of the warning language that is required on the roster bill.

The centralized biller is responsible for providing the beneficiary with a record of the pneumococcal vaccination.

The information in items 1 through 8 below must be included with the individual or entity’s annual request to participate in centralized billing:

1. Estimates for the number of beneficiaries who will receive influenza virus vaccinations;
2. Estimates for the number of beneficiaries who will receive pneumococcal vaccinations;
3. The approximate dates for when the vaccinations will be given;
4. A list of the States in which influenza virus and pneumococcal clinics will be held;
5. The type of services generally provided by the corporation (e.g., ambulance, home health, or visiting nurse);
6. Whether the nurses who will administer the influenza virus and pneumococcal vaccinations are employees of the corporation or will be hired by the corporation specifically for the purpose of administering influenza virus and pneumococcal vaccinations;
7. Names and addresses of all entities operating under the corporation’s application;
8. Contact information for designated contact person for centralized billing program.
DOLLAR AMOUNT IN CONTROVERSY REQUIRED TO SUSTAIN APPEAL RIGHTS

CMS has announced the dollar amount that must remain in controversy to sustain appeal rights beginning January 1, 2019. The amount that must remain in controversy for Administrative Law Judge (ALJ) hearing requests filed on or before December 31, 2018, is $160. **This amount will remain at $160 for ALJ hearing requests filed on or after January 1, 2019.** The amount that must remain in controversy for reviews in Federal District Court requested on or before December 31, 2018, is $1,600. **This amount will increase to $1,630 for appeals to Federal District Court filed on or after January 1, 2019.**
CHOOSING THE APPROPRIATE DATE OF SERVICE

CMS has issued MLN Matters article Special Edition 17023 (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE17023.pdf), Guidance on Coding and Billing Date of Service on Professional Claims. This article replaces a previous WPS GHA article. SE17023 discusses multiple types of services and provides the correct date of service to submit to Medicare. You can find more information in Correct Date of Service for Specific Services: https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/correct-dos-specific-services/
2019 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List

MLN Matters Number: MM11085
Related Change Request (CR) Number: 11085
Related CR Release Date: January 11, 2019
Effective Date: January 1, 2019
Related CR Transmittal Number: R4200CP
Implementation Date: February 12, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment (DME) MACs) for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items or services paid under the DMEPOS fee schedule.

PROVIDER ACTION NEEDED

CR11085 updates the list of HCPCS codes for MACs and DME MACs. Please make sure your billing staffs are aware of these updates.

WHAT YOU NEED TO KNOW

The Centers for Medicare & Medicaid Services (CMS) annually updates a spreadsheet that contains a list of the HCPCS codes for DME MAC and Part B MAC jurisdictions to reflect codes that are either added or discontinued (deleted) each year. The jurisdiction list is an Excel file and is available at http://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html. The file is also available as an attachment to CR11085.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
Document History

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<td>January 11, 2019</td>
<td>Initial article released.</td>
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NOTE: Deleted codes are valid for dates of service on or before the date of deletion.
NOTE: Updated codes are in bold.
NOTE: The jurisdiction list includes codes that are not payable by Medicare. Please consult the Medicare contractor in whose jurisdiction a claim would be filed in order to determine coverage under Medicare.

NOTE: All Local Carrier language has been changed to Part B MAC

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<td>Part B MAC if incident to a physician's service (not separately payable). If other, DME MAC.</td>
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| A4360 - A4435 | Urinary Supplies | If provided in the physician's office for a temporary condition, the item is incident to the physician's service & billed to the Part B MAC. If provided in the physician's office or other place of service for a permanent condition, the item is a prosthetic device &
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<td>A4450 - A4456</td>
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<td>A4595</td>
<td>TENS Supplies</td>
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<td>A4600</td>
<td>Sleeve for Intermittent Limb Compression Device</td>
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<td>A4601-A4602</td>
<td>Lithium Replacement Batteries</td>
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<td>A4604</td>
<td>Tubing for Positive Airway Pressure Device</td>
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<tr>
<td>A4605</td>
<td>Tracheal Suction Catheter</td>
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<td>A4606</td>
<td>Oxygen Probe for Oximeter</td>
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<td>A4608</td>
<td>Transtracheal Oxygen Catheter</td>
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<tr>
<td>A4611 - A4613</td>
<td>Oxygen Equipment Batteries and Supplies</td>
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<tr>
<td>A4614</td>
<td>Peak Flow Rate Meter</td>
<td>Part B MAC if incident to a physician's service (not separately payable). If other, DME MAC.</td>
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<td>A4615 - A4629</td>
<td>Oxygen &amp; Tracheostomy Supplies</td>
<td>Part B MAC if incident to a physician's service (not separately payable). If other, DME MAC.</td>
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<tr>
<td>A4641 - A4642</td>
<td>Imaging Agent; Contrast Material</td>
<td>Part B MAC</td>
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<td>Tissue Marker, Implanted</td>
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<td>A4649</td>
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<td>Implantable Radiation Dosimeter</td>
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<td>A4651-A4932</td>
<td>Supplies for ESRD</td>
<td>DME MAC (not separately payable)</td>
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<td>Additional Ostomy Supplies</td>
<td>If provided in the physician's office for a temporary condition, the item is incident to the physician's service &amp; billed to the Part B MAC. If provided in the physician's office or other place of service for a permanent condition, the item is a prosthetic device &amp; billed to the DME MAC.</td>
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<td>A5102-A5200</td>
<td>Additional Incontinence and Ostomy Supplies</td>
<td>If provided in the physician's office for a temporary condition, the item is incident to the physician's service &amp; billed to the Part B MAC. If provided in the physician's office or other place of service for a permanent condition, the item is a prosthetic device &amp; billed to the DME MAC.</td>
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<td>Therapeutic Shoes</td>
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<td>A6010-A6024</td>
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<td>Electronic Bowel Irrigation System</td>
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<td>E0370</td>
<td>Heel Pad</td>
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<td>E0371 - E0373</td>
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<tr>
<td>E0485 - E0486</td>
<td>Oral Device to Reduce Airway</td>
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<td>Part B MAC if incident to a physician's service or used in an implanted infusion pump. If other, DME MAC.</td>
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<tr>
<td>J7170-J7179</td>
<td>Clotting Factors</td>
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<td>J7180 - J7195</td>
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<td>J7196 - J7197</td>
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<td>J7198</td>
<td>Anti-inhibitor; per I.U.</td>
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<tr>
<td>J7199 - J7211</td>
<td>Other Hemophilia Clotting Factors</td>
<td>Part B MAC</td>
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<td>J7296 - J7307</td>
<td>Contraceptives</td>
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<td>J7308 - J7309</td>
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<td>Ganciclovir, Long-Acting Implant</td>
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<td>J7330</td>
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<td>J7336</td>
<td>Capsaicin</td>
<td>Part B MAC</td>
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<tr>
<td>J7340</td>
<td>Carbidopa/Levodopa</td>
<td>Part B MAC if incident to a physician’s service or used in an implanted infusion pump. If other, DME MAC.</td>
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<td>J7342-J7345</td>
<td>Ciprofloxacin otic &amp; Topical Aminolevulinic Acid</td>
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<td>J7500-J7599</td>
<td>Immunosuppressive Drugs</td>
<td>Part B MAC if incident to a physician's service or used in an implanted infusion pump. If other, DME MAC.</td>
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<td>J7604-J7699</td>
<td>Inhalation Solutions</td>
<td>Part B MAC if incident to a physician's service. If other, DME MAC.</td>
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<tr>
<td>J7799-J7999</td>
<td>NOC Drugs, Other than Inhalation Drugs</td>
<td>Part B MAC if incident to a physician's service or used in an implanted infusion pump. If other, DME MAC.</td>
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<td>J8498</td>
<td>Anti-emetic Drug</td>
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<td>J8499</td>
<td>Prescription Drug, Oral, Non Chemotherapeutic</td>
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<td>Oral Anti-Cancer Drugs</td>
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<td>Chemotherapy Drugs</td>
<td>Part B MAC if incident to a physician's service or used in an implanted infusion pump. If other, DME MAC.</td>
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<td>K0195</td>
<td>Elevating Leg Rests</td>
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<td>K0455</td>
<td>Infusion Pump used for Uninterrupted Administration of Epoprostenal</td>
<td>DME MAC</td>
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<td>K0462</td>
<td>Loaner Equipment</td>
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<tr>
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<td>External Infusion Pump Supplies &amp; Continuous Glucose Monitor</td>
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<td>Defibrillator Accessories</td>
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<td>Wheelchair Cushion</td>
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<td>K0672</td>
<td>Soft Interface for Orthosis</td>
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<td>K0730</td>
<td>Inhalation Drug Delivery System</td>
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<tr>
<td>K0733</td>
<td>Power Wheelchair Accessory</td>
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<td>K0738</td>
<td>Oxygen Equipment</td>
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<tr>
<td>K0739</td>
<td>Repair or Nonroutine Service for DME</td>
<td>Part B MAC if implanted DME. If other, DME MAC</td>
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<td>K0740</td>
<td>Repair or Nonroutine Service for Oxygen Equipment</td>
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<td>Suction Pump and Dressings</td>
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<td>Custom DME, other than Wheelchair</td>
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<td>Orthotics</td>
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<td>L5000-L5999</td>
<td>Lower Limb Prosthetics</td>
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<td>L6000-L7499</td>
<td>Upper Limb Prosthetics</td>
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<td>L7510-L7520</td>
<td>Repair of Prosthetic Device</td>
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<td>Prosthetics</td>
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<td>Unlisted Procedure for Miscellaneous Prosthetic Services</td>
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<td>L8500-L8501</td>
<td>Artificial Larynx; Tracheostomy Speaking Valve</td>
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<td>L8505</td>
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<td>DME MAC</td>
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<tr>
<td>L8507</td>
<td>Voice Prosthesis, Patient Inserted</td>
<td>DME MAC</td>
</tr>
<tr>
<td>L8509</td>
<td>Voice Prosthesis, Inserted by a Licensed Health Care Provider</td>
<td>Part B MAC for dates of service on or after 10/01/2010. DME MAC for dates of service prior to 10/01/2010.</td>
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<td>L8510</td>
<td>Voice Prosthesis</td>
<td>DME MAC</td>
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<td>L8511 - L8515</td>
<td>Voice Prosthesis</td>
<td>Part B MAC if used with tracheoesophageal voice prostheses inserted by a licensed health care provider. If other, DME MAC</td>
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<tr>
<td>L8600 - L8699</td>
<td>Prosthetic Implants</td>
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<td>L8701-L8702</td>
<td>Assist Device</td>
<td>DME MAC</td>
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<td>L9900</td>
<td>Miscellaneous Orthotic or Prosthetic Component or</td>
<td>Part B MAC if used with implanted prosthetic device. If other, DME MAC.</td>
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<td>Q0035</td>
<td>Cardio-kymography</td>
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<td>Q0081</td>
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<td>Smear Preparation</td>
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<td>Q0144</td>
<td>Azithromycin Dihydrate</td>
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<td>Q0161 - Q0181</td>
<td>Anti-emetic</td>
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<td>Q0477 - Q0509</td>
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<td>Q0510 - Q0514</td>
<td>Drug Dispensing Fees</td>
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<td>Q0515</td>
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<td>Q1004 - Q1005</td>
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<td>Q2009</td>
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<td>Q2026 - Q2028</td>
<td>Injectable Dermal Fillers</td>
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<td>Q2052</td>
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<td>Q3027 - Q3028</td>
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<td>Drug Subject to Competitive Acquisition Program</td>
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<td>Imaging Agents</td>
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<tr>
<td>Q9958 - Q9983</td>
<td>Imaging Agents &amp; Radiology Supplies</td>
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<td>Hydrophilic Contact Lenses</td>
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<td>Contact Lenses, Scleral</td>
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<tr>
<td>V2599</td>
<td>Contact Lens, Other Type</td>
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<td>V2700 - V2780</td>
<td>Miscellaneous Vision Service</td>
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<td>Lenses</td>
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<td>V2799</td>
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<td>V5362 - V5364</td>
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Annual Update to the Per-Beneficiary Therapy Amounts

MLN Matters Number: MM11055  Related Change Request (CR) Number: CR 11055
Related CR Release Date: November 30, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4178CP  Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians, therapists, and other providers submitting claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice MACs, for outpatient therapy services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11055 describes the annual per-beneficiary incurred expense amounts now known as the KX modifier thresholds, and related policy updates for CY 2019. These amounts were previously associated with the financial limitation amounts that were more commonly referred to as “therapy caps” before the application of the therapy limits/caps was repealed when the Bipartisan Budget Act of 2018 (BBA of 2018) was signed into law. Another provision of the BBA of 2018 lowers the threshold of the targeted medical review process as explained in the Background section below.

For CY 2019, the KX modifier threshold amount for physical therapy (PT) and speech-language pathology (SLP) services combined is $2,040. For occupational therapy (OT) services, the CY 2019 threshold amount is $2,040. Make sure that your billing staffs are aware of these updates.

BACKGROUND

Effective for January 1, 2018, section 50202 of the Bipartisan Budget Act of 2018, P.L. 115-123 (BBA of 2018) amended section 1833(g) of the Social Security Act (the Act) to repeal the application of the therapy caps and the therapy caps exceptions process while also retaining and adding limitations to ensure appropriate therapy. The therapy caps or financial limitations originally applied through section 4541(c) of the Balanced Budget Act of 1997, P.L. 105-33 (1997 BBA) are no longer applicable to beneficiaries.

A separate provision of section 50202 of the BBA of 2018 adds section 1833(g)(7)(A) of the Act to preserve the former therapy cap amounts as thresholds above which claims must include the KX modifier to confirm that services are medically necessary as justified by appropriate documentation in the medical record. Claims from suppliers or providers for therapy services above these amounts without the KX modifier are denied. These amounts are now known as...
the KX modifier thresholds.

Just as with the incurred expenses for the therapy cap amounts, there is one KX modifier threshold amount for physical therapy (PT) and speech-language pathology (SLP) services combined and a separate amount for occupational therapy (OT) services. These per-beneficiary amounts under section 1833(g) of the Act (as amended by 1997 BBA) are updated each year by the Medicare Economic Index (MEI).

For CY 2019, the KX modifier threshold amounts are: (a) $2,040 for PT and SLP services combined, and (b) $2,040 for OT services.

Another provision of section 50202 of the BBA of 2018 adds section 1833(g)(7)(B) of the Act which maintains the targeted medical review process (first established through section 202 of the Medicare Access and CHIP Reauthorization Act of 2015), but at a lower threshold than the $3,700 amount established as part of the therapy caps exceptions process via section 3005 of the Middle Class Tax Relief and Jobs Creation Act of 2012. For CY 2018 (and each successive calendar year until 2028, at which time it is indexed annually by the MEI), this now-termed Medical Review (MR) threshold amount is $3,000 for PT and SLP services combined and $3,000 for OT services.

For more information, please see the pages for Therapy Services of CMS-1693-F on the CMS web page at the following link for PFS Federal Regulation Notices: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

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<th>Date of Change</th>
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<tr>
<td>December 4, 2018</td>
<td>Initial article released.</td>
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ub04@healthforum.com

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Implementation to Exchange the List of Electronic Medical Documentation Requests (eMDR) for Registered Providers via the Electronic Submission of Medical Documentation (esMD) System

MLN Matters Number: MM11003
Related Change Request (CR) Number: 11003
Related CR Release Date: February 1, 2019
Effective Date: July 1, 2019
Related CR Transmittal Number: R2248OTN
Implementation Date: July 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 11003 makes the changes required to send Additional Documentation Request (ADR) letters to participating providers via the (esMD) system.

A CR to effectuate the exchange of ADR letters to registered providers via the esMD system will be released at a later date.

Make sure your billing staffs are aware of these changes.

BACKGROUND

In response to a number of requests from Medicare providers, the Centers for Medicare & Medicaid Services (CMS) is adding the functionality to send ADR letters electronically. CMS conducted a pilot supporting the electronic version of the ADR letter known as Electronic Medical Documentation Request (eMDR) via the esMD system. Since the eMDRs may contain Protected Health Information (PHI) data being sent to the prospective provider, CMS will require a valid consent from the authorized individual representing the provider along with the destination details including any delegation to their associated or representing organizations such as Health Information Handlers (HIHs).

The sender (esMD) will have to complete the required identity proofing and always make sure to check for any registration updates before sending each eMDR. CR 11003 will effectuate the automation of eMDR registration and any corresponding updates will be done with esMD support.

CMS is requiring its review contractors to support sending ADR letters electronically as eMDRs. The Payment Error Rate Measurement contractors are exempted from this mandate. The Comprehensive Error Rate Testing (CERT) contractors and the Quality Improvement Organizations (QIO) can opt to participate in the eMDR process.
Registration Assumptions

- A provider (by billing National Provider Identifier (NPI)) registering for the first time to receive eMDR will receive both electronically and by postal mail for the first three ADRs.
- A provider enrollment for MAC portals and Direct Data Entry (DDE) (Part A) are separate from eMDR enrollment and registration.
- A provider (by billing NPI) registering for eMDR is applicable to receive eMDRs for all its Provider Transaction Access Numbers (PTANs).

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).


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Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier

MLN Matters Number: MM11061 Related Change Request (CR) Number: 11061
Related CR Release Date: February 1, 2019 Effective Date: July 1, 2019
Related CR Transmittal Number: R4227CP Implementation Date: July 1, 2019

PROVIDER TYPE AFFECTED
This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED
Change Request (CR) 11061 sunsets the requirement for Independent Laboratories to use the CB modifier to bill separately for renal dialysis laboratory tests. Make sure your billing staff is aware of these changes.

BACKGROUND
The Skilled Nursing Facility (SNF) Consolidated Billing (CB) provision requires a SNF to include on its Part A bill almost all of the services that its residents receive during the course of a Part A covered stay. There are several categories of services that the Social Security Act (Section 1888(e)(2)(A)(ii) (https://www.ssa.gov/OP_Home/ssact/title18/1888.htm) specifically excludes from this provision. These excluded services remain separately billable under Part B by the outside provider or supplier that furnishes them.

One of the excluded categories encompasses those items and services that fall within the scope of the Part B benefit that covers chronic dialysis for beneficiaries with ESRD (see the Social Security Act (Section 1861(s)(2)(F)) at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm).

Prior to January 1, 2011
Prior to January 1, 2011, Medicare paid independent laboratories directly for furnishing diagnostic tests that were ESRD dialysis-related. For purposes of the SNF CB, ESRD dialysis-related was defined as:

1. The beneficiary must be an ESRD beneficiary.
2. The test must have been ordered by an ESRD facility.
3. The test must relate directly to the dialysis treatment of the beneficiary’s ESRD.
Therefore, an independent laboratory could be paid separately (outside of the SNF CB) for an ESRD dialysis-related diagnostic test furnished to a SNF Part A resident, provided the test was outside the ESRD facility’s composite rate when the diagnostic test was billed with the CB modifier—services ordered by a dialysis facility physician as part of the ESRD beneficiary’s dialysis benefit, is not part of the composite rate, and is separately reimbursable.

**Note:** [CR 2475](#) established the CB modifier, and [CR 2906](#) revised the criteria for using the CB modifier.

**January 1, 2011, ESRD Prospective Payment System (PPS)**

The Medicare Improvements for Patients and Providers Act ([MIPPA](#); Section 153(b)) required the implementation of the ESRD PPS effective January 1, 2011.

The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methods for the reimbursement of separately billable outpatient ESRD related items and services. The ESRD PPS provides a single payment to ESRD facilities (that is, hospital-based providers of services and renal dialysis facilities) that pays for all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient’s home, drugs, biologicals, laboratory tests, training, and support services.

The ESRD PPS includes CB requirements for limited Part B services included in the ESRD facility’s bundled payment. The Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of items and services that are subject to Part B CB and are, therefore, no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

[CR 7064](#) (also see MLN Matters Article [MM7064](#)) established the ESRD PPS CB requirements, which are discussed on the CMS website located at this link: [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html).

Since the implementation of the ESRD PPS, independent laboratories are no longer able to bill Medicare directly for any diagnostic test that is related to the treatment of ESRD as payment for the test is already included in the ESRD PPS base rate paid to the ESRD facility. CMS inadvertently did not eliminate the use of the CB modifier in the ESRD PPS.

**CR 11061 July 1, 2019, Sunset of CB Modifier**

Therefore, CR 11061 sunsets the requirement for independent laboratories to use the “CB” HCPCS modifier to bill separately for renal dialysis laboratory tests.

Effective January 1, 2011, independent laboratories are no longer allowed to report the CB modifier. All laboratory tests determined to be furnished for the treatment of ESRD are paid in the ESRD facility bundled payment and therefore, may only be reported by the ESRD facility.

Therefore, effective with dates of service on or after July 1, 2019, the CB modifier, which is a payment mechanism for independent laboratories to report when requesting separate payment outside the SNF CB for ESRD dialysis-related services, will not be available.
Effective with dates of service on or after July 1, 2019, claims with the CB modifier will be returned to the provider (RTP) with the following codes:

- Reason code 31164 - Invalid line item modifier or line item date of service is not within or equal to modifier effective and termination date
- CARC Code 182 - "Procedure modifier was invalid on the date of service."
- Group Code CO - Contractual Obligation.

With the January 1, 2011, implementation of the ESRD PPS and effective for date of service on or after July 1, 2019, Exhibit 1 (see "Medicare Claims Processing Manual" Chapter 16) is no longer recognized as the list of separately billable ESRD dialysis-related services. Instead, a list of the recognized renal dialysis laboratory tests that are subject to Part B ESRD PPS CB requirements, are considered routinely performed for the treatment of ESRD, and are not separately paid when provided to ESRD beneficiaries by providers or suppliers other than the ESRD facility, is located on the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

The list of renal dialysis laboratory tests provided in the Part B ESRD PPS CB requirements is not an all-inclusive list. For laboratory tests not included in this list, the distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD beneficiary’s ordering practitioner. If the practitioner orders such a laboratory test for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS, is the responsibility of the ESRD facility and is excluded from the SNF PPS. More information regarding renal dialysis services payable under the ESRD PPS is available in the "Medicare Benefit Policy Manual", Chapter 11.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic tests that are not directly related to the beneficiary’s ESRD are subject to the SNF CB requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

**Note:** A patient’s physician or practitioner may order a laboratory test that is included on the list of items and services subject to CB edits for reasons other than for the treatment of ESRD. When this occurs, the SNF CB applies.

### ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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New Modifier for Expanding the Use of Telehealth for Individuals with Stroke

MLN Matters Number: MM10883  Related Change Request (CR) Number: 10883
Related CR Release Date: September 28, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R2142OTN  Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians and providers billing Medicare Administrative Contractors (MACs) for stroke telehealth services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change request (CR) 10883 establishes use of a new Healthcare Common Procedure Coding System (HCPCS) modifier, G0 (G Zero), to be appended on claims for telehealth services that are furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke. Make certain your billing staff is aware of this new code.

BACKGROUND

Section 50325 of the Bipartisan Budget Act of 2018 amended section 1834(m) of the Act by adding a new paragraph (6) that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished.

Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act.

In order to implement the requirements described in Section 50325 of the Bipartisan Budget Act
of 2018, Centers for Medicare & Medicaid Services (CMS) is proposing to create a new modifier that would be used to identify acute stroke telehealth services. The distant site practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. Section 50325 of the Bipartisan Budget Act of 2018 did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. Practitioners are responsible for assessing whether it would be clinically appropriate to use this modifier with codes from the Medicare telehealth list. By billing with this modifier, practitioners are indicating that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke.

KEY POINTS

This new modifier will be part of the annual January 2019 HCPCS update

- Effective for claims with dates of service on and after January 1, 2019, MACs will accept new informational HCPCS modifier G0 to be used to identify Telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.
- Modifier G0 is valid for all:
  - Telehealth distant site codes billed with Place of Service (POS) code 02 or Critical Access Hospitals, CAH method II (revenue codes 096X, 097X, or 098X); or
  - Telehealth originating site facility fee, billed with HCPCS code Q3014.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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New Waived Tests

MLN Matters Number: MM11080
Related Change Request (CR) Number: 11080
Related CR Release Date: January 11, 2019
Effective Date: April 1, 2019
Related CR Transmittal Number: R4195CP
Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR11080 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its MACs of the new tests so that they can accurately process claims. Make sure your billing staffs are aware of these CLIA-related changes.

BACKGROUND

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that CMS only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, Medicare edits laboratory claims at the CLIA certificate level. However, the tests mentioned on the first page of the list attached to CR11080 (CPT codes: 81002, 81025, 82270, 82272, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

The latest tests approved by the FDA as waived tests under CLIA are listed below. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are as follows:

- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Panel Dip M300
• 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M300
• 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M2000
• 86618QW, August 30, 2018, Quidel Sofia 2 {Fingerstick whole blood}
• 80305QW, October 2, 2018, McKesson Medical-Surgical, McKesson Drugs of abuse PPX Test Cup
• 80305QW, October 4, 2018, Jant Pharmacal Corp. Accutest VALUPAK Drug Screen Cup
• 80305QW, October 9, 2018, McKesson Medical-Surgical Inc. McKesson Multi Panel Drugs of abuse Test Cup
• 83036QW, October 23, 2018, Alere Technologies AS, AS100 Analyzer
• 83036QW, October 23, 2018, Alere Technologies AS, Afinion 2 Analyzer
• 80305QW, November 2, 2018, American Screening LLC, Precision Plus Quick Cup Tests
• 80305QW, November 2, 2018, American Screening LLC, Precision DX Quick Cup Tests
• 87804QW, November 21, 2018, Polymedco Inc., Poly stat Flu A&B {for use with nasal and nasopharyngeal swabs}
• 87634QW, November 23, 2018, Mesa Biotech Accula (Accula RSV Test)

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Next Generation Accountable Care Organization (ACO) Model 2019 Benefit Enhancement

MLN Matters Number: MM10824 Revised  Related Change Request (CR) Number: 10824
Related CR Release Date: October 5, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R210DEMO  Implementation Date: January 7, 2019

Note: This article was revised on December 14, 2018, to reflect a revised CR10824 issued on October 5. In the article, the CR release date, transmittal number, and the Web address of the CR are also revised. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for providers who are participating in Next Generation Accountable Care Organizations (NGACOs) and submitting claims to Medicare Administrative Contractors (MACs) for certain care management home visit services to Medicare beneficiaries that would not otherwise be covered by Original Fee-For-Service (FFS) Medicare.

PROVIDER ACTION NEEDED

Change Request (CR) 10824 provides instruction on implementing one new Benefit Enhancement for program year four of the NGACO Model.

BACKGROUND

The goal of the NGACO Model is to improve the quality of care, population health outcomes, and patient experience for the beneficiaries who choose traditional FFS Medicare. The Model provides greater alignment of financial incentives and greater access to tools that may aid beneficiaries and providers in achieving better health at lower costs. Some of the tools that are available to beneficiaries and providers are conditional waivers of certain Medicare payment requirements, called Benefit Enhancements. These Benefit Enhancements currently include the Three-Day Skilled Nursing Facility Rule Waiver, the Post-Discharge Home Visits Waiver, and the Telehealth Expansion Waiver. There are Medicare Learning Network articles available describing each of these and the links for them are available in the Additional Information section.

New Benefit Enhancement for 2019 - Care Management Home Visits

Building upon the NGACOs’ experience in offering the Post-Discharge Home Visits Benefit
Enhancement, the Model will offer a new Care Management Home Visits Benefit Enhancement to equip the NGACOs with a new tool to provide home visits proactively and in advance of a potential hospitalization. Next Generation Participants and Preferred Providers who have initiated a care treatment plan for aligned beneficiaries will be eligible to receive up to two Care Management Home Visits within 90 days of seeing that Next Generation Participant or Preferred Provider.

CMS will extend the conditional Medicare payment rule waiver issued under the Post-Discharge Home Visits Benefit Enhancement to establish the Care Management Home Visits Benefit Enhancement. Specifically, the scope of covered items and services under this Benefit Enhancement include those services and supplies that would be covered under Medicare Part B and are furnished “incident to” the professional services of a physician or other practitioner.

With the exception that CMS will waive the direct supervision requirement such that the services and supplies may be furnished by auxiliary personnel under the billing physician’s or other billing practitioner’s general supervision, this new Care Management Home Visits Benefit Enhancement will provide NGACO Participants and Preferred Providers greater flexibility to furnish these services within a beneficiary’s home or place of residence.

The items and services provided as part of these care management home visits are intended to supplement, rather than substitute for, visits to a primary care provider or specialist in a traditional health care setting. As such, these home visits are not intended to be performed on an ongoing basis, nor to serve as a substitute for the Medicare home health benefit, nor as the primary mechanism to meet beneficiaries’ care needs. Also, note that this is not a home health benefit, and beneficiaries eligible to receive home health services will not be eligible for this Benefit Enhancement.

The Healthcare Common Procedure Coding System (HCPCS) codes for the Care Management Home Visit services are:

- **G0076**: Brief (20 minutes) care management home visit for a new patient. For use only in a Medicare-approved Center for Medicare & Medicaid Innovation (CMMI) model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

- **G0077**: Limited (30 minutes) care management home visit for a new patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

- **G0078**: Moderate (45 minutes) care management home visit for a new patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

- **G0079**: Comprehensive (60 minutes) care management home visit for a new patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)
• G0080: Extensive (75 minutes) care management home visit for a new patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0081: Brief (20 minutes) care management home visit for an existing patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0082: Limited (30 minutes) care management home visit for an existing patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0083: Moderate (45 minutes) care management home visit for an existing patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0084: Comprehensive (60 minutes) care management home visit for an existing patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0085: Extensive (75 minutes) care management home visit for an existing patient. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0086: Limited (30 minutes) care management home care plan oversight. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

• G0087: Comprehensive (60 minutes) care management home care plan oversight. For use only in a Medicare-approved CMMI model. (Services must be furnished within a beneficiary’s home, domiciliary, rest home, assisted living and/or nursing facility.)

These codes should be submitted on Type of Bill: 85X, with Revenue Codes 96X, 97X, or 98X. The payment rates will be in the Medicare Physician Fee Schedule (MPFS). However, Medicare will reimburse the lesser of the billed charge or MPFS rate for Critical Access Hospital Method II providers billing on Type of Bill 85X, with Revenue Codes 96X, 97X, or 98X.

ADDITIONAL INFORMATION

Information on the CRs previously implemented for the Next Generation ACO Model are available at:


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<td>The article was revised on August 29, 2018, to reflect a revised CR10824 issued on August 28. The CR was revised to show this is year four of the NGACO model. The article was revised accordingly. In the article, the CR release date, transmittal number, and the Web address of the CR are also revised. All other information remains the same.</td>
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Next Generation Accountable Care Organization (NGACO) Model Post Discharge Home Visit HCPCS

MLN Matters Number: MM10907 Revised  Related Change Request (CR) Number: 10907
Related CR Release Date: November 28, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R215DEMO  Implementation Date: April 1, 2019

Note: This article was revised on November 29, 2018, to reflect a revised CR10907 issued on November 28. The CR was revised to show the correct HCPCS codes of G2001 - G2009 and G2013 - G2015 for NGACO Model Post Discharge Home Visits. The article was revised accordingly. Also, the CR release date, transmittal number, and the Web address of the CR are revised in the article. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for providers who are participating in Next Generation Accountable Care Organizations (NGACOs) and submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR10907 makes modifications to the operations of a current benefit enhancement offered by the NGACO Model. Claims for Post Discharge Home Visit Waiver shall be processed for reimbursement and paid when they meet the appropriate payment requirements as outlined in CR10907. Make sure your billing staffs are aware of these changes.

BACKGROUND

The Social Security Act (the Act) (Section 1115A; https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm) added by the Affordable Care Act (Section 3021; 42 U.S.C. 1315a; https://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf) authorizes the Centers for Medicare & Medicaid Services (CMS) to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and the Child Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries’ care.

The aim of the NGACO Model is to improve the quality of care, population health outcomes, and patient experience for beneficiaries who choose traditional Medicare Fee-for-Service (FFS). The benefit provides greater alignment of financial incentives and greater access to tools that may aid beneficiaries and providers in achieving better health at lower costs.
In order to emphasize high-value services and support the ability of ACOs to manage the care of beneficiaries, CMS is issuing the authority under Section 1115A of the Act (added by Section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment requirements as part of the NGACO Model. An ACO may choose not to implement all or any of these benefit enhancements. Applicants will be asked questions specific to their proposed implementation of these benefit enhancements, but acceptance into the NGACO Model is not contingent upon an ACO implementing any particular benefit enhancement.

Participants in the NGACO Model are required to provide implementation information to CMS, which, upon approval, will enable the ACO’s use of the optional benefit enhancements. Each optional benefit enhancement will have such an “implementation plan” requiring, for example:

1. Descriptions of the ACO’s planned strategic use of the benefit enhancement
2. Self-monitoring plans to demonstrate meaningful efforts to prevent unintended consequences
3. Documented authorization by the governing body to participate in the benefit enhancement

**Note:** RTI International is the specialty contractor creating the Next Generation ACO provider alignment files.

For dates of service of April 1, 2019, and later, MACs will allow NGACO, including the Vermont (VT) ACO, post discharge home visit claims for licensed clinicians under the general supervision of an NGACO or VT ACO provider when this benefit enhancement is elected by the provider for the Date of Service (DOS) on the claims and only when the claim contains the following HCPCS codes: G2001; G2002; G2003; G2004; G2005; G2006; G2007; G2008; G2009; G2013; G2014; and G2015. This applies to Type of Bill (TOB) 85X, Rev Codes 96X; 97X; and 98X.

The payment rate for these HCPCS codes will be in the annual Medicare Physician Fee Schedule (MPFS). Medicare will reimburse Critical Access Hospital Method II providers billing on TOB 85X with Revenue codes 96X, 97X, and 98X based on the lesser of the billed charge or the MPFS rate.

Note that MACs will reject or return as unprocessable if a claim or if separate claims with the same DOS contains a Post Discharge Home Visit HCPCS code and a Care Management Home Visit HCPCS code.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).
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Quarterly Influenza Virus Vaccine Code Update - January 2019

MLN Matters Number: MM10871  Revised Related Change Request (CR) Number: 10871
Related CR Release Date: September 27, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4141CP  Implementation Date: January 7, 2019

Note: This article was revised on December 14, 2018 to reflect the revised CR10871 issued on September 27. In the article, the CR release date, transmittal number, and the Web address for accessing CR10871 are revised. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10871 provides instructions for payment and edits for Medicare’s Common Working File (CWF) and Fiscal Intermediary Shared System (FISS) to include and update new or existing influenza virus vaccine codes. This update includes one new influenza virus vaccine code: 90689. Please make certain your billing staffs are aware of this update.

BACKGROUND

Effective for claims processed with Dates of Service (DOS) on or after January 1, 2019, influenza virus vaccine code 90689 (Influenza virus vaccine quadrivalent (IIV4), inactivated, adjuvanted, preservative free, 0.25mL dosage, for intramuscular use) will be payable by Medicare. The short descriptor is VACC IIV4 NO PRSRV 0.25ML IM. This new code will be included on the 2019 Medicare Physician Fee Schedule Database file update and the annual Healthcare Common Procedure Coding System (HCPCS) update.

Except as noted below, MACs will use the Centers for Medicare & Medicaid Services (CMS) Seasonal Influenza Vaccines Pricing webpage: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html to obtain the payment rate for 90689. The new influenza virus vaccine code 90689 is not retroactive to August 1, 2018. No claims should be accepted for influenza virus vaccine code 90689 between the DOS August 1, 2018, and December 31, 2018. If claims are received in January 2019 with code 90689 for DOS between August 1, 2018, and December 31, 2018, MACs will follow their normal
course of action for codes billed prior to their effective date.

**Payment Basis for Institutional Claims**

MACs will pay for influenza virus vaccine code 90689 with a Type of Service (TOS) of V based on reasonable cost to

- Hospitals (Type of Bill 12X and 13X)
- Skilled Nursing Facilities (22X and 23X)
- Home Health Agencies (34X)
- Hospital-based renal dialysis facilities (72X)
- Critical Access Hospitals (85X)

MACs will pay for influenza virus vaccine code 90689 with a TOS of V based on the lower of the actual charge or 95 percent of the Average Wholesale Price (AWP), to:

- Indian Service Hospitals (IHS) (12X and 13X)
- Hospices (81X and 82X)
- IHS Critical Access Hospitals (85X)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (75X)
- Independent Renal Dialysis Facilities (72X)

**Note:** In all cases, coinsurance and deductible do not apply.

**ADDITIONAL INFORMATION**

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Quarterly Update of HCPCS Codes Used for Home Health Consolidated Billing Enforcement

MLN Matters Number: MM11040  Related Change Request (CR) Number: 11040
Related CR Release Date: November 16, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R4170CP  Implementation Date: April 1, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Home Health Agencies (HHAs) and other providers submitting claims to Medicare Administrative Contractors (MACs) for home health services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article is based on CR 11040 which provides the quarterly update of Healthcare Common Procedure Coding System (HCPCS) codes used for Home Health (HH) consolidated billing effective April 1, 2019. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The Social Security Act (Section 1842(b)(6); https://www.ssa.gov/OP_Home/ssact/title18/1842.htm) requires that payment for home health services provided under a home health plan of care is made to the home health agency (HHA). This requirement is in regulations at 42 CFR 409.100 (https://www.ecfr.gov/cgi-bin/text-idx?SID=dade7fe79f01c67f9304262v8e8a95e7e&mc=true&node=pt42.2.409&rgn=dlv5#se42.2.409_1100) and in Medicare instructions provided in Chapter 10, Section 20 of the Medicare Claims Processing Manual (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf).

The Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of HCPCS codes that are subject to the consolidated billing provision of the Home Health Prospective Payment System (HH PPS).

With the exception of therapies performed by physicians and supplies incidental to physician services and supplies used in institutional settings, services appearing on this list that are submitted on claims to your MAC will not be paid separately on dates when a beneficiary for whom such a service is being billed is in a home health episode (that is, under a home health plan of care administered by a HHA).

Medicare will only directly reimburse the primary home health agencies that have opened such episodes during the episode periods. Therapies performed by physicians, supplies incidental to
physician services and supplies used in institutional settings are not subject to HH consolidated billing.

The HH consolidated billing code lists are updated annually, to reflect the annual changes to the HCPCS code set itself. Additional updates may occur as frequently as quarterly in order to reflect the creation of temporary HCPCS codes (for example, ‘K’ codes) throughout the calendar year. The new coding identified in each update describes the same services that were used to determine the applicable HH PPS payment rates. No additional services will be added by these updates; that is, new updates are required by changes to the coding system, not because the services subject to HH consolidated billing are being redefined.

There are no codes being added to the HH consolidated billing non-routine supply code list in this update. However, the following code is being added to the HH consolidated billing therapy code list:

- 92597 - Evaluation for use and/or fitting of voice prosthetic device to supplement oral speech

**Note:** This is not a new therapy code. This code was removed from the HH consolidated billing therapy code list in error in January 2003. CR11040 corrects this error and restores the code to the list.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

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Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 25.0, Effective January 1, 2019

MLN Matters Number: MM11044  Related Change Request (CR) Number: 11044
Related CR Release Date: November 30, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4175CP  Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11044 updates the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) edits, which relate to Chapter 23, Section 20.9 of the Medicare Claims Processing Manual (Pub. 100-04). Please make sure your billing staffs are aware of these updates.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) developed the NCCI to promote national correct coding methodologies and to control improper coding that leads to inappropriate payment in Medicare Part B claims.

Version 25.0 will include all previous versions and updates from January 1, 1996, to the present. In the past, NCCI was organized in two tables: Column 1/Column 2 Correct Coding Edits and Mutually Exclusive Code (MEC) Edits. In order to simplify the use of NCCI edit files (two tables), on April 1, 2012, CMS consolidated these two edit files into the Column One/Column Two Correct Coding edit file. Separate consolidations have occurred for the two practitioner NCCI edit files and the two NCCI edit files used for the Outpatient Code Editor (OCE).

It will only be necessary to search the Column One/Column Two Correct Coding edit file for active or previously deleted edits. CMS no longer publishes a Mutually Exclusive edit file on its website for either practitioner or outpatient hospital services, since all active and deleted edits will appear in the single Column One/Column Two Correct Coding edit file on each website. The
edits previously contained in the Mutually Exclusive edit file are NOT being deleted but are being moved to the Column One/Column Two Correct Coding edit file.

Refer to the CMS NCCI website for additional information at http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html.

The coding policies developed are based on coding conventions defined in the American Medical Association’s Current Procedural Terminology (CPT) manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practice, and review of current coding practice.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 25.1 Effective April 1, 2019

MLN Matters Number: MM11126 Related Change Request (CR) Number: 11126
Related CR Release Date: January 11, 2019 Effective Date: April 1, 2019
Related CR Transmittal Number: R4193CP Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR11126 updates the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) edits, which relate to Chapter 23, Section 20.9 of the Medicare Claims Processing Manual. Please make sure your billing staffs are aware of these updates.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) developed the NCCI to promote national correct coding methods and to control improper coding that leads to inappropriate payment in Part B claims.

Version 25.1 includes all previous versions and updates from January 1, 1996 to the present. In the past, NCCI was organized in two tables: Column 1/Column 2 Correct Coding Edits and Mutually Exclusive Code (MEC) Edits. To simplify the use of NCCI edit files (two tables), on April 1, 2012, CMS consolidated these two edit files into the Column One/Column Two Correct Coding edit file. Separate consolidations occurred for the two practitioner NCCI edit files and the two NCCI edit files used for the Outpatient Code Editor (OCE). You only have to search the Column One/Column Two Correct Coding edit file for active or previously deleted edits. CMS no longer publishes a Mutually Exclusive edit file for either practitioner or outpatient hospital services, since all active and deleted edits will appear in the single Column One/Column Two Correct Coding edit file. The edits previously available in the Mutually Exclusive edit file are NOT deleted but are moved to the Column One/Column Two Correct Coding edit file.
Refer to the CMS NCCI webpage for additional information at http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html.

These coding policies are based on coding conventions defined in the American Medical Association’s Current Procedural Terminology manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practice, and review of current coding practice.

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Revision of Definition of the Physician Supervision of Diagnostic Procedures, Clarification of DSMT Telehealth Services, and Establishing a Modifier for Expanding the Use of Telehealth for Individuals with Stroke

MLN Matters Number: MM11043
Related Change Request (CR) Number: 11043

Related CR Release Date: November 30, 2018
Effective Date: January 1, 2019

Related CR Transmittal Number: R251BP and R4173CP
Implementation Date: January 2, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

This article is based on CR 11043, which:

- Revises the definition of "Personal Supervision" of the Physician Supervision of Diagnostic Procedures indicator to specify that procedures performed by a Registered Radiologist Assistant (RRA) or a Radiology Practitioner Assistant (RPA) may be performed under direct supervision
- Adds instructions to use modifier G0 (G zero) to identify Telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke
- Clarifies requirements for when Diabetes Self-Management Training (DSMT) services may be paid as a telehealth service

Please be sure your staffs are aware of these changes.

BACKGROUND

The Physician Supervision of Diagnostic Procedures indicator specifies a level of physician supervision required for certain diagnostic tests. The levels of supervision are "general," "direct," and "personal" supervision, and each of these levels of supervision have a corresponding indicator value assigned to each diagnostic procedure.
The Centers for Medicare & Medicaid Services (CMS) is revising its policy to specify that beginning with dates of services on or after January 1, 2019, diagnostic procedures that are furnished by a Radiologist Assistant, who CMS defines as either RRAs, who are certified by The American Registry of Radiologic Technologists, and RPAs, who are certified by the Certification Board for Radiology Practitioner Assistants, require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations. CMS notes that for diagnostic imaging tests requiring a general level of physician supervision, this policy revision does not change the level of physician supervision to direct supervision. Otherwise, the diagnostic imaging tests must be performed as specified elsewhere under 42 Code of Federal Regulations (CFR), section 410.32(b).

Be aware that beginning with dates of services on or after January 1, 2019, the description for Physician Supervision of Diagnostic Procedures indicator "03" on the Medicare Physician Fee Schedule is revised to say the following:

"03 = Procedure must be performed under the personal supervision of a physician. (Diagnostic imaging procedures performed by a Registered Radiologist Assistant (RRA) who is certified and registered by The American Registry of Radiologic Technologists (ARRT) or a Radiology Practitioner Assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA) and is authorized to furnish the procedure under state law, may be performed under direct supervision)."

Special rules for telehealth services for acute stroke telehealth services

Section 50325 of the Bipartisan Budget Act of 2018 amended section 1834(m) of the Social Security Act (the Act) by adding a new paragraph (6) that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary.

Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Section 1834(m)(6)(B) of the Act specifies that acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act. This CR instructs MACs on billing procedures for these services.

CR 11043 clarifies CMS policy to accept new informational HCPCS modifier G0 (G zero) to be used to identify Telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke. Modifier G0 is valid for all:

- Telehealth distant site codes billed with Place of Service (POS) code 02 or Critical Access Hospitals, CAH method II (revenue codes 096X, 097X, or 098X) or
- Telehealth originating site facility fee, billed with HCPCS code Q3014.
Diabetes Self-Management Training (DSMT) Services

CMS is clarifying DSMT policy to specify that all 10 hours of the initial DSMT training and the two (2) hours of annual follow-up DSMT training may be furnished via telehealth in cases when injection training is not applicable.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

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Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)

MLN Matters Number: MM10567 Revised
Related Change Request (CR) Number: 10567
Related CR Release Date: January 11, 2019
Effective Date: April 30, 2018
Related CR Transmittal Number: R4198CP
Implementation Date: April 30, 2018

We revised this article on January 11, 2019, to reflect the revised CR 10567 issued on January 11. The CR revisions had no impact on the content of the article. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Skilled Nursing Facilities (SNFs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you about Change Request (CR) 10567, which advises you that the Centers for Medicare & Medicaid Services (CMS) has revised the Skilled Nursing Facility Notice of Non-coverage (SNF ABN), Form CMS-10055. With this revision, CMS is discontinuing the five Skilled Nursing Facility (SNF) Denial Letters (namely, the Intermediary Determination of Noncoverage, the UR Committee Determination of Admission, the UR Committee Determination on Continued Stay, the SNF Determination on Admission and the SNF Determination on Continued Stay), and the Notice of Exclusion from Medicare Benefits (NEMB-SNF), Form CMS-20014. Please ensure that your billing staffs are aware of these changes.

Please note that the Notice of Medicare Non-Coverage (NOMNC), Form CMS-10123 is not being discontinued with this revised SNF ABN. More information on the NOMNC is available at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expeditied-Determination-Notices.html.

BACKGROUND

The authorization for these requirements are Section 1879 of the Social Security Act and 42 Code of Federal Regulations (CFR) 411.404(b) and (c), which specify written notice requirements. These requirements are fulfilled by the SNF ABN.
In order for SNFs to transfer liability to an Original Medicare beneficiary for items or services paid under Medicare Part A (SNF Prospective Payment System (PPS)), the SNF must issue a SNF ABN for:

- An item or service that is usually paid for by Medicare, but may not be paid for in this particular instance because it is not medically reasonable and necessary, or
- Custodial care.

Attached to CR10567 is a revised Chapter 30 of the Medicare Claims Processing Manual. This revised manual chapter provides details on SNF ABN standards and also provides information about:

- Situations in which a SNF ABN should be given
- Situations in which a SNF ABN is not needed to transfer financial liability to the beneficiary
- SNF ABN specific delivery issues
- Special rules for SNF ABNs
- Establishing when beneficiary is on Notice of Non-coverage

Note: Further details are available at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-SNFABN-.html. You may download the revised Form CMS-10055 in the Downloads section of that webpage.

SNFs will continue to use the Advance Beneficiary Notice of Non-coverage (ABN, Form CMS-R-131) for items or services that Medicare may be deny under Medicare Part B.

Please note that SNFs may start to implement this new notice any time up to the implementation date of CR10567. Upon the CR10567 implementation on April 30, 2018, the use of the new notice is mandatory.

The revised notice incorporates suggestions for changes made by users of the ABN and by beneficiary advocates based on experience with the current form, refinements made to similar liability notices through consumer testing and other means, as well as related Medicare policy changes and clarifications.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list
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Updates to Reflect Removal of Functional Reporting Requirements and Therapy Provisions of the Bipartisan Budget Act of 2018

MLN Matters Number: MM11120
Related Change Request (CR) Number: 11120
Related CR Release Date: January 25, 2019
Effective Date: January 1, 2019
Related CR Transmittal Numbers: R4214CP, R255BP
Implementation Date: February 26, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for therapists, physicians, certain nonphysician practitioners and other providers of therapy services – including physical therapy (PT), occupational therapy (OT) and speech-language pathology (SLP) services – who submit professional or institutional claims to Medicare Administrative Contractors (MACs) for therapy services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11120 updates both the Medicare Benefit Policy Manual and Medicare Claims Processing Manual to reflect recent changes in outpatient therapy services billing instructions and payment policies related to the Bipartisan Budget Act of 2018 and the Calendar Year (CY) 2019 Medicare Physician Fee Schedule (MPFS) Final Rule. These policy revisions include: (a) the repeal of the application of the outpatient therapy caps and the retention of the therapy cap amounts as thresholds of incurred expenses above which claims must include a modifier to confirm services are medically necessary as shown by medical record documentation; and, (b) the discontinuation of the functional reporting requirements. Please make sure your billing staffs are aware of these changes.

BACKGROUND

Section 50202 of the Bipartisan Budget Act of 2018 (BBA) repeals application of the Medicare outpatient therapy caps but retains the former cap amounts as a threshold of incurred expenses above which claims must include a KX modifier as a confirmation that services are medically necessary as justified by appropriate documentation in the medical record.

After a consideration of stakeholders’ requests for burden reduction and a review of the Middle Class Tax Relief and Jobs Creation Act of 2012 (MCTRJCA) requirements, the Centers for Medicare & Medicaid Services (CMS) concluded in the CY 2019 MPFS final rule that continued
collection of functional reporting data through the same format would not yield additional information to inform future analyses. The rule ended the functional reporting requirements to reduce burden of reporting for providers of therapy services.

CR 11120 updates Chapters 12 and 15 of the Medicare Benefit Policy Manual and Chapter 5 of the Medicare Claims Policy Manual to reflect these changes to law and regulation. **Note:** The relevant manual chapters are attached to CR 11120 for your review.

Effective for dates of service on or after January 1, 2018, providers of therapy services shall continue to report the KX modifier on claims as applicable. The modifier no longer represents an exception request but serves as a confirmation that services are medically necessary as justified by appropriate documentation in the medical record after the beneficiary has exceeded the threshold of incurred expenses.

Effective for dates of service on or after January 1, 2019, HCPCS G-codes and severity modifiers for functional reporting are no longer required on claims for therapy services.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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FUTURE ARTICLE FOR HUMAN GRANULOCYTE/MACROPHAGE COLONY STIMULATING FACTORS BILLING AND CODING GUIDELINES


The new article supports human granulocyte colony-stimulating factors drugs that are produced by recombinant DNA technology with the use of bacteria and a human G-CSF gene. G-CSF regulates the production of neutrophils (a WBC) within the bone marrow (where blood cells are manufactured naturally in the body). Neutrophils are an essential in the body's fight against infections.

The new article will efficiently support the billing and coding guidance that was in L34699. A lapse in coverage will not occur.

The future article will be viewable February 1, 2019, on the Medicare Coverage Database (https://www.cms.gov/medicare-coverage-database) and on the WPS GHA Local Coverage Determination (LCDs) and Coverage Articles (https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/lcds-and-coverage-articles) web page.
International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)

MLN Matters Number: MM11005 Revised
Related CR Release Date: November 9, 2018
Related CR Transmittal Number: R2202OTN

Related Change Request (CR) Number: 11005
Effective Date: April 1, 2019, unless otherwise noted in requirements
Implementation Date: April 1, 2019, for Medicare Shared Systems, for local MACs 60 days from release of CR 11005

Note: This article was revised on January 4, 2019, to show the correct effective date of April 1, 2019. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11005 constitutes a maintenance update of ICD-10 conversions and other coding updates specific to National Coverage Determinations (NCDs). These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received. Please make sure your billing staffs are aware of these updates.

BACKGROUND

Previous NCD coding changes appear in ICD-10 quarterly updates are available on the Centers for Medicare & Medicaid Services (CMS) website at https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new policy NCDs. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent quarterly releases and individual CRs as appropriate. No policy-related changes are included with the ICD-10 quarterly updates. Any policy related changes to NCDs continue to be implemented via the current, long-standing NCD process.

Please follow the link below for the NCD spreadsheets included with CR: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR11005.zip
Relevant NCD coding changes in CR 11005 include:

- NCD20.7 – Percutaneous Transluminal Angioplasty (PTA)
- NCD80.11 – Vitrectomy
- NCD110.21 – Erythropoiesis Stimulating Agents (ESAs) in Cancer and Neoplastic Conditions
- NCD210.2 – Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancers
- NCD220.4 – Mammograms
- NCD230.18 – Sacral Nerve Stimulation (SNS) for Urinary Incontinence

Coding (as well as payment) is a separate and distinct area of the Medicare program from coverage policy/criteria. Revisions to codes within an NCD are carefully and thoroughly reviewed and vetted by CMS and are not intended to change the original intent of the NCD. The exception to this is when coding revisions are released as official implementation of new or reconsidered NCD policy following a formal national coverage analysis.

Providers should be aware that translations from ICD-9 to ICD-10 are not consistent one-to-one matches, nor are all ICD-10 codes appearing in a complete General Equivalent Mappings (GEMs) mapping guide or other mapping guides appropriate when reviewed against individual NCD policies. In addition, for those policies that expressly allow MAC discretion, there may be changes to those NCDs based on current review of those NCDs against ICD-10 coding. For these reasons, there may be certain ICD-9 codes that were once considered appropriate prior to ICD-10 implementation that are no longer considered acceptable.

MACs shall use default Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) messages where appropriate:

- Remittance Advice Remark Codes (RARC) N386 with Claims Adjustment Reason Codes (CARC) 50, 96, and/or 119. See latest CAQH CORE update.

When denying claims associated with the attached NCDs, except where otherwise indicated, MACs shall use

- Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32, or with occurrence code 32 and a GA modifier, indicating a signed Advance Beneficiary Notice (ABN) is one file).

- Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is one file). For modifier GZ, use CARC 50 and Medicare Summary Notice (MSN) 8.81 per instructions in CR 7228/TR 2148.

**Note:** MACs shall adjust any claims processed in error associated with CR 11005 that are brought to their attention.
ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)

MLN Matters Number: 11134
Related Change Request (CR) Number: 11134
Related CR Release Date: February 1, 2019
Effective Date: July 1, 2019 - Unless otherwise indicated
Related CR Transmittal Number: R2243OTN
Implementation Date: July 1, 2019, – shared system edits, MAC local edits, April 2, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 11134 constitutes a maintenance update of International Classification of Diseases, 10th Revision (ICD-10) conversions and other coding updates specific to National Coverage Determinations (NCDs). These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received.

Make sure that your billing staffs are aware of these changes.

BACKGROUND

Previous NCD coding changes appear in ICD-10 quarterly updates that are available on the Centers for Medicare & Medicaid Services (CMS) website at https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new policy NCDs.

Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent quarterly releases and individual CRs as appropriate. No policy-related changes are included with the ICD-10 quarterly updates. Any policy related changes to NCDs continue to be implemented via the current, long-standing NCD process.

The translations from ICD-9 to ICD-10 are not consistent one-to-one matches, nor are all ICD-10 codes appearing in a complete General Equivalence Mappings (GEMs) mapping guide, or other mapping guides appropriate, when reviewed against individual NCD policies. In addition, for those policies that expressly allow MAC discretion, there may be changes to those NCDs based on current review of those NCDs against ICD-10 coding. For these reasons, there may be certain ICD-9 codes that were once considered appropriate prior to ICD-10 implementation that are no longer considered acceptable.
Please follow the link below for the NCD spreadsheets included with CR 11134:

Relevant NCD coding changes in CR 11134 include:

- NCD20.29 Hyperbaric Oxygen Therapy (HBO)
- NCD110.18 Aprepitant for Chemotherapy-Induced Emesis
- NCD110.23 Stem Cell Transplantation (formerly NCD110.8.1)
- NCD160.18 Vagus Nerve Stimulation (VNS)
- NCD160.24 Deep Brain Stimulation (DBS) for Essential Tremor and Parkinson’s Disease
- NCD110.21 Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions
- NCD150.3 Bone Mineral Density Studies

When denying claims associated with the above NCDs, except where otherwise indicated, MACs will use:

- Remittance Advice Remark Codes (RARC) N386 with Claim Adjustment Reason Code (CARC) 50, 96, and/or 119. See latest CAQH CORE update.
- Group Code PR (Patient Responsibility); assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32, or with occurrence code 32 and a GA modifier, indicating that a signed Advance Beneficiary Notice (ABN) is on file).
- Group Code CO (Contractual Obligation), assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
- For modifier GZ, use CARC 50.

**Note:** MACs will adjust any claims processed in error associated with CR 11134 that are brought to their attention.

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Local Coverage Determinations (LCDs)

MLN Matters Number: MM10901 Revised Related Change Request (CR) Number: 10901
Related CR Release Date: January 30, 2019 Effective Date: September 26, 2018
Related CR Transmittal Number: R857PI Implementation Date: January 8, 2019

Note: We revised the article on February 1, 2019, to reflect the revised CR 10901 issued on January 30, 2019, to include the updates in Chapter 13 of the “Medicare Program Integrity Manual”, which were erroneously not updated in the most recent online manual change. The effective date in the article was also corrected. We also revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10901 notifies MACs that, in accordance with Section 4009 of H.R. 34-21st Century Cures Act (Public Law No: 114-255), the Centers for Medicare & Medicaid Services (CMS) is updating the Medicare Program Integrity Manual with detailed changes to the Local Coverage Determination (LCD) process. You should ensure that your staffs are aware of these changes.

BACKGROUND

Through feedback received in the proposed Calendar Year (CY) 2018 Physician Fee Schedule (PFS) Rule (82 FR 33950), and through meetings and correspondence; stakeholders, including providers and health care associations, have provided CMS with valuable insight regarding modernization of the LCD process.

Most stakeholders acknowledged that the local coverage process is an important means to provide decisions related to the items and services that benefit Medicare’s beneficiaries and to ensure beneficiary access to life saving and medically necessary products and procedures. However, there is concern about the lack of local coverage process transparency, including notifying stakeholders of proposed revisions to, and drafting of, new LCDs.
Additional stakeholder concerns include: ineffective MAC processes for soliciting from, and providing to, stakeholders feedback on information provided during open public meetings, a lack of non-physician representation on Contractor Advisory Committees (CACs), and concerns that CAC meetings are not open to the public.

In CR10901, the revisions to the Medicare Program Integrity Manual, Chapter 13, CMS is revising instructions to MACs, reflecting policy process changes in response to the new statutory (21st century Cures Act) requirements and to the stakeholder comments. These changes will help to increase transparency, clarity, consistency, reduce provider burden and enhance public relations while retaining the ability to be responsive to local clinical and coverage policy concerns.

The 2016 21st Century Cures Act included changes to the LCD process, adding language to 1862(l)(5)(D) of the Social Security Act (the Act) to describe the LCD process. Section 1862(l)(5)(D), of the Act requires each MAC that develops an LCD to make available on their website, at least 45 days before the effective date of such determination, the following information:

- Such determination in its entirety
- Where and when the proposed determination was first made public
- Hyperlinks to the proposed determination and a response to comments submitted to the MAC with respect to such proposed determination
- A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence
- An explanation of the rationale that supports such determination

CMS revamped the format of the manual so that it could be used as a roadmap to understand the steps of the local coverage process, which enable stakeholders to effectively engage in the process. This transparency also carries through to the reconsideration process, which is a process by which stakeholders can request a MAC take a second look at an existing decision using evidence that has developed since its first review.

The manual also sets forth consistent requirements for communication to providers and other stakeholders to occur at predictable milestones so anyone with an interest in the local policy can stay informed as the policy moves through the process.

**NEW LCD PROCESS**

The key parts of the New LCD Process are summarized as follows:

1. The New LCD Process may begin with informal meetings in which interested parties within the MAC’s jurisdiction can discuss potential LCD requests. These educational meetings, which are not required, can be held either in person, using web-based technologies, or via teleconference, which allow discussions before requestors submit a formal request.

2. New LCD Requests
The New LCD Request Process is a mechanism through which interested parties within a MAC’s jurisdiction can request a new LCD. In this process, MACs will consider all new LCD requests from:

- Beneficiaries residing or receiving care in the MAC’s jurisdiction
- Health care professionals doing business in the MAC’s jurisdiction
- Any interested party doing business in the MAC’s jurisdiction

MACs will consider a New LCD Request to be a complete, formal request if the following requirements are met. The request:

- Is in writing and is sent to the MAC via email, facsimile or written letter
- Clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service applies
- Identifies the language that the requestor wants in an LCD
- Includes a justification supported by peer-reviewed evidence (full copies of published evidence must be included or the request is not valid)
- Addresses relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service
- Fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

Within 60 calendar days of the day they receive the request; MACs will review the materials and determine whether the request is complete or incomplete. If the request is complete, the MAC will follow the New LCD Process, as described in the revised manual. If, however, the process is incomplete, they will respond, in writing, to the requestor explaining why the request was incomplete.

3. Clinical Guidelines, Consensus Documents and Consultation

During an LCD’s development, MACs should (when applicable and available) supplement their research with clinical guidelines, consensus documents, or consultation by experts (recognized authorities in the field), medical associations or other health care professionals for an advisory opinion. They will summarize the opinions they receive as a result of this consultation with health care professional expert(s), professional societies, and others prior to the drafting of a proposed or final LCD, and include this information in the proposed or final LCD. Note that acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance of the item or service by the medical community.

4. Publication of the Proposed LCD

The public announcement of a MAC’s proposed determination begins with the date the proposed LCD is published on the Medicare Coverage Database (MCD) at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Once the proposed LCD is published, MACs will provide a minimum of 45 calendar days for public
comment, and will contact the CMS if they determine an extension to the comment period is needed.

These processes shall be used for all LCDs except in the following situations:

- Revised LCD Being Issued for Compelling Reasons.
- Revised LCD that Makes a Non-Substantive Correction - For example, typographical or grammatical errors that do not substantially change the LCD.
- Revised LCD that Makes a Non-discretionary Coverage Update - Contractors shall update LCDs to reflect changes in NCDs or when a conflict with national policy occurs, coverage provisions in interpretive manuals, and payment systems.
- Revise LCD to effectuate an Administrative Law Judge’s decision to nullify an existing LCD due to an LCD Challenge.

5. Contractor Advisory Committee (CAC)

The CAC is to be composed of health care professionals, beneficiary representatives, and representatives of medical organizations; and is used to supplement the MAC's internal expertise, and to ensure an unbiased and contemporary consideration of "state of the art" technology and science. Additionally, all CAC meetings will be open to the public to attend and observe.

MACs will establish one CAC per state or have the option of establishing one CAC per jurisdiction or multi-jurisdictional CAC with representation from each state. If a MAC chooses to have one CAC per jurisdiction or multi-jurisdictional CAC, the MAC must endeavor to ensure that each state has a full committee and the opportunity to discuss the quality of the evidence used to make a determination.

The CAC’s purpose is to provide a formal mechanism for health care professionals to be informed of the evidence used in developing the LCD and promote communications between the MACs and the health care community. The CAC is advisory in nature, with the final decision on all issues resting with MACs.

6. Open Meeting

After the proposed LCD is made public, MACs will hold open meetings to discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in their jurisdiction. Interested parties (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, caregivers, etc.) can make presentations of information related to the proposed LCDs. Members of the CAC may also attend these open meetings. MACs must notify the public about the dates and location for the open meeting. MACs have the option of setting up email electronic mailing lists to announce this information or may use other education methods to adequately inform the public. The electronic mailing list or other method should clearly identify the location, dates and telephone/video/on-line conference information for the open meeting to ensure that this information is clearly distinguished from the information for the CAC meetings.

7. Publication of the Final Determination
After the close of the comment period and the required meetings and consultation, the final LCD and the Response to Comment (RTC) Article will be published on the MCD.

8. Response to Public Comments

MACs will respond to all comments received during the comment period of the proposed LCD by using the RTC article associated with the LCD. The RTC Article is published on the start date of the notice period. The RTC Article will remain publicly available indefinitely on the MCD or the MCD Archive.

9. Notice Period

The date the final LCD is published on the MCD, marks the beginning of the required notice period of at least 45 calendar days before the LCD can take effect. If the notice period is not extended by the MAC, the effective date of the LCD is the 46th calendar day after the notice period began.

Full details of this new process are in the updated manual which is an attachment to CR10901.

**LCD RECONSIDERATION PROCESS**

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC’s jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative. This process is summarized as follows:

1. MACs shall consider all LCD reconsideration requests from:
   - Beneficiaries residing or receiving care in a contractor’s jurisdiction
   - Providers doing business in a contractor’s jurisdiction
   - Any interested party doing business in a contractor’s jurisdiction

2. MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall **not** be accepted for other documents including:
   - National Coverage Determinations (NCDs);
   - Coverage provisions in interpretive manuals;
   - Proposed LCDs;
   - Template LCDs, unless or until they are adopted and in effect by the contractor;
   - Retired LCDs;
   - Individual claim determinations
   - Bulletins, articles, training materials; and
   - Any instance in which no LCD exists, that is, requests for development of an LCD.

3. Process Requirements - The requestor shall submit a valid LCD reconsideration request to the appropriate MAC, following instructions on the MAC’s website. Within 60 calendar days
of the day the request is received, the MAC shall determine whether the request is valid or invalid. If the request is invalid, the MAC will respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the MAC will open the LCD and follow the LCD process as outlined in the above for new LCDs or include the LCD on the MAC’s waiting list. The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait-listing, of the reconsideration request.

OTHER IMPORTANT CHANGES

Other key changes to the manual include the following:

- MACs shall finalize or retire all proposed LCDs within one calendar year of publication date on the MCD.
- Upon further notice from CMS, it will no longer be appropriate to routinely include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All codes will be removed from LCDs and placed in billing & coding articles that are linked to the LCD.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

As part of the CMS commitment to continuous improvement, CMS invites interested stakeholders to submit feedback on their experience with the revised LCD process. CMS will collect feedback via submissions to LCDmanual@cms.hhs.gov and consider additional revisions based on stakeholder feedback.
## DOCUMENT HISTORY

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<td>January 11, 2019</td>
<td>We revised the article to reflect the revised CR 10901 issued on January 11. In the article, we added language to show that MACs have the discretion to host multi-jurisdictional CACs. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.</td>
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National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)

MLN Matters Number: MM10878
Related Change Request (CR) Number: 10878

Related CR Release Date: November 30, 2018
Effective Date: March 16, 2018

Related CR Transmittal Number: R210NCD
Implementation Date: March 8, 2019 - A/B MACs

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10878 informs, effective March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) covers diagnostic laboratory tests using next generation sequencing when performed in a Clinical Laboratory Improvement Amendments- certified laboratory when ordered by a treating physician and when specific requirements are met. Make sure your billing staffs are aware of this change.

This revision to the “Medicare National Coverage Determinations Manual” is a national coverage determination (NCD). NCDs are binding on MACs with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR Section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

BACKGROUND

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. NGS is one technique that can measure one or more genetic variation as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.
Patients with advanced cancer can have recurrent, relapsed, refractory, metastatic, and/or stages III or IV of cancer. Clinical studies show that genetic variations in a patient's cancer can, in concert with clinical factors, predict how each individual responds to specific treatments.

In application, a report of results of a diagnostic laboratory test using NGS (that is, information on the cancer’s genetic variations) can contribute to predicting a patient’s response to a given drug: good, bad, or none at all. Applications of NGS to predict a patient’s response to treatment occurs ideally prior to initiation of the drug.

CMS reviewed the evidence for laboratory diagnostic tests using NGS in patients with cancer, and determined that such tests with analytical and clinical validity, and clinical utility, could also improve health outcomes for Medicare beneficiaries with advanced cancer. Therefore, CMS shall cover certain diagnostic laboratory tests using NGS when requirements are met.

Effective for claims with dates of service on or after March 16, 2018, CMS has determined that the evidence is sufficient to cover diagnostic laboratory tests that use NGS under specified conditions. CMS will cover such testing under the Medicare program for beneficiaries with recurrent, relapsed, refractory, metastatic cancer, or advanced stages III or IV cancer if the beneficiary has either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician, and decided to seek further cancer treatment (e.g., therapeutic chemotherapy). The test must be ordered by the treating physician, performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, and have all of the following requirements met:

- Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic;
- An FDA-approved or -cleared indication for use in that patient’s cancer; and,
- Results provided to the treating physician for management of the patient using a report template to specify treatment options.

Additionally, MACs may determine coverage of other diagnostic laboratory tests using NGS for patients with cancer only when the test is performed in a CLIA-certified laboratory, ordered by the treating physician and the patient has:

- Either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and,
- Either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and,
- Decided to seek further cancer treatment (for example, therapeutic chemotherapy).
A diagnostic laboratory test using NGS is non-covered when cancer patients do not have the above-noted indications for cancer under either national or local coverage criteria.

**ADDITIONAL INFORMATION**

The official instruction, CR10878, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R210NCD.pdf. Attachment 1 of CR10878 contains a list of covered clinical diagnostic laboratory tests using NGS and respective allowed ICD-10 diagnosis codes for the listed effective dates.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

**DOCUMENT HISTORY**

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<td>December 10, 2018</td>
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**NCD 20.4 Implantable Cardiac Defibrillators (ICDs)**

MLN Matters Number: MM10865 Revised
Related Change Request (CR) Number: 10865

Related CR Release Date: December 13, 2018
Effective Date: February 15, 2018

Related CR Transmittal Number: R211NCD
Implementation Date: February 26, 2019 - MAC local edits

Note: This article was revised on December 17, 2018, to reflect a revised CR10865 issued on December 13. In the article, two sentences are added at the end of the Provider Action Needed section to emphasize that this coverage policy no longer requires trial-related coding on claims for dates of service on or after February 15, 2018. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is unchanged.

**PROVIDER TYPES AFFECTED**

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**PROVIDER ACTION NEEDED**

CR 10865 and the Medicare National Coverage Determinations (NCD) Manual Transmittal reflects the Centers for Medicare & Medicaid Services (CMS) final decision dated February 15, 2018, regarding the reconsideration of NCD 20.4, Implantable Defibrillators (ICDs). Make sure your billing staffs are aware of this decision. Effective February 15, 2018, coverage policy is no longer contingent on participation in a trial/study/registry. Therefore, claims with a Date of Service (DOS) on or after February 15, 2018, no longer require any trial-related coding.

**BACKGROUND**

An ICD is an electronic device designed to diagnose and treat life-threatening Ventricular Tachyarrhythmias (VTs). The device consists of a pulse generator and electrodes for sensing and defibrillating. This therapy has been shown in trials to improve survival and reduce sudden cardiac death in patients with certain clinical characteristics.

Section 20.4 of the Medicare NCD Manual establishes conditions of coverage for ICDs. In 1986, CMS first issued an NCD providing limited coverage of ICDs and the policy has been expanded over the years. CMS last reconsidered this NCD in 2005. Effective for claims with dates of service on or after February 15, 2018, CMS will cover ICDs for the following patient indications:
1. Patients with a personal history of sustained VT or cardiac arrest due to Ventricular Fibrillation (VF). Patients must have demonstrated:
   - An episode of sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or
   - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.

2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure; or,
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have New York Heart Association (NYHA) Class II or III heart failure, LVEF ≤ 35%. Additionally, patients must not have:
   - Had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

4. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of cardiac arrest or sustained VT, NYHA Class II or III heart failure, LVEF < 35%, and been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
   - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or,
   - Had an MI within the past 40 days; or,
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For these patients identified in items 2 through 5 above, a formal shared decision-making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of
the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in Section 1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision-making encounter may occur at a separate visit.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (for example, not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:
   - Significant, irreversible brain damage; or,
   - Any disease, other than cardiac disease (for example, cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
   - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a CABG or PCI with angioplasty and/or stenting within the past 3 months, or had an MI within the past 40 days:

- Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in NCD 20.4 for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;
- Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, as with cardiac resynchronization therapy, when used as a bridge-to-transplant to prolong survival until a donor becomes available, MACs determine coverage of ICDs.

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B investigational device exemption (IDE) trials per regulation at 42 CFR 405.201.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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Update to Intensive Cardiac Rehabilitation (ICR) Programs

MLN Matters Number: MM11117 Related Change Request (CR) Number: 11117
Related CR Release Date: February 1, 2019 Effective Date: February 9, 2018
Related CR Transmittal Number: R4222CP Implementation Date: March 19, 2019

PROVIDER TYPE AFFECTED

This article is intended for providers who bill Medicare Administrative Contractors (MACs) for Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (ICR) program services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article is based on Change Request (CR) 11117 which informs MACs about Section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), which amended Section 1861(eee)(4)(B) of the Social Security Act (the Act) to expand coverage of ICR to additional conditions that became effective February 9, 2018. Make sure that your billing staff is aware of these changes.

BACKGROUND

The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, Pub. L. No. 110-275, Section 144 (2008) established coverage for cardiac rehabilitation programs and ICR programs under Part B. These provisions are primarily codified in section 1861(eee) of the (the Act. The Centers for Medicare & Medicaid Services (CMS) implemented the statutory provisions through rulemaking codified at 42 CFR 410.49 that were effective January 1, 2010.

Effective January 1, 2010, Medicare Part B covered ICR program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.

Effective February 9, 2018, Section 51004 of the BBA of 2018, Pub. L. No. 115-123 (2018), amended Section 1861(eee)(4)(B) of the Act to expand coverage in an ICR to the following additional conditions:

- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) Class II to IV symptoms despite
being on optimal heart failure therapy for at least 6 weeks; or

- Any additional condition for which the Secretary has determined that a cardiac rehabilitation program will be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

**Expanded Coverage**

CMS plans to amend the ICR regulations specified at [42 CFR 410.49](https://www.govinfo.gov/content/pkg/FR-2018-02-08/pdf/2018-03645.pdf) to reflect this expanded coverage. CMS anticipates that the changes will be included in the 2020 Medicare Physician Fee Schedule notice of proposed rulemaking. However, because the expanded coverage under the statutory change was effective upon enactment, expanded ICR coverage for these conditions will be made effective for services furnished on or after February 9, 2018. See Pub. 100-02, “Medicare Benefit Policy Manual”, Chapter 15, Section 232 and Pub 100-04, Chapter 32, Section 140.3.

**Note:** For claims with dates of service on or after February 9, 2018, but received before the implementation date of CR 11117, MACs will not search their files, but they will adjust claims brought to their attention.

### ADDITIONAL INFORMATION


### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 6, 2019</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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Updates to Immunosuppressive Guidance

MLN Matters Number: MM11072  Related Change Request (CR) Number: CR 11072
Related CR Release Date: December 31, 2018  Effective Date: April 3, 2019
Related CR Transmittal Number: R4189CP  Implementation Date: April 3, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for immunosuppressive drugs provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11072 updates guidance in the Medicare Claims Processing Manual regarding the provision of covered immunosuppressive drugs to inpatients for use after a transplant procedure. Make sure your billing staffs are aware of these updates.

BACKGROUND

Inpatient facilities (for example, hospitals) are responsible for providing drugs during a beneficiary’s inpatient stay. However, once the beneficiary has returned home, Part B suppliers (including pharmacies) provide the immunosuppressive drugs, and the DME MACs make the payments for Part B covered immunosuppressive drugs.

In certain cases, a beneficiary who has received a transplant does not return home immediately after discharge. In order to ensure timely beneficiary access to prescribed immunosuppressive medications at the time of discharge, suppliers may deliver the initial prescriptions of a beneficiary’s immunosuppressive drugs to an alternate address, such as the transplant facility or alternative location where the beneficiary is temporarily staying, for example, temporary housing, instead of delivering the drugs to the patient’s home address.

Note that this is an optional, not mandatory, process. If the supplier ships immunosuppressive drugs to an alternate address, all parties involved, including the beneficiary and the transplant facility, must agree to the use of this approach. All other applicable Medicare and DME MAC billing requirements continue to apply. This provision is limited to prescriptions that will be billed on the first claim that the supplier submits for the beneficiary after the beneficiary is discharged from an inpatient facility.
The following conditions also apply:

- The immunosuppressive drug must be medically necessary on the date of discharge; that is, there is a valid prescription for an immunosuppressive drug that is reasonable and necessary and is clinically required to be available no later than the date of discharge for home use.

- Early and/or direct delivery to the transplant facility does not change the inpatient facility’s responsibility to provide all immunosuppressive drugs that the beneficiary requires during their entire inpatient stay.

- The supplier must not:
  - Mail, or otherwise dispense the drugs any earlier than 2 days before the beneficiary’s anticipated discharge date. (It is the supplier’s responsibility to confirm the beneficiary’s discharge date.)
  - Submit a claim for payment prior to the beneficiary’s actual date of discharge.
  - Claim payment for additional costs that the supplier incurs in ensuring that the immunosuppressive medications are delivered to the alternative location. Additionally, the supplier also must not bill Medicare or the beneficiary for redelivery if it is necessary.

This new guidance may be used with the early delivery provision already described in Section 80.3.3, and all other applicable Medicare and DME MAC billing requirements continue to apply.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

**DOCUMENT HISTORY**

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>December 31, 2018</td>
<td>Initial article released.</td>
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</table>

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INFORMATION ON WEBSITE

WPS GHA publishes Local Coverage Determinations (LCDs) on its website:
https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources

If you cannot gain access to the Internet from your office or home, you might try one of the many public libraries that offer Internet access. You may request a hard copy of a retired LCD by writing to our Freedom of Information (FOI) Unit.

WPS GHA
Attn: Freedom of Information Act (FOIA)
P.O. Box 1604
Omaha, NE 68101

NEW POLICIES

The following are new policies. Be sure to note the effective date of the new policy, as the policy will not appear as an active policy until the effective date. Prior to the effective date, the policy can be found by selecting the link "Display Future Effective Documents" within the CMS Medicare Coverage Database (MCD):

Visit our website at the link below for more information:

March 2019

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Coding Article for MolDX: Breast Cancer Index™ (BCI) Gene Expression Test LCD L37913</td>
<td>A56335</td>
<td>NA</td>
<td>04/15/2019</td>
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<tr>
<td>J5/J8</td>
<td>Coding Article for MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer LCD L37921</td>
<td>A56333</td>
<td>NA</td>
<td>04/15/2019</td>
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<td>MolDX: Breast Cancer Index™ (BCI) Gene Expression Test</td>
<td>L37913</td>
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<td>04/15/2019</td>
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<td>J5/J8</td>
<td>MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer</td>
<td>L37921</td>
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<td>04/15/2019</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Oncotype DX® Genomic Prostate Score Coding and Billing Article</td>
<td>A56334</td>
<td>NA</td>
<td>04/15/2019</td>
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<td>J5/J8</td>
<td>Posterior Tibial Nerve Stimulation (PTNS) Billing and Coding Guidelines</td>
<td>A56331</td>
<td>NA</td>
<td>04/15/2019</td>
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<tr>
<td></td>
<td>This article will be replacing the retired L34436 Posterior Tibial Nerve Stimulation (PTNS) (04/14/2019). This article will efficiently support the billing and coding guidance which was in L34436. A lapse in coverage will not occur.</td>
<td></td>
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<tr>
<td>J5/J8</td>
<td>Billing and Coding Guidelines for Chiropractic Services</td>
<td>A56273</td>
<td>NA</td>
<td>03/19/2019</td>
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<tr>
<td></td>
<td>This article contains the billing and coding guidance that was in our L34585 Chiropractic Services LCD.</td>
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<tr>
<td>J5/J8</td>
<td>Human Granulocyte/Macrophage Colony Stimulating Factors Billing and Coding Guidelines</td>
<td>A56274</td>
<td>NA</td>
<td>03/19/2019</td>
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<tr>
<td></td>
<td>This article will be replacing the retired LCD L34699 Human Granulocyte/Macrophage Colony Stimulating Factors (03/18/2019). This article will efficiently support the billing and coding guidance that was in L34699. A lapse in coverage will not occur.</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: clonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies</td>
<td>A56277</td>
<td>NA</td>
<td>03/19/2019</td>
</tr>
<tr>
<td>J5/J8</td>
<td>Billing and Coding Guidelines for Foot Care</td>
<td>A56232</td>
<td>NA</td>
<td>02/16/2019</td>
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<tr>
<td></td>
<td>This article contains the billing and coding guidance that was in our L36404 Foot Care LCD.</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs)</td>
<td>L37766</td>
<td>MolDX-043</td>
<td>02/16/2019</td>
</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC)</td>
<td>L37915</td>
<td>MolDX-047</td>
<td>02/16/2019</td>
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</tbody>
</table>
## RETIRED POLICIES

The following are retired policies. Be sure to note the effective date of the retired policy, as the policy will not appear as retired until the effective date.

Visit our website at the link below for more information:

### March 2019

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Posterior Tibial Nerve Stimulation (PTNS)</td>
<td>L34436</td>
<td>GSURG-043</td>
<td>04/14/2019</td>
</tr>
</tbody>
</table>

LCD L34436 to be retired 04/14/2019 and replaced with the Article Posterior Tibial Nerve Stimulation (PTNS) Billing and Coding Guidelines effective 04/15/2019. This article will efficiently support the billing and coding guidance which was in L34436. A lapse in coverage will not occur.

### February 2019

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Chiropractic Services and Billing and Coding Guidelines</td>
<td>L34585</td>
<td>CHIRO-001</td>
<td>03/18/2019</td>
</tr>
</tbody>
</table>

This LCD and Billing and Coding Guidelines for Chiropractic Services are being retired due to Change Request 10901 Local Coverage Determinations (LCDs) which does not allow us to include national policy language in our LCDs. Please see our new coverage article A56273 Billing and Coding Guidelines for Chiropractic Services.

Coverage information can be found in CMS Internet-Only Manual (IOM) Publication, 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 30.5 Chiropractor’s Services; Section 40.4 Definition of Physician /Practitioner; Section 220 - Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance; and Section 240 Chiropractic Services – General to Section 240.1.5 Treatment Parameters.

CMS Internet-Only Manual (IOM) Publication, 100-04 Medicare Claims Processing Manual, Chapter 12, Section 220 - Chiropractic Services and Chapter 23, Section 20.9.1.1 - Instructions for Codes with Modifiers (Only) A/B MACs (B).

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Flow Cytometry</td>
<td>L34651</td>
<td>PATH-016</td>
<td>03/18/2019</td>
</tr>
</tbody>
</table>

Retirement 03/18/2019 due to the non-applicable, outdated, clinical information to support the guidance provided. Products/services contained within in the policy will no longer be denied based on the verbiage of the policy. Any service billed to Medicare must be reasonable and medically necessary.

<table>
<thead>
<tr>
<th>Contract</th>
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<th>WPS Policy #</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Human Granulocyte/Macrophage Colony Stimulating Factor</td>
<td>L34699</td>
<td>INJ-019</td>
<td>03/18/2019</td>
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</table>

LCD L34699 retired 03/18/2019 and replaced with the Article Human Granulocyte/Macrophage Colony Stimulating Factors Billing and Coding Guidelines.
This article will efficiently support the billing and coding guidance which was in L34699. A lapse in coverage will not occur.

J5/J8  
**MoIDX: Pigmented Lesion Assay (PLA) and PLA Score**  
Policy # DL37669  
MoIDX-040  
Effective Date 02/01/2019

This proposed draft is being retired and will not be finalized.

### January 2019

**J5/J8**  
**Foot Care**  
Policy # L36404  
FT-002  
Effective Date 02/15/2019

This LCD is being retired due to Change Request 10901 Local Coverage Determinations (LCDs) which does not allow us to include national policy language in our LCDs. Please see our new coverage article A56232 Billing and Coding Guidelines for Foot Care.

Coverage information can be found in the CMS Internet-Only Manual (IOM) Publication, 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 290 – Foot Care, and in the CMS IOM Publication 100-03, Medicare National Coverage Determination Manual, Section 70.2.1 – Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy). For information on the exclusion of payment for routine foot care see: 42 CFR Section 411.15 Particular services excluded from coverage and Title XVIII of the Social Security Act, section 1862 (a)(13)(C).

### REVISED POLICIES

The following are revised policies. Be sure to note the effective date of the revised policy, as the policy will not appear as an active policy until the effective date. Prior to the effective date, the policy can be found by selecting the link "Display Future Effective Documents" within the CMS Medicare Coverage Database (MCD):


Visit our website at the link below for more information:


### March 2019

**J5/J8**  
**Intraarticular Knee Injections of Hyaluronan Billing Guidelines**  
Policy # A56157  
Billing the injection procedure  
Added CPT code 20611 to following statement:

The appropriate site modifier (RT or LT) must be appended to CPT code 20610 or CPT code 20611 to indicate if the service was performed unilaterally and modifier (-50) must be appended to indicate if the service was performed bilaterally.

**J5/J8**  
**Lab: Special Histochemical Stains and Immunohistochemical Stains**  
Policy # L36805  
Effective Date 03/01/2019
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>The word “Lab” was added to the title of this LCD and a link to the College of American Pathologists (CAP) Cancer Protocol Templates (<a href="https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates">https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates</a>) was added to the fourth reference in the Sources of Information section.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: Biomarkers in Cardiovascular Risk Assessment</td>
<td>L36523</td>
<td>MolDX-003</td>
<td>03/01/2019</td>
</tr>
<tr>
<td>J5/J8</td>
<td>Diagnosis Z13.220 has been removed from this LCD. It is on the Medicare NCD Coding Policy Manual and Change Report as a non-covered diagnostic code.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: clonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies</td>
<td>A56277</td>
<td>NA</td>
<td>03/19/2019</td>
</tr>
<tr>
<td>J5/J8</td>
<td>Changed “testing” to “treatment” in the following sentence: This coverage decision allows Medicare Administrative Contractors to cover a next generation sequencing test for cancer diagnoses in beneficiaries with advanced cancer who are seeking additional treatment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: Coding and Billing for Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia</td>
<td>A55738</td>
<td>NA</td>
<td>07/20/2018</td>
</tr>
<tr>
<td>J5/J8</td>
<td>CPT code 81120 had been added for billing IDH1 test. 81120 IDH1 (ISOCITRATE DEHYDROGENASE 1 [NADP+], SOLUBLE) (EG, GLIOMA), COMMON VARIANTS (EG, R132H, R132C)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>The Abbott RealTime IDH1 by Abbott Molecular is the only test that has received FDA approval to be used as an aid in identifying acute myeloid leukemia (AML) patients with an isocitrate dehydrogenase-1(IDH1) mutation for treatment with TIBSOVO® (ivosidenib).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>TIBSOVO® (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>Abbott RealTime IDH1 by Abbott Molecular meets the reasonable and necessary criteria for Medicare reimbursement, effective 7/20/2018.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>To report an Abbott RealTime IDH1 service, please submit the following claim information: Select the CPT 81120 for claims on or after 07/20/2018.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer

Added 0047U and removed 81479 - Unlisted Molecular Pathology Procedure.

0047U Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score.

### MolDX: Prometheus IBD sgi Diagnostic Policy

<table>
<thead>
<tr>
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<th>WPS Policy #</th>
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<tr>
<td>J5/J8</td>
<td>MolDX: Prometheus IBD sgi Diagnostic Policy</td>
<td>L37539</td>
<td>MolDX-035</td>
<td>03/01/2019</td>
</tr>
</tbody>
</table>

- Added the following information under Evolution of IBD Testing:
  - The American College of Gastroenterology, in its guideline on the clinical management of Crohn's Disease in adults, states that serologic tests are not routinely recommended to establish a diagnosis of CD.4

- Additionally, serological studies evaluating anti-glycan antibodies and antibodies to microbial antigens are being studied to support the diagnosis of inflammatory bowel disease, but the reliability of these tests in helping establish a diagnosis is still not sufficient.5

- Removed the following information:
  - The AGA states that serologic testing may have important consequences in terms of counseling, prognosis, and the choice of medical and surgical therapies5. Additionally, serological studies evaluating antibodies against Saccharomyces cerevisiae, antineutrophil cytoplasmic antibodies, antibodies directed against CBir1, OmpC are evolving to provide adjunctive support for the diagnosis of CD but are not sufficiently sensitive or specific to be recommended for use as a screening tools.

- Reference #4 and #6 were updated in the Bibliography:

### February 2019

<table>
<thead>
<tr>
<th>Contract</th>
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<th>WPS Policy #</th>
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<td>J5/J8</td>
<td>2019 MolDX CPT/HCPCS Code Updates</td>
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<td>01/01/2019</td>
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- 2019 MolDX CPT/HCPCS Code Updates

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<tr>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Blepharoplasty Blepharoptosis and Brow Lift</td>
<td>L34528</td>
<td>OPHTH-022</td>
<td>10/01/2018</td>
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- ICD-10 Code Updates: added the following diagnosis codes: H57.811 Brow ptosis, right
<table>
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<tr>
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<td>Drug Administration Coding</td>
<td>A54176</td>
<td>NA</td>
<td>02/01/2019</td>
</tr>
<tr>
<td></td>
<td>Added J0517 benralizumab (Fasenra™) to the list of drugs that should not be</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>billed using a chemotherapy administration code.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>Foodborne Gastrointestinal Panels</td>
<td>L37766</td>
<td>MolDX-043</td>
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<tr>
<td></td>
<td>Identified by Multiplex Nucleic Acid Amplification Tests (NAATs)</td>
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<tr>
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<td>“MolDX” has been removed from the title of this LCD.</td>
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<tr>
<td></td>
<td>Diagnosis code Y92.238 has been removed from the LCD; effective 03/19/2019.</td>
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<tr>
<td></td>
<td>Y92.238 Other place in hospital as the place of occurrence of the external</td>
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<td>cause.</td>
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<tr>
<td>J5/J8</td>
<td>Human Granulocyte/Macrophage Colony Stimulating Factor</td>
<td>L34699</td>
<td>INJ-019</td>
<td>02/01/2019</td>
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<tr>
<td></td>
<td>CMS National Coverage Policy added Change Request 10894, Transmittal 4121,</td>
<td></td>
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<tr>
<td></td>
<td>Annual Update Reminder. 12/21/2018 CMS issued corrected HCPCS. Effective</td>
<td></td>
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<tr>
<td></td>
<td>01/01/2019.</td>
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<tr>
<td></td>
<td>Updates to J. Indications for Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5</td>
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<tr>
<td></td>
<td>mg.</td>
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<tr>
<td></td>
<td>Removed (C9399/J3490) and replaced with (Q5111).</td>
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<td>Change Request 10894, Transmittal 4121, August 24, 2018. 2019 Healthcare</td>
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<td>Common Procedure Coding System (HCPCS) Annual Update Reminder.</td>
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<td>12/21/2018 CMS issued corrected HCPCS. Effective 01/01/2019.</td>
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<td>Group 1 Paragraph: removed from free text:</td>
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<tr>
<td></td>
<td>(C9399/J3490) Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.</td>
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<td>Group 1 Codes: removed from table:</td>
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<tr>
<td></td>
<td>C9399 Unclassified Drugs or Biologicals</td>
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<tr>
<td></td>
<td>J3490 Unclassified Drugs and</td>
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<td></td>
<td>J3590 Unclassified Biologics.</td>
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<td>Group 1 Codes: added to table:</td>
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<tr>
<td></td>
<td>Q5111 Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.</td>
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<td>C9399/J3490 Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.</td>
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<td>Group 10 Paragraph: replaced with</td>
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<tr>
<td></td>
<td>Q5111 Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg.</td>
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<tr>
<td></td>
<td>Removed Not Otherwise Classified Drug Billing Guidance from policy.</td>
<td></td>
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</tbody>
</table>
Anticipated retirement of LCD L34699 on 03/18/2019 to be replaced with the Article Human Granulocyte/Macrophage Colony Stimulating Factors Billing and Coding Guidelines. This article will efficiently support the billing and coding guidance which was in L34699. A lapse in coverage will not occur.

### J5/J8 MolDX: Coding and Billing for Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MolDX: Coding and Billing for Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia</td>
<td>A55738</td>
<td>NA</td>
<td>07/20/2018</td>
</tr>
</tbody>
</table>

IDH1 has been added to the title of this article. The following information has been added to the article:

The Abbott RealTime IDH1 by Abbott Molecular is the only test that has received FDA approval to be used as an aid in identifying acute myeloid leukemia (AML) patients with an isocitrate dehydrogenase-1(IDH1) mutation for treatment with TIBSOVO® (ivosidenib).

TIBSOVO® (ivosidenib) is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.

Abbott RealTime IDH1 by Abbott Molecular meets the reasonable and necessary criteria for Medicare reimbursement, effective 7/20/2018.

To report an Abbott RealTime IDH1 service, please submit the following claim information:
Select the CPT 81121 for claims on or after 07/20/2018.

### J5/J8 MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing

<table>
<thead>
<tr>
<th>Policy Title</th>
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<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing</td>
<td>MolDX-002</td>
<td>NA</td>
<td>02/01/2019</td>
</tr>
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</table>

The information contained in NCD 90.1 Pharmacogenomic testing to Predict Warfarin Responsiveness has been removed from the policy.

Removed:
Effective August 3, 2009, the Centers for Medicare & Medicaid Services (CMS) believes that the available evidence supports that coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the Act) is appropriate for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness by any method, and is therefore covered only when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin who:

- Have not been previously tested for CYP2C9 or VKORC1 alleles; and
- Have received fewer than five days of warfarin in the anticoagulation regimen for which the testing is ordered; and
- Are enrolled in a prospective, randomized, controlled clinical study when that study meets the standards as outlined in NCD 90.1 - Pharmacogenomic Testing to Predict Warfarin Responsiveness.

A reference to NCD 90.1 Pharmacogenomic testing to Predict Warfarin Responsiveness has been listed under the Warfarin section.
**Contract Policy Title CMS MCD Policy # WPS Policy # Effective Date**

<table>
<thead>
<tr>
<th>Contract</th>
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<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td><strong>2019 CPT/HCPCS Code Updates</strong></td>
<td>NA</td>
<td>NA</td>
<td>01/01/2019</td>
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**January 2019**

**Contract** | **Policy Title** | **CMS MCD Policy #** | **WPS Policy #** | **Effective Date** |
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<tbody>
<tr>
<td>J5/J8</td>
<td><strong>Category III Codes</strong></td>
<td>L35490</td>
<td>PHYS-084</td>
<td>01/01/2019</td>
</tr>
</tbody>
</table>

See 2019 CPT/HCPCS Code Updates for annual CPT/HCPCS code updates.

Deleted the Group 3 codes for leadless pacemaker.

- 0387T Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular
- 0389T Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report, leadless pacemaker system
- 0390T Peri-procedural device evaluation (in person) and programming of device system parameters before or after surgery, procedure or test with analysis, review and report, leadless pacemaker system
- 0391T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system

Removed the corresponding Group 3 Paragraph.

Group 3 Paragraph: For Part B only. Effective for dates of service on or after January 18, 2017, contractors shall cover leadless pacemakers through CED when procedures are performed in CMS-approved CED studies per NCD 20.8.4.

Removed the corresponding Group 3 Paragraph.

For Part B only. The following ICD-10 Codes are used to support medical necessity with CPT codes 0387T, 0389T, 0390T and 0391T.

Removed the corresponding Group 3 table of ICD-10 diagnosis code.

Z00.6 Examination for examination for normal comparison and control in clinical research program

Removed the following Utilization Guidelines language.

0387T, 0389T, 0390T, and 0391T For Part B only.

The leadless pacemaker eliminates the need for a device pocket and insertion of a
pacing lead which are integral elements of traditional pacing systems. The removal of these elements eliminate an important source of complications associated with traditional pacing systems while providing similar benefits. Leadless pacemakers are delivered via catheter to the heart, and function similarly to other transvenous single-chamber ventricular pacemakers. Effective January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when procedures are performed in Food and Drug Administration (FDA) approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:
- an associated ongoing FDA approved post-approval study; or
- completed an FDA post-approval study.
Please see NCD for Leadless Pacemakers (20.8.4) for claims processing instructions (see CR 10117, Transmittal #3815, dated 07/28/2017).

Removed the Related National Coverage Documents, 20.8.4 Leadless Pacemakers. (The leadless pacemaker system now has true codes.)

J5/J8 Coding Radiopharmaceutical Agents

Added the following verbiage in Miscellaneous Radiopharmaceuticals section:
10. A9513 Lutetium lu 177, dotatate, therapeutic, 1 millicurie
   For the treatment of adult patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs).
   (CPT 79101)

11. A9589 Instillation, hexaminolevulinate hydrochloride, 100 mg
   A diagnostic agent instilled into the bladder for detection of carcinoma of the bladder. (CPT 52000, 52204, 52214 - 55240.
   Typographical error noted in Section A Line 9 of incorrect listing of CPT code 78652; correction made: CPT code 78650.

J5/J8 Erythropoiesis Stimulating Agents (ESAs)

CMS National Coverage Policy Section Added:
CR 10859 Transmittal 2200 Issued 11/02/2018: Tenth Revisions (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) NCD 110.21 Erythropoiesis Stimulating Agents (ESAs in Cancer) effective January 1, 2019

CR 11005 Transmittal 2202 Issued 11/9/2018 International Classification of Diseases, 10th Revision, (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) NCD 110.21 Erythropoiesis Stimulating Agents (ESAs in Cancer) effective January 1, 2017.

Group 4 Paragraph:
C. Indications other than Renal Disease
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Human Granulocyte/Macrophage Colony Stimulating Factor</td>
<td>L34699</td>
<td>INJ-019</td>
<td>01/01/2019</td>
</tr>
</tbody>
</table>

1. Anemias related to therapy with Zidovudine (AZT)

   Added to Group 4 Codes:
   D61.1 Drug-induced aplastic anemia

   Group 6 Codes added:
   Z79.899* Other long term (current) drug therapy.

   Removed Group 7 Paragraph and Group 7 Codes.
   Group 7 Code Z79.899* relocated to Group 6 Code table.

   Group 10 Paragraph:
   Removed: Dual Diagnosis necessary for J0881, J0885, and Q5106 and
   Replaced: Both Diagnoses necessary for J0881, J0885, and Q5106.

   Group 10 Codes added:
   Z01.818 Encounter for other preprocedural examination
   Removed Group 12 Paragraph and Group 12 Codes.
   Group 12 Code Z01.818 relocated to Group 10 Code table.

   Reformatted numerical order of paragraphs and code tables.

   Group C: Indications other than Renal Disease
   Anemia associated with cancer and related Neoplastic conditions.
   Added: This policy does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) and does not contain specific diagnosis codes related to NCD 110.21 for the use of ESAs in cancer and related neoplastic conditions.

   Group 6 Paragraph
   Anemia associated with chemotherapeutic medications when medically necessary for a non-cancer diagnosis or following stem cell transplantation and associated immunosuppression.
   Added: This policy does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) and does not contain specific diagnosis codes related to NCD 110.21 for the use of ESAs in cancer and related neoplastic conditions.

See 2019 CPT/HCPCS Code Updates for annual CPT/HCPCS code updates.

Long description change Q5101: Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram

Group 1 Paragraph removed from free text:
Q5108 Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg
<table>
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<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
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<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>Q5110</td>
<td>Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram</td>
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</tr>
</tbody>
</table>

Group 1 Paragraph added to free text:

C9399/J3490 Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg

Group 1 Codes added to Table:
C9399 Unclassified Drugs or Biologicals
J3490 Unclassified Drugs
J3590 Unclassified Biologics
Q5108 Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg
Q5110 Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram

Coverage Indication, Limitations, and/or Medical Necessity created:
J. Indications for Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg (C9399/J3490). FDA approval date 11/02/2018. Effective date 11/02/2018.

1. Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

Created Group 10 Paragraph
C9399/J3490 Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg

Created Group 10 Codes
D61.810 Antineoplastic chemotherapy induced pancytopenia
D70.1 Agranulocytosis secondary to cancer chemotherapy
T45.1X5A Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S Adverse effect of antineoplastic and immunosuppressive drugs, sequela
Z51.11 Encounter for antineoplastic chemotherapy
Z92.21 Personal history of antineoplastic chemotherapy

Added Not Otherwise Classified Drug Billing

Not Otherwise Classified (NOC) codes are used when there is absolutely no existing true code for the service, procedure, drug or biological being provided. Claims utilizing “J”/NOC codes are subject to Medical Review.

When a specific HCPCS code does not exist, list the appropriate “J”/NOC code:
J3490: Unclassified drugs
J3590: Unclassified biologics or
J9999: Not otherwise classified, antineoplastic drugs.

When an NOC code is billed, documentation must identify specifically for what the NOC code is being billed for, supporting the service, procedure, and drug biological being provided.

Coverage for medication is based on the patient’s condition, the appropriateness of the dose and route of administration, based on the clinical condition and the
standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition.

The HCPCS is updated annually to reflect changes in the practice of medicine and provision of health care. CMS posts on its Web site the annual alpha-numeric HCPCS file for the upcoming year, historically, at the end of each October. Providers are encouraged to access CMS web site to see the new, revised, and discontinued alpha-numeric codes for the upcoming year.

Office/Clinic Coding

When using a drug Unclassified/NOC code (J3490, J3590, J9999) list the name of the drug, the amount of the drug that is administered and wasted if applicable, strength of dosage if appropriate; method of administration in the electronic narrative 2400/SV101-7 which is equivalent to line 19 of the CMS 1500 form. List the units of service as one in 2400/SV1-04 data element of the ANSI 837 5010 or in item 24G of the CMS 1500 form.

Occasionally, the strength of the drug will also be needed on NOC claims. If the NOC ASP pricing file lists the name of the drug with its strength it must also be included on line 19. Example: Sodium Bicarbonate 8.4%.

Hospital Outpatient Departments Coding

Hospital outpatient departments are allowed to bill for new drugs, biologicals, and therapeutic radiopharmaceuticals that are approved by the FDA on or after January 1, 2004 for which pass-through status has not been approved and a C-code and APC payment have not been assigned using the “unclassified” drug/biological HCPCS code C9399 (Unclassified drugs or biological). Drugs, biologicals, and therapeutic radiopharmaceuticals that are assigned to HCPCS code C9399.

List one unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Medicare determines the proper payment of NOC drugs and biologicals by the narrative information, not the number of units billed.

Medicare will reject as unprocessable claims for NOC drugs and biologicals if any of the information above is missing, or if the NOC code is billed with more than one unit of service. (Note: The remittance notice will include remark code M123, "Missing/incomplete/invalid name, strength, or dosage of the drug furnished," even if the rejection is due to the number of units billed.)

As you may know, pricing for NOC J-codes is determined by the information provided on the Average Sales Price (ASP) NOC pricing file. If the ASP NOC file lists the strength for a drug on the file, this indicates that the drug comes in different strengths. Medicare payment varies depending on the strength given. When billing Medicare for an NOC J-code, you can determine if the drug comes in different strengths by accessing the ASP NOC pricing files on the CMS website.
<table>
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<tr>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Independent Diagnostic Testing Facilities- physician supervision and technician requirements</td>
<td>A54953</td>
<td>NA</td>
<td>01/01/2019</td>
</tr>
</tbody>
</table>

See 2019 CPT/HCPCS Code Updates for annual CPT/HCPCS code updates.

Description corrections:
- 95017 Perq & icut allg test venoms
- 95018 Perq & ic allg test drugs/biol
- 95076 Ingest challenge ini 120 min
- 95079 Ingest challenge addl 60 min
- 95907 Nvr cndj tst 1-2 studies
- 95908 Nvr cndj tst 3-4 studies
- 95909 Nvr cndj tst 5-6 studies
- 95910 Nvr cndj tst 7-8 studies
- 95911 Nvr cndj tst 9-10 studies
- 95912 Nvr cndj tst 11-12 studies
- 95913 Nvr cndj tst 13/> studies and
- 95924 Ans parasymp & symp w/tilt


The title of this LCD has been changed from MolDX: Xpresys Lung to MolDX: BDX-XL2. All references to Xpresys Lung have been changed to BX-XL2 throughout this document.

The following information was removed from the Coverage Summary section:
- The test is ordered by a physician certified in the XL2 Certification and Training Registry (CTR), and
- The following information is recorded: all clinical risk factors to calculate the Mayo, VA, and Brock cancer risk predictors; PET result (if used), physician pre-test risk assessment, physician post-test lung nodule management recommendation, any subsequent procedures (non-invasive or invasive), and clinical diagnosis based on those procedures (i.e., benign or malignant)

The Strength of the evidence has been changed from limited to Moderate:
Analysis of Evidence
(Rationale for Determination)
Level of evidence
Quality-Moderate
Strength- Moderate
Weight – Limited

The following information has been added to the policy:
Data collected by Biodesix through ongoing studies will support utility including:
- All clinical risk factors to calculate the Mayo, VA, and Brock cancer risk
predictors;
- PET result (if used),
- Physician-assessed pre-test cancer risk assessment,
- Physician post-test lung nodule management recommendation,
- Any subsequent procedures (non-invasive or invasive), and
- Clinical diagnosis based on those procedures (i.e., benign or malignant).

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<tr>
<td>J5/J8</td>
<td>MolDX: BRCA1 and BRCA2 Genetic Testing</td>
<td>L36813</td>
<td>MolDX-007</td>
<td>01/01/2019</td>
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</table>

The section on Multigene Panels has been updated. It now reads as follows:

Multigene Panels***

The indications and limitations of coverage listed in National Coverage Determination (NCD) 90.2 (Next Generation Sequencing- NGS) apply to genetic testing for susceptibility to breast or ovarian cancer. While the NGS NCD Section 90.2 B describes specific coverage criteria for nationally covered tests, Section 90.2D permits coverage of other NGS as a diagnostic laboratory test for patients with cancer when performed and ordered according to the requirements described by the NCD. According to Section D of the NGS NCD AB Medicare Administrative Contractors (AB MACs) may cover next generation sequencing tests in patients with cancer. As such, genetic testing for susceptibility to breast or ovarian cancer with multi-gene NGS panels (not otherwise covered under NCD 90.2 Section B) may be covered by this AB MAC as reasonable and necessary when ALL of the NCD criteria are met in addition to the following:

- Pre-test genetic counseling by a cancer genetics professional has been performed and post-test genetic counseling by a cancer genetics professional meeting NCCN accreditation criteria is planned;
- All genes in the panel are relevant to the personal and family history for the individual being tested (panels with genes that are not relevant to the individual’s personal and family history are not reasonable and necessary);
- Criteria listed under "Personal History of Female Breast Cancer" and/or "Personal History of Other Cancer" are met.
- Individual also meets criteria for at least ONE hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to HBOC, Li-Fraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.

CMS National Coverage Policy


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<tr>
<td>J5/J8</td>
<td>MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing</td>
<td>L36398</td>
<td>MolDX-002</td>
<td>01/01/2019</td>
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</table>

The title of this LCD has been changed from MolDX: Genetic Testing for CYP2C19, CYP2D6, CYP2C9, and VKORC1 to MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing.

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</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>MolDX: Molecular Diagnostic Tests</td>
<td>L36807</td>
<td>MolDX-004</td>
<td>01/01/2019</td>
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</tbody>
</table>
G0452 has been removed from this LCD effective 09/28/2017:
G0452 Molecular pathology procedure: physician interpretation and report.

See 2019 CPT/HCPCS Code Updates for annual CPT/HCPCS code updates.

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<td>(MDT)</td>
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J5/J8 Not Otherwise Classified Chemotherapy Agents (NOC) Billing and Coding Guidelines

A55640 NA 01/01/2019

The title of this Article has been changed from Not Otherwise Classified Chemotherapy Agents (NOC) to Not Otherwise Classified Chemotherapy Agents (NOC) Billing and Coding Guidelines.

CPT/HCPCS Code annual update
Group 1 Paragraph:
Removed J9999/C9467 Rituximab and hyaluronidase human/Rituxin Hycela.
True code assigned: J9311

Please refer to LCD L37205 Chemotherapy Drugs and their Adjuncts for Coverage Indications, Limitations, and/or Medical Necessity.

Removed:
When an NOC code is billed, two separate documents will be required to support the claim:
- The document which supports the service, procedure, drug biological being provided.
- A separate document which identifies specifically for what the NOC code is being billed.

Replaced with:
When an NOC code is billed, documentation must identify specifically for what the NOC code is being billed, supporting the service, procedure, and drug biological being provided.

Added supporting Not Otherwise Classified (NOC) Billing guidance to Article Text:

List one unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Medicare determines the proper payment of NOC drugs and biologicals by the narrative information, not the number of units billed.

Medicare will reject as unprocessable claims for NOC drugs and biologicals if any of the information above is missing, or if the NOC code is billed with more than one unit of service. (Note: The remittance notice will include remark code M123, "Missing/incomplete/invalid name, strength, or dosage of the drug furnished," even if the rejection is due to the number of units billed.)

Pricing for NOC J-codes is determined by the information provided on the Average Sales Price (ASP) NOC pricing file. If the ASP NOC file lists the strength for a drug,
this indicates that the drug comes in different strengths. Medicare payment varies depending on the strength given. When billing Medicare for an NOC J-code, please access the ASP NOC pricing files on the CMS website to determine the different strengths.


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<td>J5/J8</td>
<td>Psychological and Neuropsychological Testing &amp; Billing and Coding Guidelines</td>
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See 2019 CPT/HCPCS Code Updates for annual CPT/HCPCS code updates.

Removed the following statement from the Coverage Guidelines section entitled Psychological testing: CPT codes 96101, 96102, 96103, 96105, 96111.

Removed the following statement from the Coverage Guidelines section entitled Neuropsychological Testing: CPT codes 96116, and 96118, 96119 and 96120.

Removed the following statement from 5. Feedback session: This service is usually billed with CPT code 96118.

Added the following statement to the Billing and Coding Guideline:
*Please note this section of the IOM was last updated effective 01/01/2006 and codes 96101, 96102, 96103, 96111, 96118, 96119 and 96120 are deleted effective 12/31/2018.

Removed the following italicized IOM quoted language in the Billing and Coding Guideline because it refers to deleted codes:
Medicare Part B coverage of psychological tests and neuropsychological tests is authorized under section 1861(s)(3) of the Social Security Act. Payment for psychological and neuropsychological tests is authorized under section 1842(b)(2)(A) of the Social Security Act. The payment amounts for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are effective January 1, 2006, and are billed for tests administered by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. Additionally, there is no authorization for payment for diagnostic tests when performed on an “incident to” basis.

Under the diagnostic tests provision, all diagnostic tests are assigned a certain level of supervision. Generally, regulations governing the diagnostic tests provision require that only physicians can provide the assigned level of supervision for diagnostic tests. However, there is a regulatory exception to the supervision requirement for diagnostic psychological and neuropsychological tests in terms of who can provide the supervision. That is, regulations allow a clinical psychologist (CP) or a physician to perform the general supervision assigned to diagnostic psychological and neuropsychological tests.

In addition, nonphysician practitioners such as nurse practitioners (NPs), clinical
nurse specialists (CNSs) and physician assistants (PAs) who personally perform diagnostic psychological and neuropsychological tests are excluded from having to perform these tests under the general supervision of a physician or a CP. Rather, NPs and CNSs must perform such tests under the requirements of their respective benefit instead of the requirements for diagnostic psychological and neuropsychological tests. Accordingly, NPs and CNSs must perform tests in collaboration (as defined under Medicare law at section 1861(aa)(6) of the Act) with a physician. PAs perform tests under the general supervision of a physician as required for services furnished under the PA benefit.

Furthermore, physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill three test codes as “sometimes therapy” codes. Specifically, CPT codes 96105, and 96111 may be performed by these therapists. However, when PTs, OTs and SLPs perform these three tests, they must be performed under the general supervision of a physician or a CP.

Who May Bill for Diagnostic Psychological and Neuropsychological Tests

- Independently Practicing Psychologists (IPPs)
- PTs, OTs and SLPs – see qualifications under chapter 15, sections 220-230.6 of the Benefits Policy Manual, Pub. 100-02.

Psychological and neuropsychological tests performed by a psychologist (who is not a CP) practicing independently of an institution, agency, or physician’s office are covered when a physician orders such tests. An IPP is any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where furnishing services or, if the jurisdiction does not issue licenses, if provided by any practicing psychologist. (It is CMS’ understanding that all States, the District of Columbia, and Puerto Rico license psychologists, but that some trust territories do not. Examples of psychologists, other than CPs, whose psychological and neuropsychological tests are covered under the diagnostic tests provision include, but are not limited to, educational psychologists and counseling psychologists.)

The A/B MAC (B) must secure from the appropriate State agency a current listing of psychologists holding the required credentials to determine whether the tests of a particular IPP are covered under Part B in States that have statutory licensure or certification. In States or territories that lack statutory licensing or certification, the A/B MAC (B) checks individual qualifications before provider numbers are issued. Possible reference sources are the national directory of membership of the...
American Psychological Association, which provides data about the educational background of individuals and indicates which members are board-certified, the records and directories of the State or territorial psychological association, and the National Register of Health Service Providers. If qualification is dependent on a doctoral degree from a currently accredited program, the A/B MAC (B) verifies the date of accreditation of the school involved, since such accreditation is not retroactive. If the listed reference sources do not provide enough information (e.g., the psychologist is not a member of one of these sources), the A/B MAC (B) contacts the psychologist personally for the required information. Generally, A/B MACs (B) maintain a continuing list of psychologists whose qualifications have been verified.

NOTE: When diagnostic psychological tests are performed by a psychologist who is not practicing independently, but is on the staff of an institution, agency, or clinic, that entity bills for the psychological tests.

The A/B MAC (B) considers psychologists as practicing independently when:
- They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;
- The persons they treat are their own patients; and
- They have the right to bill directly, collect and retain the fee for their services.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:
- The office is confined to a separately-identified part of the facility which is used solely as the psychologist’s office and cannot be construed as extending throughout the entire institution; and
- The psychologist conducts a private practice, i.e., services are rendered to patients from outside the institution as well as to institutional patients.

Payment for Diagnostic Psychological and Neuropsychological Tests
Expenses for diagnostic psychological and neuropsychological tests are not subject to the outpatient mental health treatment limitation, that is, the payment limitation on treatment services for mental, psychoneurotic and personality disorders as authorized under Section 1833(c) of the Act. The payment amount for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are billed for tests performed by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. CPs, NPs, CNSs and PAs are required by law to accept assigned payment for psychological and neuropsychological tests. However, while IPPs are not required by law to accept assigned payment for these tests, they must report the name and address of the physician who ordered the test on the claim form when billing for tests.

CPT Codes for Diagnostic Psychological and Neuropsychological Tests
The range of CPT codes used to report psychological and neuropsychological tests is 96101-96120. CPT codes 96101, 96102, 96103, 96105, and 96111 are appropriate for use when billing for psychological tests. CPT codes 96116, 96118,
Contract Policy Title

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All of the tests under this CPT code range 96101-96120 are indicated as active codes under the physician fee schedule database and are covered if medically necessary.

Payment and Billing Guidelines for Psychological and Neuropsychological Tests

The technician and computer CPT codes for psychological and neuropsychological tests include practice expense, malpractice expense and professional work relative value units. Accordingly, CPT psychological test code 96101 should not be paid when billed for the same tests or services performed under psychological test codes 96102 or 96103. CPT neuropsychological test code 96118 should not be paid when billed for the same tests or services performed under neuropsychological test codes 96119 or 96120. However, CPT codes 96101 and 96118 can be paid separately on the rare occasion when billed on the same date of service for different and separate tests from 96102, 96103, 96119 and 96120.

Under the physician fee schedule, there is no payment for services performed by students or trainees. Accordingly, Medicare does not pay for services represented by CPT codes 96102 and 96119 when performed by a student or a trainee. However, the presence of a student or a trainee while the test is being administered does not prevent a physician, CP, IPP, NP, CNS or PA from performing and being paid for the psychological test under 96102 or the neuropsychological test under 96119.

Removed the following Coding Guideline statements in the Billing and Coding Guideline:

Services 96101, 96116, 96118 and 96125 report time as (a) face-to-face with the patient and (b) time spent interpreting and preparing the report.

CPT code 96119 is reported for tests administration by a technician who is hired, trained, and directly supervised by a practitioner licensed by the State to provide neuropsychological testing. During testing, the qualified health professional frequently checks with the technician to monitor the patient’s performance and make any necessary modifications to the test battery or assessment plan. When all tests have been administered, the qualified health professional meets with the patient again to answer any questions (AMA CPT Assistant, November 2006). The time spent reviewing the results of these tests and writing the report is also reported using the same CPT code 96119.

Code 96120 is reported for computer-administered neuropsychological testing, with subsequent interpretation and report of the specific tests by the physician, psychologist, or other qualified health care professional.

Assessments may include testing by a technician and a computer with interpretation and report by the physician, psychologist or qualified health professional. Therefore, it is appropriate in such cases to report all 3 codes 96118-96120. (AMA CPT Assistant, November 2006; CMS Medline, June 2008). However, when this is done each code must represent separately identifiable documented services. The time
spent for the interpretation of a test cannot be combined into the time spent on another service.

Removed the following Billing Guidelines statements:

1) A technician employed and supervised by the primary qualified health care profession who interpretation tests, may perform Central Nervous System Assessments /Tests CPT codes 96102 or 96119. Central Nervous System Assessments/Tests CPT codes 96103 or 96120 may be performed by a computer supervised by the primary provider.

2) CPT codes 96102 and 96119 describe tests administered by a technician and the provider’s time for the interpretation and the report of each individual test and the report of each individual test result. The integration of all the test data determines the cognitive profile. The provider’s time for interpretation of the test is billed under CPT code used to bill the test.

3) CPT codes 96103 and 96120 describe computer tests and the provider’s time for the interpretation and the report. No time is billed for these codes.

4) Per Medicare regulations Central Nervous System Assessments/Tests CPT codes 96101-96125 may not be reimbursed to clinical social workers.

5) Physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill CPT codes 96105, 96110 and 96111 as “sometimes therapy” services, services that follow the rules for Physical/Occupational/speech language pathologists. However, when PTs, OTs and SLPs administer these tests, they must be under the general supervision of a physician or clinical psychologists.

6) CPT code 96125 has been established to report tests performed by speech-language pathologists and occupational therapists. When the test is performed by other Medicare providers, they should not use CPT code 96125 but rather, the appropriate CPT codes 96101-96103 or 96118-96120 should be used.

Added the following Billing Guidelines statements:

1) For assessment of aphasia and cognitive performance testing use code 96105.

2) For developmental/behavioral screening and testing use codes 96110, 96112, 96113, and 96127.

3) For neurobehavioral status examinations for psychological/ neuropsychological testing use codes 96116 and 96121.

4) For testing evaluation services for psychological/ neuropsychological testing use codes 96130, 96131, 96132, and 96133.

5) For test administration and scoring for psychological/ neuropsychological testing use codes 96136, 96137, 96138 and 96139.

6) For automated testing and results for psychological/ neuropsychological testing use code 96146.
# Electronic Data Interchange (EDI)

## Claim Status Category and Claim Status Codes Update

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<th>MLN Matters Number: MM11073</th>
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<td>Related CR Release Date: December 21, 2018</td>
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### PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

CR 11073 updates, as needed, the Claim Status and Claim Status Category Codes used for the Accredited Standards Committee (ASC) X12 276/277, Health Care Claim Status Request and Response and ASC X12 277 Health Care Claim Acknowledgment transactions. Make sure your billing staffs are aware of these updates.

### BACKGROUND

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires all covered entities to use only Claim Status Category Codes and Claim Status Codes approved by the National Code Maintenance Committee in the ASC X12 276/277 Health Care Claim Status Request and Response transaction standards adopted under HIPAA for electronically submitting health care claims status requests and responses. These codes explain the status of submitted claim(s). Proprietary codes may not be used in the ASC X12 276/277 transactions to report claim status.

The National Code Maintenance Committee meets at the beginning of each ASC X12 trimester meeting (January/February, June, and September/October) and makes decisions about additions, modifications, and retirement of existing codes. The Committee allow the industry 6 months for implementation of newly added or changed codes.

The codes sets are available at [http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-category-codes/](http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-category-codes/) and [http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/](http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/). Included in the code lists are specific details, including the date when a code was added, changed, or deleted. All code changes approved during the January 2019 committee meeting shall be posted on these sites on or about March 1, 2019.
The Centers for Medicare & Medicaid Services (CMS) will issue additional CRs regarding the need for future updates to these codes. When instructed, MACs must update their claims systems to ensure that the current version of these codes is used in their claim status responses. These code changes are to be used in editing of all ASC X12 276 transactions processed on or after the date of implementation and to be reflected in the ASC X12 277 transactions issued on and after the date of implementation of CR11073.

The MACs must comply with the requirements contained in the current standards adopted

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

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Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE

MLN Matters Number: MM11039 Related Change Request (CR) Number: 11039
Related CR Release Date: November 16, 2018 Effective Date: April 1, 2019
Related CR Transmittal Number: R4168CP Implementation Date: April 1, 2019

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment (DME) MACs and Home Health & Hospice (HH&H) MACs, for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11039 instructs MACs and Medicare’s Shared System Maintainers (SSMs) to update systems based on the CORE 360 Uniform use of CARC, RARC and CAGC rule publications. These system updates are based on the CORE Code Combination List to be published on or about February 1, 2019. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The Department of Health and Human Services (DHHS) adopted the Phase III (CAQH CORE, EFT, and ERA Operating Rule Set that was implemented on January 1, 2014, under the Affordable Care Act (ACA).

The Health Insurance Portability and Accountability Act amended the Social Security Act by adding Part C—Administrative Simplification—to Title XI, requiring the Secretary of HHS to
adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information.

CR11039 deals with the regular update in CAQH CORE defined code combinations per Operating Rule 360 - Uniform Use of CARC and RARC (835) Rule.

CAQH CORE will publish the next version of the Code Combination List on or about February 1, 2019. This update is based on the CARC and RARC updates as posted at the Washington Publishing Company (WPC) website on or about November 1, 2018. This will also include updates based on market-based review that CAQH CORE conducts once a year to accommodate code combinations that are currently being used by health plans including Medicare, as the industry needs them. Visit [http://www.wpc-edi.com/Reference](http://www.wpc-edi.com/Reference) for CARC and RARC updates and [http://www.caqh.org/sites/default/files/core/phase-iii/code-combinations/CORE-required_CodeCombos.xlsx?token=_29xvBua](http://www.caqh.org/sites/default/files/core/phase-iii/code-combinations/CORE-required_CodeCombos.xlsx?token=_29xvBua) for CAQH CORE defined code combination updates.

The Affordable Care Act mandates all health plans, including Medicare, must comply with CORE 360 Uniform Use of CARCs and RARCs (835) rule or CORE developed maximum set of CARC/RARC and CAGC combinations for a minimum set of four (4) business scenarios. Medicare can use any code combination if the business scenario is not one of the four (4) CORE defined business scenarios. With the four (4) CORE defined business scenarios, Medicare must use the code combinations from the lists published by CAQH CORE.

### ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

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Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update

MLN Matters Number: MM11038  Related Change Request (CR) Number: 11038
Related CR Release Date: November 16, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R4167CP  Implementation Date: April 1, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11038 updates the Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) lists and instructs Medicare Shared System Maintainers (SSMs) to update Medicare Remit Easy Print (MREP) and PC Print. Be sure your staff are aware of these changes and obtain the updated MREP and/or PC Print software if they use that software.

BACKGROUND

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) instructs health plans to be able to conduct standard electronic transactions adopted under HIPAA using valid standard codes. Medicare policy states that CARCs and RARCs, as appropriate, which provide either supplemental explanation for a monetary adjustment or policy information that generally applies to the monetary adjustment, are required in the remittance advice and coordination of benefits transactions.

The Centers for Medicare & Medicaid Services (CMS) instructs MACs to conduct updates based on the code update schedule that results in publication three times per year – around March 1, July 1, and November 1. CMS provides CR11038 as a code update notification indicating when updates to CARC and RARC lists are available on the Washington Publishing Company (WPC) website. Medicare's SSMs must implement code deactivation, making sure that any deactivated code is not used in original business messages and allowing the deactivated code in derivative messages. The SSMs must make sure that Medicare does not
report any deactivated code on or after the effective date for deactivation as posted on the WPC website. If any new or modified code has an effective date later than the implementation date specified in CR 11038, MACs must implement on the date specified on the WPC website at http://wpc-edi.com/Reference/.

A discrepancy between the dates may arise, as the WPC website is only updated three times per year and may not match the CMS release schedule. The MACs and the SSMs must get the complete list for both CARC and RARC from the WPC website to obtain the comprehensive lists for both code sets and determine the changes that are included on the code list since the last code update CR (CR 10620).

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

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General Information

Medicare Claims Processing Manual, Chapter 30 Revisions

MLN Matters Number: MM10848
Related Change Request (CR) Number: 10848
Related CR Release Date: January 11, 2019
Effective Date: April 15, 2019
Related CR Transmittal Number: R4197CP
Implementation Date: April 15, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

CR10848 revises the Medicare Claims Processing Manual, Chapter 30. The current policy in Chapter 30 is not changing. The Centers for Medicare & Medicaid Services (CMS) is revising the chapter to provide improved formatting and readability. CMS also added a glossary to assist you with common terminology within the chapter. The revised chapter is attached to CR10848. Make sure your billing staffs are aware of these changes.

BACKGROUND

As a reminder, the Financial Liability Protections (FLP) provisions of the Social Security Act (the Act) protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions apply after Medicare makes a coverage determination for an item or service. CMS outlines the following FLP provisions in CR10848:

- Limitation on Liability (LOL) under Section 1879(a)-(g) of the Social Security Act (the Act)
- Refund Requirements (RR) for Non-assigned Claims for Physicians Services under Section 1842(l) of the Act
- RR for Assigned and Non-assigned Claims for Medical Equipment and Supplies under Sections 1834(a)(18), 1834(j)(4), and 1879(h) of the Act.

In most cases, the FLP provisions apply only to beneficiaries enrolled in the Original Medicare Fee-For-Service (FFS) program Parts A and B. The FLP provisions apply only when both of the following conditions are met:
• Medicare denies payment for Items and/or services on the basis of specific statutory provisions

• Provider likely had knowledge that Medicare was likely to deny payment for the items and/or services

The LOL provisions, Section 1879(a)-(g) of the Act, fall under the FLP provisions and provide financial relief and protection to beneficiaries, health care providers, and suppliers by permitting Medicare payment to be made, or requiring refunds, for certain items and/or services for which Medicare payment would otherwise be denied. When it is determined that a review falls under the LOL provisions, evidence must show that either a healthcare provider, supplier or the beneficiary knew or should have known that Medicare was going to deny payment on the item or service.

42 Code of Federal Regulations (CFR) 411.404 provides criteria for beneficiary knowledge based on written notice. However, Section 1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the LOL provision. Beneficiary knowledge is established when the health care provider/supplier gives a valid written notice (such as issuing an Advance Beneficiary Notice of Non-coverage (ABN), Form CMS-R-131). Beneficiary knowledge may be established when the beneficiary receives notice of a recent claim denial for the same item or service.

If the health care provider/supplier had actual knowledge of the non-coverage of item and/or service in a particular case, could reasonably have been expected to have such knowledge or the beneficiary was shown not to have knowledge (found not liable), the Medicare program will not make a payment to the healthcare provider/supplier.

Generally, Medicare provides forms (for example, the ABN, Form CMS-R-131, Skilled Nursing Facility ABN, Form CMS-10055) for health care providers and suppliers to use as a way to provide written notice to beneficiaries. The health care provider/supplier should issue the applicable written notice each time, and as soon as it makes the assessment that Medicare payment certainly or probably will not be made in order to transfer potential financial liability to the beneficiary. The written notice allows the beneficiary to:

• Make an informed decision whether or not to receive the item and/or service

• Better participate in his/her own health care treatment decisions

A health care provider/supplier should follow specific written notice standards when issuing the written notice as evidence of the beneficiary’s knowledge for the purposes of the FLP provisions.

ADDITIONAL INFORMATION

The official instruction, CR10848, issued to your MAC regarding this change is available at

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list

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New Physician Specialty Code for Undersea and Hyperbaric Medicine

MLN Matters Number: MM10666 Revised Related Change Request (CR) Number: 10666
Related CR Release Date: December 19, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4184CP, Implementation Date: January 7, 2019
R309FM

Note: This article was revised on December 20, 2018, to reflect the revised CR10666 issued on December 19. The CR was revised to clarify certain MAC reporting requirements for the D2 specialty, the taxonomy requirements for the D4 specialty, and to reflect the D1 specialty code as a supplier specialty and not a physician specialty. In this article, only the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change Request (CR) 10666 informs you that the Centers for Medicare & Medicaid Services (CMS) has established a new Physician Specialty code for Undersea and Hyperbaric Medicine. This new code is D4. Make sure your billing staffs are aware of these changes.

BACKGROUND

Physicians self-designate their Medicare physician specialty on the Medicare enrollment application (CMS-855I or CMS-855O) or via the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) when they enroll in the Medicare program. Medicare physician specialty codes describe the specific/unique types of medicine that physicians (and certain other suppliers) practice. Specialty codes are used by CMS for programmatic and claims processing purposes.

The CMS-855I and CMS-855O paper applications will be updated to reflect the new physician specialty in the future. In the interim, providers shall select the 'Undefined physician type' option
on the enrollment application and specify Undersea and Hyperbaric Medicine in the space provided.

Existing enrolled providers who want to update their specialty to reflect the new specialty must submit a change of information application to their Medicare Administrative Contractor (MAC). Providers may submit an enrollment application to initially enroll or update their specialty within 60 days of the implementation date of the new specialty.

MACs will recognize Undersea and Hyperbaric Medicine (D4) as a valid specialty type for the following edits:

- Ordering/Referring
- Critical Access Hospital (CAH) Method II Attending and Rendering
- Attending, operating, or other physician or non-physician practitioner listed on a CAH claim

**ADDITONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

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Processing Instructions to Update the Standard Paper Remit (SPR)

MLN Matters Number: MM11112
Related Change Request (CR) Number: 11112
Related CR Release Date: February 1, 2019
Effective Date: July 1, 2019
Related CR Transmittal Number: R2245OTN
Implementation Date: July 1, 2019

PROVIDER TYPE AFFECTED
This MLN Matters Article is intended for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED
Change Request (CR) 11112 instructs MACs to update their systems to ensure that SPRs mailed after July 1, 2019, mask the Health Insurance Claim Number (HICN), so the Social Security Number (SSN) does not show. Make sure your billing staff is aware of these instructions.

BACKGROUND
With the passage and signing of the Social Security Number Fraud Prevention Act of 2017, which became Public Law No. 115-59, the law, restricts the inclusion of SSNs on documents sent by mail by the Federal Government effective not later than 5 years after the date of its enactment.

CR 11112 instructs MACs to update their systems, effective July 1, 2019, to mask the HICNs (for example, xxxxx7777A, xxxxx7777C1) and the Railroad Retirement Board HICNs (for example, Axxxxx1370, WCxxxxx2388, and CAxxxxx1) on any print file used to create an SPR for mailing. The Medicare Beneficiary Identifier (MBI) will not be masked.

(Note: This masking requirement does not apply to RRB numbers issued before March 1964, which include an alpha prefix and 6 digits (for example, A000000.)

ADDITIONAL INFORMATION
If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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EDUCATION SCHEDULE

WPS GHA Learning Center

WPS GHA Provider Outreach & Education (POE) has numerous educational opportunities in our Learning Center; [http://wpsghalearningcenter.com/store-catalog](http://wpsghalearningcenter.com/store-catalog). We offer on-demand learning, allowing you to access the education at your convenience. We also offer live events via seminar, teleconference, and webinar on many subjects. You may browse through and register for these events in the Learning Center. Our education offers Certificates of Achievements identifying the length of time of the education. You may use these certificates (without an index number) to receive Continuing Education Units (CEUs) from most accrediting organization.

We provide all educational materials in an electronic format. Participants are responsible for accessing/printing the materials. To locate, choose the Additional References tab within the individual course in our Learning Center.

Visit the WPS GHA Learning Center and look for the upcoming events that are being offered in 2019:

**Teleconferences**

**New to Medicare Series** – WPS GHA has developed a series of teleconferences specifically for provider staff who are new to working in the Medicare environment. If you or your staff has worked for less than a year with Medicare claims, these teleconferences present basic billing and coverage information in a clear, understandable format.

- 03/05/2019 — New to Medicare: Getting Started with Provider Enrollment
- 04/02/2019 — New to Medicare: Determining Patient Eligibility
- 05/07/2019 — New to Medicare: Determining Covered Services
- 06/04/2019 — New to Medicare: Handling Overpayments

**Provider Enrollment (PE) Series** – This year WPS GHA is highlighting provider enrollment education with a series of teleconferences created to assist various types of providers with the Medicare enrollment process. Check the WPS GHA Learning Center throughout the year to register for these teleconferences.

- 03/20/2019 — PE for Physicians
- 05/15/2019 — PE for Non-Physician Practitioners
- 07/17/2019 — PE for Clinics and Group Practices
- 08/21/2019 — PE for Community Outpatient Rehab Facilities
- 09/18/2019 — PE for Medicare Suppliers
- 10/16/2019 — PE for Physical Therapist, Occupational Therapist and Speech-Language Pathologist

**Ambulance suppliers** have an opportunity to ask questions related to the Medicare ambulance benefit during an ambulance question and answer teleconference. The teleconference will not
have a formal presentation but will focus on addressing pre-submitted inquiries, as well as questions asked during the live call.

- 03/13/2019 — Ambulance Question and Answer Teleconference

Webinars

**Skilled Nursing Facility (SNF) Series** – WPS GHA will be offering education on various topics relating to SNF Part A and Part B Billing. The webinars will be held every second Thursday of the month starting in April. For more information on each topic, check the WPS GHA Learning Center monthly to register for sessions.

- 11/14/2019 — SNF Consolidated Billing (CB)/Communications/Professional Services
- 12/12/2019 — SNF CB Institutional Services

In Person Events

Coming Soon – Medicare Day of Learning (MDL)

The multi-session single day event is designed to give participants control over their education. You will be able to choose from 18 unique breakout sessions including appeals, telehealth, preventing denials, evaluation and management (E/M) for 2019, and so much more. The event will contain 6 contact hours from 8:00 am to 4:00 pm followed by an optional question and answer session with the WPS GHA staff.

The MDL events are one of the most popular and well attended, so watch your eNews for registration information and mark your calendar for one of the following dates:

- 04/30/2019 — Gateway Hotel and Conference Center — Ames, Iowa
- 05/21/2019 — Lifelong Learning Center — Norfolk, Nebraska
- 07/16/2019 — Century II Performing Arts & Convention Center — Wichita, Kansas
- 07/18/2019 — University Plaza Hotel and Convention Center — Springfield, Missouri
- 08/20/2019 — Delta Hotels Kalamazoo Conference Center — Kalamazoo, Michigan
- 08/21/2019 — Holiday Inn City Centre — Lafayette, Indiana

In the Works

The WPS GHA Provider Outreach and Education Team is currently working on the following topics for upcoming education:

- Appeals
- Care Management
- Claims Review & Findings
- Critical Care
- Drug Screening
- Evaluation and Management 2019
- Hospital Notices
- Inpatient Psychiatric Facilities
- Medicare Resources
- Medicare Secondary Payer
- Preventing Part A Denials
- Preventing Part B Denials
- Skilled Nursing Facility Notices
- Expansion of Telehealth Services
- Wound Care

Continue to watch the Wednesday eNews for the most current education topics available.

**MEDICARE LEARNING NETWORK (MLN)**

We encourage you to visit the Medicare Learning Network, the place for official CMS Medicare fee-for-service provider educational information. There you can find one of our most popular products, MLN Matters national provider education articles. These articles help you understand new or changed Medicare policy and how those changes affect you. A full array of other educational products (including Web-based training courses, hard copy and downloadable publications, and CD-ROMs) are also available and can be accessed at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html). You can also find other important Web sites by visiting the Physician Center Web page at: [http://www.cms.gov/Center/Provider-Type/Physician-Center.html](http://www.cms.gov/Center/Provider-Type/Physician-Center.html), and the All Fee-For-Service Providers Web page at: [https://www.cms.gov/Center/Provider-Type/All-Fee-For-Service-Providers-Center.html](https://www.cms.gov/Center/Provider-Type/All-Fee-For-Service-Providers-Center.html).

In addition to educational products, the MLN also offers providers and suppliers opportunities to learn more about the Medicare program through MLN National Provider Calls. These national conference calls, held by CMS for the Medicare Fee-For-Service provider and supplier community, educate and inform participants about new policies and/or changes to the Medicare program. Offered free of charge, continuing education credits may be awarded for participation in certain National Provider Calls. To learn more about MLN National Provider Calls including upcoming calls, registration information, and links to previous call materials, visit [http://www.cms.gov/Outreach-and-Education/Outreach/NPC/index.html](http://www.cms.gov/Outreach-and-Education/Outreach/NPC/index.html).

**QUARTERLY PROVIDER UPDATE**

The Quarterly Provider Update is a comprehensive resource published by the Centers for Medicare & Medicaid Services (CMS) on the first business day of each quarter. It is intended to make it easier for providers, suppliers, and the general public to understand the changes CMS is proposing or making.

CMS publishes this update to inform the public about the following:

- Regulations and major policies completed or cancelled.
- New/Revised manual instructions


We encourage you to bookmark this web page and visit it often for this valuable information. To receive notification when regulations and program instructions are added throughout the
quarter, sign up for the Quarterly Provider Update Listserv at: https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_460.
UNSOLICITED/VOLUNTARY REFUNDS

The acceptance of a voluntary refund as repayment for the claims specified in no way affects or limits the rights of the Federal Government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.

Ambulance Inflation Factor for Calendar Year 2019 and Productivity Adjustment

MLN Matters Number: MM11031
Related Change Request (CR) Number: 11031
Related CR Release Date: November 30, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4172CP
Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for ambulance providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Medicare Part B ambulance services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11031 furnishes the Calendar Year (CY) 2019 Ambulance Inflation Factor (AIF) for determining the payment limit for ambulance services. The AIF for CY 2019 is 2.3 percent. Make sure that your billing staffs are aware of this change.

BACKGROUND

Section 1834(l)(3)(B) of the Social Security Act provides the basis for an update to the payment limits for ambulance services that is equal to the percentage increase in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending with June of the previous year. On March 23, 2010, the Affordable Care Act (Pub. L. 111-148) was enacted. Following the enactment of Pub. L. 111-148, the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152 (enacted on March 30, 2010), amended certain provisions of Pub. L. 111-148. These public laws are collectively known as the Affordable Care Act (ACA). Section 3401 of the ACA amended Section 1834(l)(3) of the Act to apply a productivity adjustment to this update equal to the 10-year moving average of changes in economy-wide private nonfarm business multi-factor productivity (MPF) beginning January 1, 2011. The resulting update percentage is referred to as the AIF.

Section 3401 of the ACA requires that specific Prospective Payment System (PPS) and Fee Schedule (FS) update factors be adjusted by changes in economy-wide productivity. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business MFP (as projected by the Secretary of Health and Human Services (the Secretary) for the 10-year period ending with the applicable fiscal
The MFP for CY 2019 is 0.6 percent and the CPI-U for 2019 is 2.9 percent. According to the ACA, the CPI-U is reduced by the MFP, even if this reduction results in a negative AIF update. Therefore, the AIF for CY 2019 is 2.3 percent.

The Part B coinsurance and deductible requirements apply to payments under the ambulance fee schedule.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

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April 2019 Quarterly ASP Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM11151  Related Change Request (CR) Number: 11151
Related CR Release Date: January 25, 2019  Effective Date: April 1, 2019
Related CR Transmittal Number: R4213CP  Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters® Article is for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

BACKGROUND

The Average Sales Price (ASP) methodology is based on quarterly data submitted to the Centers for Medicare & Medicaid Services (CMS) by manufacturers. CMS supplies the MACs with the ASP and Not Otherwise Classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions available in Chapter 4, Section 50 of the Medicare Claims Processing Manual found at https://www.cms.gov/Regulations-and-Guidance/Guidance-Manuals/Downloads/clm104c04.pdf.

WHAT YOU NEED TO KNOW

CR11151 instructs MACs to download and implement the April 2019 and, if released, the revised January 2019, October 2018, July 2018, and April 2018 ASP drug pricing files for Medicare Part B drugs via the CMS Virtual Data Center (CDC). Medicare will use these files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after April 1, 2019, with dates of service April 1, 2019, through June 30, 2019. Make sure your billing staffs are aware of these changes.

CR11151 addresses the following pricing files:

- April 2019 ASP and ASP NOC -- Effective Dates of Service: April 1, 2019, through June 30, 2019
- January 2019 ASP and ASP NOC -- Effective Dates of Service: January 1, 2019, through March 31, 2019
- October 2018 ASP and ASP NOC -- Effective Dates of Service: October 1, 2018, through December 31, 2018
• July 2018 ASP and ASP NOC -- Effective Dates of Service: July 1, 2018, through September 30, 2018
• April 2018 ASP and ASP NOC -- Effective Dates of Service: April 1, 2018, through June 30, 2018

For any drug or biological not listed in the ASP or NOC drug-pricing files, MACs will determine the payment allowance limits in accordance with the policy described in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3, which is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf.

For any drug or biological not listed in the ASP or NOC drug-pricing files that is billed with the KD modifier, MACs will determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of Durable Medical Equipment (DME) on or after January 1, 2017, associated with the passage of the 21st Century Cures Act.

ADDITIONAL INFORMATION


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Calendar Year (CY) 2019 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM11076 Revised  
Related Change Request (CR) Number: 11076
Related CR Release Date: January 17, 2019  
Effective Date: January 1, 2019
Related CR Transmittal Number: R4208CP  
Implementation Date: January 7, 2019

Note: We revised the article on January 18, 2019, to reflect the revised CR issued on January 17. The revised CR deleted code 0008U from the list of revised codes effective January 1, 2019. We deleted that code from the article. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11076 provides instructions for the Calendar Year (CY) 2019 Clinical Laboratory Fee Schedule (CLFS), mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. Make sure your billing staffs are aware of these updates.

BACKGROUND

The CY 2019 updates are as follows:

Next CLFS Data Collection Period

Section 1834A of the Social Security Act ("the Act"), as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule, "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule," (CMS-162-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to the Centers for Medicare & Medicaid Services (CMS) certain private payer rate information (applicable information) for their component applicable laboratories. The next data collection period (the period where applicable
information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2019, through June 30, 2019, and the next 6-month window is July 1, 2019, through December 31, 2019 (the period where laboratories and reporting entities assess whether the applicable laboratory thresholds are met and review and validate applicable information before it is reported to CMS).

The next data-reporting period is January 1, 2020, through March 31, 2020, where applicable information is reported to CMS. This data will be used to calculate revised private payer rate-based CLFS rates, effective January 1, 2021. Specific directions on data collection and data reporting are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.

Revisions to the Definition of Applicable Laboratory

The Physician Fee Schedule (PFS) final rule entitled, “Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019,” (CMS-1693-F) was displayed in the Federal Register on November 1, 2018, and was published on November 23, 2018. In the CY 2019 PFS final rule, CMS made two revisions to the regulatory definition of Applicable Laboratory:

1. Effective January 1, 2019, Medicare Advantage plan revenues are excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold); and
2. Effective January 1, 2019, hospitals that bill for their non-patient laboratory services may use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low-expenditure threshold.

Effective January 1, 2019, the regulatory definition of an applicable laboratory is summarized below. An applicable laboratory means an entity that:

1. Is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (42 CFR Section 493.2);
2. The laboratory bills Medicare under its own National Provider Identifier (NPI) or
   a. For hospital outreach laboratories: Bills Medicare Part B on the Form CMS-1450 under TOB 14x
3. The laboratory must meet a “majority of Medicare revenues,” threshold, where it receives more than 50 percent of its total Medicare revenues from one or a combination of the CLFS or the PFS in a data collection period. For purposes of determining whether a laboratory meets the “majority of Medicare revenues” threshold, total Medicare revenues includes: fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance. **Effective January 1, 2019, total Medicare revenues no longer includes Medicare Advantage payments under Medicare Part C.**
4. The laboratory must meet a “low expenditure” threshold, where it receives at least $12,500 of its Medicare revenues from the CLFS in a data collection period.
Coding for Health Common Procedure Coding System (HCPCS)

Panel Codes

As laboratories are aware, the implementation of PAMA required Medicare to pay the weighted median of private payer rates for each separate HCPCS code. Prior to PAMA implementation, CMS paid for certain chemistry tests using Automated Test Panels (ATPs), which used claims processing logic to apply a bundled rate to sets of these codes, depending on how many of these chemistry tests were ordered. This logic no longer exists under PAMA guidelines. HCPCS codes include those from the AMA Current Procedural Technology (CPT) Manual, that are in the category of Organ or Disease Oriented panels, which are panels that consist of groups of specified tests. Because CMS no longer has payment logic to roll up panel pricing, laboratories shall report the panel test where appropriate and not report separately the tests that make up that panel. This is also consistent with recent changes in CMS’s National Correct Coding Initiative (NCCI) manual. For example, if the individually ordered tests are cholesterol (CPT code 82465), triglycerides (CPT code 84478), and HDL cholesterol (CPT code 83718), the service shall be reported as a lipid panel (CPT code 80061). If the laboratory repeats one of these component tests as a medically reasonable and necessary service on the same date of service, the CPT code corresponding to the repeat laboratory test may be reported with modifier 91 appended. For additional information on coding for these codes, please refer to the NCCI Policy Manual for Medicare Services for CY 2019, available at https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html, specifically Chapter I, Section N (Laboratory Panel), and Chapter X, Section C (Organ or Disease Oriented Panels).

Update to Fees

Based on Section 1833(h)(2)(A)(i) of the Act, available at https://www.ssa.gov/OP_Home/ssact/title18/1833.htm, the annual update to the local clinical laboratory fees for CY 2019 is 2.30 percent. Beginning January 1, 2019, this update applies only to pap smear tests. For a pap smear test, Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the National Limitation Amount, but not less than a national minimum payment amount. However, for pap smear tests, payment may also not exceed the actual charge. The CY 2019 national minimum payment amount is $14.99 (This value reflects the CY 2018 national minimum payment with a 2.3 percent increase or $14.65 times 1.0230). The affected codes for the national minimum payment amount are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2019 is 2.3 percent (See 42 CFR 405.509(b)(1)).

The Part B deductible and coinsurance do not apply for services paid under the CLFS.

Access to Data File

Internet access to the CY 2019 CLFS data file will be available after December 1, 2018, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. It will be available in multiple formats, including Excel, text, and comma delimited.
Public Comments and Final Payment Determinations

On June 25, 2018, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2018 codes and the new CY 2019 CPT codes. CMS published a notice of the meeting in the Federal Register on March 30, 2018. CMS got recommendations from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. Additional written comments from the public were accepted until October 22, 2018. CMS also posted a summary of the public comments and the rationale for the final payment determinations at the same webpage shown in the previous sentence.

Pricing Information

The CY 2019 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual basis. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2019, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2019 CLFS also includes codes that have a “QW” modifier to both identify codes and determine payment for tests performed by a laboratory having only a CLIA certificate of waiver.

Mapping Information - Pricing

- Reconsidered code 81326 is priced at the same rate as code 81322.
- Reconsidered code 81334 is priced at the same rate as code 81272.
- New code 0011M is priced at the same rate as code 0005U.
- New code 0012M is priced at the same rate as code 0005U.
- New code 0013M is priced at the same rate as code 0005U.
- New code 0018U is to be gapfilled.
- New code 0019U is to be gapfilled.
- New code 0020U is to be deleted.
- New code 0021U is to be gapfilled.
- New code 0022U is to be gapfilled.
- New code 0023U is to be gapfilled.
- New code 0024U is priced at the same rate as code 83704.
- New code 0025U is priced at the same rate as code G0480.
- New code 0026U is priced at the same rate as code 81545.
- New code 0027U is priced at the same rate as 1.33 times code 0017U.
- New code 0028U is to be deleted.
- New code 0029U is to be gapfilled.
- New code 0030U is to be gapfilled.
• New code 0031U is priced at the same rate as code 81227.
• New code 0032U is priced at the same rate as code 81230.
• New code 0033U is priced at the same rate as 2 times code 81230.
• New code 0034U is priced at the same rate as code 81225 plus code 81335.
• New code 0035U is to be gapfilled.
• New code 0036U is priced at the same rate as code 81415.
• New code 0038U is priced at the same rate as code 82306.
• New code 0039U is priced at the same rate as code 86225.
• New code 0040U is priced at the same rate as 2.5 times code 81206.
• New code 0041U is to be gapfilled.
• New code 0042U is to be gapfilled.
• New code 0043U is to be gapfilled.
• New code 0044U is to be gapfilled.
• New code 0045U is priced at the same rate as code 81519.
• New code 0046U is priced at the same rate as code 81245.
• New code 0047U is priced at the same rate as code 81519.
• New code 0048U is to be gapfilled.
• New code 0049U is priced at the same rate as code 81310.
• New code 0050U is to be gapfilled.
• New code 0051U is priced at the same rate as code G0483.
• New code 0052U is priced at the same rate as code 83701.
• New code 0053U is to be gapfilled.
• New code 0054U is priced at the same rate as code G0482.
• New code 0055U is to be gapfilled.
• New code 0056U is to be gapfilled.
• New code 0057U is to be gapfilled.
• New code 0058U is priced at the same rate as code 86835.
• New code 0059U is priced at the same rate as code 86835.
• New code 0060U is priced at the same rate as code 81420.
• New code 0061U is priced at the same rate as 5 times code 88738.
• New code 81345 is priced at the same rate as code 81403.
• New code 82642 is priced at the same rate as code 82634.
• New code 81333 is priced at the same rate as code 81401.
• New code 81596 is priced at the same rate as code 0001M.
• New code 81518 is priced at the same rate as code 81519.
• New code 81236 is priced at the same rate as code 81406.
• New code 81237 is priced at the same rate as code 81210.
• New code 81233 is priced at the same rate as code 81210.
• New code 81320 is priced at the same rate as code 81225.
• New code 81305 is priced at the same rate as code 81210.
• New code 81443 is priced at the same rate as code 81412.
• New code 81163 is priced at the same rate as code 81406 plus code 81216.
• New code 81164 is priced at the same rate as code 81405 plus code 81406.
• New code 81165 is priced at the same rate as code 81406.
• New code 81166 is priced at the same rate as code 81405.
• New code 81167 is priced at the same rate as code 81406.
• New code 83722 is priced at the same rate as code 83704.
• New code 81306 is priced at the same rate as code 81225.
• New code 81171 is priced at the same rate as code 81401.
• New code 81172 is priced at the same rate as code 81404.
• New code 81204 is priced at the same rate as code 81401.
• New code 81173 is priced at the same rate as code 81405.
• New code 81174 is priced at the same rate as code 81403.
• New code 81177 is priced at the same rate as code 81401.
• New code 81178 is priced at the same rate as code 81401.
• New code 81183 is priced at the same rate as code 81401.
• New code 81179 is priced at the same rate as code 81401.
• New code 81180 is priced at the same rate as code 81401.
• New code 81181 is priced at the same rate as code 81401.
• New code 81182 is priced at the same rate as code 81401.
• New code 81184 is priced at the same rate as code 81401.
• New code 81185 is priced at the same rate as code 81407.
• New code 81186 is priced at the same rate as code 81403.
• New code 81187 is priced at the same rate as code 81401.
• New code 81188 is priced at the same rate as code 81401.
• New code 81189 is priced at the same rate as code 81404.
• New code 81190 is priced at the same rate as code 81403.
• New code 81234 is priced at the same rate as code 81401.
• New code 81239 is priced at the same rate as code 81404.
• New code 81284 is priced at the same rate as code 81401.
• New code 81285 is priced at the same rate as code 81404.
• New code 81286 is priced at the same rate as code 81404.
• New code 81289 is priced at the same rate as code 81403.
• New code 81271 is priced at the same rate as code 81401.
• New code 81274 is priced at the same rate as code 81404.
• New code 81312 is priced at the same rate as code 81401.
• New code 81329 is priced at the same rate as code 81401.
• New code 81336 is priced at the same rate as code 81405.
• New code 81337 is priced at the same rate as code 81403.
• New code 81343 is priced at the same rate as code 81401.
• New code 81344 is priced at the same rate as code 81401.
• New code 87634QW is priced at the same rate as code 87634.
• Existing code 81211 is to be deleted.
• Existing code 81213 is to be deleted.
• Existing code 81214 is to be deleted.
• Existing code 0001M is to be deleted.
Laboratory Costs Subject to Reasonable Charge Payment in CY 2019

Hospital outpatient claims are paid under a reasonable charge basis (see Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index (CPI) for the 12-month period ending June 30 of each year, as set forth in 42 CFR 405.509(b)(1). The CPI update for CY 2019 is 2.90 percent.

Manual instructions for determining the reasonable charge payment are available in Chapter 23, Sections 80 through 80.8 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf. If there is not sufficient charge data for a code, the instructions permit considering charges for other, similar services and price lists.

Services described by HCPCS codes in the following list are performed for independent dialysis facility patents. Chapter 8, Section 60.3 of the Medicare Claims Processing Manual available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf, instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the Hospital Outpatient Prospective Payment System (OPPS).

Codes – Blood Products


Payment for the following codes should be applied to the blood deductible as instructed in Chapter 3, Sections 20.5 through 20.5.4 of the Medicare General Information, Eligibility, and Entitlement Manual:

- P9010, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9057, and P9058.

**Note:** Biologic product not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for code P9041, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.

Codes – Transfusion Medicine

86850, 86860, 86870, 86880, 86885, 86886, 86890, 86891, 86900, 86901, 86902, 86904, 86905, 86906, 86920, 86921, 86922, 86923, 86927, 86930, 86931, 86932, 86945, 86950, 86960, 86965, 86970, 86971, 86972, 86975, 86976, 86977, 86978, and 86985
Codes – Reproductive Medicine Procedures
89250, 89251, 89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89290, 89291, 89335, 89337, 89342, 89343, 89344, 89346, 89352, 89353, 89354, and 89356

New Codes Effective October 1, 2018

Proprietary Laboratory Analysis (PLAs)
The following new codes have been added to the national HCPCS file with an effective date of October 1, 2018. These new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July of 2019, as they were received after the 2018 public meeting. (MACs will only price PLA codes for laboratories within their jurisdiction.)

- **CPT Code: 0062U**
  - Short Descriptor: Ai sle igg&igm alys 80 bmrk
  - Long Descriptor: Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score
  - Laboratory: SLE-key® Rule Out, Veracis Inc, Veracis Inc

- **CPT Code: 0063U**
  - Short Descriptor: Neuro autism 32 amines alg
  - Long Descriptor: Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder
  - Laboratory: NPDX ASD ADM Panel I, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX

- **CPT Code: 0064U**
  - Short Descriptor: Antb tp total&rpr ia qual
  - Long Descriptor: Antibody, Treponema pallidum, total and rapid plasma reagin (RPR), immunoassay, qualitative
  - Laboratory: BioPlex 2200 Syphilis Total & RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories

- **CPT Code: 0065U**
  - Short Descriptor: Syfls tst nontreponenal antb
  - Long Descriptor: Syphilis test, non-treponemal antibody, immunoassay, qualitative (RPR)
  - Laboratory: BioPlex 2200 RPR Assay, Bio-Rad Laboratories, Bio-Rad Laboratories

- **CPT Code: 0066U**
  - Short Descriptor: Pamg-1 ia cervico-vag fluid
  - Long Descriptor: Placental alpha-micro globulin-1 (PAMG-1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen
  - Laboratory: PartoSure™ Test, Parsagen Diagnostics, Inc, Parsagen Diagnostics, Inc, a QIAGEN Company

- **CPT Code: 0067U**
  - Short Descriptor: Onc brst imhchem prfl 4 bmrk
Long Descriptor: Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score
Laboratory: BBDRisk Dx™, Silbiotech, Inc

CPT Code: 0068U
Short Descriptor: Candida species pnl amp prb
Long Descriptor: Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. krusei, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species
Laboratory: MYCODART Dual Amplification Real Time PCR Panel for 6 Candida species, RealTime Laboratories, Inc
CPT Code: 0069U
Short Descriptor: Onc clrc microrna mir-31-3p
Long Descriptor: Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score
Laboratory: miR-31now™, GoPath Laboratories, GoPath Laboratories
CPT Code: 0070U
Short Descriptor: Cyp2d6 gen com&slct rar vrnt
Laboratory: CYP2D6 Common Variants and Copy Number, Mayo Clinic, Laboratory Developed Test
CPT Code: 0071U
Short Descriptor: Cyp2d6 full gene sequence
Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure)
Laboratory: CYP2D6 Full Gene Sequencing, Mayo Clinic, Laboratory Developed Test
CPT Code: 0072U
Short Descriptor: Cyp2d6 gen cyp2d6-2d7 hybrid
Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure)
Laboratory: CYP2D6-2D7 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test
CPT Code: 0073U
Short Descriptor: Cyp2d6 gen cyp2d7-2d6 hybrid
- Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure)
  - Laboratory: CYP2D7-2D6 Hybrid Gene Targeted Sequence Analysis, Mayo Clinic, Laboratory Developed Test

  - CPT Code: 0074U
    - Short Descriptor: Cyp2d6 nonduplicated gene
    - Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, nonduplicated gene when duplication/multiplication is trans) (List separately in addition to code for primary procedure)
    - Laboratory: CYP2D6 trans-duplication/multiplication non-duplicated gene targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

  - CPT Code: 0075U
    - Short Descriptor: Cyp2d6 5' gene dup/mlt
    - Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (List separately in addition to code for primary procedure)
    - Laboratory: CYP2D6 5' gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

  - CPT Code: 0076U
    - Short Descriptor: Cyp2d6 3’ gene dup/mlt
    - Long Descriptor: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3’ gene duplication/multiplication) (List separately in addition to code for primary procedure)
    - Laboratory: CYP2D6 3’ gene duplication/multiplication targeted sequence analysis, Mayo Clinic, Laboratory Developed Test

  - CPT Code: 0077U
    - Short Descriptor: Ig paraprotein qual bld/ur
    - Long Descriptor: Immunoglobulin paraprotein (M-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype
    - Laboratory: M-Protein Detection and Isotyping by MALDI-TOF Mass Spectrometry, Mayo Clinic, Laboratory Developed Test

  - CPT Code: 0078U
    - Short Descriptor: Pain mgt opi use gnotyp pnl
    - Long Descriptor: Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder
    - Laboratory: INFINITI® Neural Response Panel, PersonalizeDx Labs, AutoGenomics Inc
New Codes Effective January 1, 2019

Proprietary Laboratory Analysis (PLAs)

The following new codes have been included in the national HCPCS file correction with an effective date of January 1, 2019 and may need to be manually added to the HCPCS file by the MACs. These new codes are also contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2019 as they were received after the 2018 public meeting. MACs shall only price PLA codes for laboratories within their jurisdiction.

New Codes

- **CPT Code: 0080U**
  - **Short Descriptor:** ONC LNG 5 CLIN RSK FACTR ALG
  - **Long Descriptor:** Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
  - **Laboratory:** BDX-XL2, Biodesix®, Inc

- **CPT Code: 0081U**
  - **Short Descriptor:** ONC UVEAL MLNMA MRNA 15 GENE
  - **Long Descriptor:** Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
  - **Laboratory:** DecisionDx®-UM, Castle Biosciences, Inc

- **CPT Code: 0082U**
  - **Short Descriptor:** RX TEST DEF 90+ RX/SBSTS UR
  - **Long Descriptor:** Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
  - **Laboratory:** NextGen Precision™ Testing, Precision Diagnostics LBN Precision Toxicology, LLC

- **CPT Code: 0083U**
  - **Short Descriptor:** ONC RSPSE CHEMO CNTRST TOMOG
  - **Long Descriptor:** Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
  - **Laboratory:** Onco4D™, Animated Dynamics, Inc

Note: MACs will not search their files to either retract payment or retroactively pay claims;
however, they should adjust claims if you bring them to their attention.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

**DOCUMENT HISTORY**

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 18, 2019</td>
<td>We revised the article to reflect the revised CR issued on January 17. The revised CR deleted code 0008U from the list of revised codes effective January 1, 2019. We deleted that code from the article. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.</td>
</tr>
<tr>
<td>December 14, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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Calendar Year (CY) 2019 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

MLN Matters Number: MM11064 Revised  Related Change Request (CR) Number: 11064
Related CR Release Date: January 18, 2019  Effective Date: January 1, 2019
Related CR Transmittal Number: R4209CP  Implementation Date: January 7, 2019

Note: We revised this article on January 22, 2019, to reflect a revised CR 11064 that was issued on January 18. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same as the changes to the CR had no impact on the substance in the article.

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items or services paid under the DMEPOS fee schedule provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11064 provides the Calendar Year (CY) 2019 annual update for the Medicare DMEPOS fee schedule. The instructions include information on the data files, update factors and other information related to the update of the fee schedule. Make sure your billing staffs are aware of these updates.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) updates the DMEPOS fee schedule on an annual basis in accordance with statute and regulations. Payment on a fee schedule basis is required for certain Durable Medical Equipment (DME), prosthetic devices, orthotics, prosthetics, and surgical dressings by Section1834 (a), (h), and (i) of the Social Security Act (the Act). Additionally, payment on a fee schedule basis is a regulatory requirement at 42 Code of Federal Regulation (CFR) Section 414.102 for Parenteral and Enteral Nutrition (PEN), splints, casts and Intraocular Lenses (IOLs) inserted in a physician’s office. The DMEPOS and PEN fee schedule files contain Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the adjusted fee schedule amounts under Section 1834(a)(1)(F) as well as codes that are not subject to the fee schedule Competitive Bidding Program (CBP) adjustments.
The key updates for CY 2019 are as follows:

**Fee Schedule Adjustment Methodologies**

Section 1834(a)(1)(F)(ii) of the Act mandates adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from CBPs for DME. Section 1842(s)(3)(B) of the Act provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from CBPs.

The methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs are established in regulations at 42 CFR Section 414.210(g). The DMEPOS and PEN fee schedule files contain HCPCS codes that are subject to the adjusted fee schedule amounts as well as codes that are not subject to the fee schedule CBP adjustments. Initial program instructions on these fee schedule adjustments are available in Transmittal 3551, CR9642, dated June 23, 2016 (MM9642 is available at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9642.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9642.pdf)), and Transmittal 3416, CR9431, dated November 23, 2015 (MM9431 is available at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9431.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9431.pdf)).

For CY 2019, the following Fee Schedule Adjustment Methodologies apply and fee schedule amounts are based on the area in which the items and services are furnished. Additional discussion of these methodologies is in the CY 2019 End-Stage Renal Disease (ESRD)/DMEPOS final rule, CMS-1691-F, which is available at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html).

**1. Fee Schedule Amounts for Areas within the Contiguous United States**

Beginning January 1, 2109, through December 31, 2020, the adjusted fee schedule amounts for items furnished in non-competitively bid rural areas are based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted fee schedule amounts updated by the covered item updates specified in Sections 1834(a)(14) and 1842(s)(B) of the Act. For non-competitively bid areas other than rural or non-contiguous areas, the fee schedules for DME and PEN codes with adjusted fee schedule amounts will continue to be based on 100 percent of the adjusted fee schedule amounts from January 1, 2019, through December 31, 2020.

To determine the adjusted fee schedule amounts, the average of Single Payment Amounts (SPAs) from CBPs located in eight different regions of the contiguous United States are used to adjust the fee schedule amounts for the states located in each of the eight regions. These Regional SPAs or RSPAs are also subject to a national ceiling (110 percent of the average of the RSPAs for all contiguous states plus the District of Columbia) and a national floor (90% of the average of the RSPAs for all contiguous states plus the District of Columbia). This methodology applies to enteral nutrition and most competitively bid DME items furnished in the contiguous United States, that is, those included in more than 10 Competitive Bidding Areas (CBAs). Fees schedule amounts for competitively bid DME items included in 10 or fewer CBAs...
receive adjusted fee schedule amounts so that they are equal to 110 percent of the average of the SPAs for the 10 or fewer CBAs.

Additionally, in determining the adjusted fees, the fee schedule amounts for areas within the contiguous United States that are designated as rural areas are adjusted to equal the national ceiling amounts described above. Regulations at section 414.202 define a rural area to be a geographical area represented by a postal ZIP code where at least 50 percent of the total geographical area of the ZIP code is estimated to be outside any Metropolitan Statistical Area (MSA). A rural area also includes any ZIP Code within an MSA that is excluded from a CBA established for that MSA.

For the January 1, 2020 fee schedule update, the adjusted fee schedule amounts in non-bid areas will receive a Consumer Price Index for all Urban Consumers (CPI-U) update per Section 414.210(g) due to the adjustments being based on SPAs from CBPs that are no longer in effect.

2. Fee Schedule Amounts for Areas outside the Contiguous United States

Fee schedule amounts for items furnished in areas outside the contiguous United States (the noncontiguous areas, such as Alaska, Guam, Hawaii) are based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted fee schedule amounts updated by the covered item updates specified in Sections 1834(a)(14) and 1842(s)(B) of the Act. Areas outside the contiguous United States receive adjusted fee schedule amounts so that they are equal to the higher of the average of SPAs for CBAs in areas outside the contiguous United States (currently only applicable to Honolulu, Hawaii) or the national ceiling amounts described above and calculated based on SPAs for areas within the contiguous United States. For the January 1, 2020 fee schedule update, the adjusted fee schedule amounts in non-bid areas will receive a CPI-U update per Section 414.210(g) due to the adjustments being based on SPAs from CBPs that are no longer in effect.

**KE Modifier**

Because the rural and non-contiguous fee schedule amounts are based in part on unadjusted fee schedule amounts, the fees for certain items included in the 2008 Original Round One CBP, denoted with the KE modifier, appear on the fee schedule file only for items furnished in rural and non-contiguous areas. Instructions and a list of the applicable KE HCPCS codes are available in Transmittal 1630, CR6270, dated November 7, 2008. From June 1, 2018, through December 31, 2020, the rural and non-contiguous KE fee schedule amounts will be based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted KE fee schedule amount updated by the covered item updates specified in Sections 1834(a)(14) and 1842(s)(B) of the Act. The non-rural fees for these KE codes will be populated with zeros on the fee schedule file since KE is not a valid option for areas without blended fees.

For certain accessories used with base equipment included in the CBP in 2008 (for example, power wheelchairs, walkers, and negative pressure wound therapy pumps), the unadjusted fee schedule amounts include a 9.5 percent reduction in accordance with Federal law if these accessories were also included in the 2008 CBP. The 9.5 percent fee reduction only applies to these accessories when they are furnished for use with the base equipment included in the
2008 CBP. Beginning June 1, 2018, in cases where accessories included in the 2008 CBP are furnished for use with base equipment that was not included in the 2008 CBP (for example, manual wheelchairs, canes and aspirators), for beneficiaries residing in rural or non-contiguous, non-competitive bid areas, suppliers should append the KE modifier to the HCPCS code for the accessory. Suppliers should not use the KE modifier with accessories that were included in the 2008 CBP and furnished for use with base equipment that was not included in the 2008 CBP when these accessories are furnished to beneficiaries residing in non-rural, non-competitive bid areas. The KE modifier is not billable for items furnished in former competitive bid areas effective January 1, 2019 (see payment methodology below).

3. Fee Schedule Amounts for former CBAs

The Round 2 Recompete, National Mail-Order Recompete, and Round One 2017 contract periods of performance expire on December 31, 2018. Due to a delay, contracts will not be in effect beginning January 1, 2019, resulting in a gap in the CBP. Beginning January 1, 2019, fee schedule amounts for items furnished in former CBAs are based on the lower of the supplier’s charge for the item or fee schedule amounts adjusted in accordance with Sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. A new fee schedule methodology will apply to items and services furnished within former CBAs in accordance with Sections 1834(a)(1)(F) and 1834(a)(1)(G) of the Act. Pursuant to 42 CFR Section 414.210(g), the fee schedules for items and services furnished in former CBAs are based on the SPAs, in effect in the CBA on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the CPI-U for the 12-month period on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day after the contract period ended with the CPI-U. Thus, for dates of service from January 1, 2019, through December 31, 2019, the adjusted fee schedule amounts for former CBAs will be derived based on the SPAs in effect in the CBA as of December 31, 2018, increased by the projected CPI-U change of 2.5 percent.

The ZIP code associated with the address used for pricing a DMEPOS claim determines the rural fee schedule payment applicability for codes with rural and non-rural adjusted fee schedule amounts. The DMEPOS Rural ZIP code file contains the ZIP codes designated as rural areas. ZIP codes for non-continental MSA are not included in the DMEPOS Rural ZIP code file. The DMEPOS Rural ZIP code file is updated on a quarterly basis as necessary.

The ZIP code associated with the permanent address of the beneficiary determines applicability of the adjusted fee schedule amounts in former CBAs. During a gap in the CBP, a former CBA ZIP code file will contain the ZIP codes and will be updated on a quarterly basis as necessary.

The following CY 2019 DMEPOS fee schedule and ZIP code Public Use Files (PUFs) will be available for State Medicaid Agencies, managed care organizations, and other interested parties at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.

1. DMEPOS Fee schedule PUF
2. PEN Fee schedule PUF
3. Rural DMEPOS ZIP code PUF
4. Former CBA Fee schedule PUF
5. Former CBA National mail order diabetic testing supply fee schedule PUF
6. Former CBA ZIP code file PUF

New Codes Added

New DMEPOS codes added to the HCPCS file, effective January 1, 2019, where applicable, are A4563, A5514, A6460, A6461, B4105, E0447, E0467, L8608, L8698, L8701, L8702, V5171, V5172, V5181, V5211, V5212, V5213, V5214, V5215, and V5221. The new codes are not to be used for billing purposes until they are effective on January 1, 2019. As part of this update, fee schedules for the following new codes will be added to the DMEPOS fee schedule file effective January 1, 2019: A4563, A5514, E0447 and E0467.

Beginning January 1, 2019, the DMEPOS fee schedule file also includes fees for the following three home infusion G-codes: G0068, G0069, and G0070.

For other new CY 2019 codes, fee schedule amounts will be established as part of the July 2019 DMEPOS fee schedule update when applicable. The DME MAC shall establish local fee schedule amounts to pay claims for new codes listed from January 1, 2019, through June 30, 2019.

For gap-filling pricing purposes, deflation factors are applied before updating to the current year. The deflation factors for 2018 by payment category are:

- 0.435 for Oxygen
- 0.437 for Capped Rental
- 0.439 for Prosthetics and Orthotics
- 0.556 for Surgical Dressings
- 0.605 for Parental and Enteral Nutrition
- 0.927 for Splints and Casts
- 0.911 for Intraocular Lenses

Codes Deleted

One HCPCS code (K0903) will be deleted from the DMEPOS fee schedule files effective January 1, 2019

Multi-Function Ventilators

Effective January 1, 2019, fees are added for new HCPCS code E0467 (Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions).

Pursuant to 42 CFR 414.222(f), the fee schedule amounts for code E0467 are established using the Medicare fee schedule amounts for ventilators and the average cost of the additional
functions performed by multi-function ventilators. The multi-function ventilator is classified under the frequent and substantial servicing payment category at Section 1834(a)(3) of the Act and payment will be made on a continuous monthly rental basis for beneficiaries who meet the Medicare medical necessity coverage criteria for a ventilator and at least one of the four additional functions of the device. Additional information on this change is in the CY 2019 End-Stage Renal Disease (ESRD)/ DMEPOS final rule, CMS-1691-F which is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

**Therapeutic Shoe Modification Codes**

CMS is also adjusting the fee schedule amounts for shoe modification codes A5503 through A5507 as part of this update in order to reflect more current allowed service data. Section 1833(o)(2)(C) of the Act required that the payment amounts for shoe modification codes A5503 through A5507 be established in a manner that prevented a net increase in expenditures when substituting these items for therapeutic shoe insert codes (A5512 or A5513). To establish the fee schedule amounts for the shoe modification codes, the base fees for codes A5512 and A5513 were weighted based on the approximated total allowed services for each code for items furnished during the second quarter of CY 2004. For 2019, CMS is updating the weighted average insert fees used to establish the fee schedule amounts for the shoe modification codes with more current allowed service data for each insert code. The base fees for A5512 and A5513 will be weighted based on the approximated total allowed services for each code for items furnished during the CY 2017. The fee schedule amounts for shoe modification codes A5503 through A5507 are revised to reflect this change, effective January 1, 2019.

**Diabetic Testing Supplies**

The fee schedule amounts for non-mail order Diabetic Testing Supplies (DTS) (without KL modifier) for codes A4233, A4234, A4235, A4236, A4253, A4256, A4258, and A4259 are not updated by the annual covered item update. In accordance with Section 1834(a)(1)(H) of the Act, the fee schedule amounts for these codes were adjusted in CY 2013 so that they are equal to the SPAs for mail order DTS established in implementing the national mail order CBP under Section 1847 of the Act. Initial program instructions on these fees are available in Transmittal 2709, CR8325, dated May 17, 2013 (MM8325 is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8325.pdf) and Transmittal 2661, CR8204 (MM8204 is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8204.pdf) dated February 22, 2013. The National Mail-Order Recompete DTS SPAs are available at https://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.

The non-mail order DTS amounts on the fee schedule will be updated each time the single payment amounts are updated. This can happen no less often than every time the mail order CBP contracts are recompeted. The CBP for mail order diabetic supplies is effective July 1, 2016, to December 31, 2018. As of January 1, 2019, payment for non-mail order diabetic supplies at the National Mail Order Recompete SPAs will continue in accordance with Section 1834(a)(1)(H) of the Act and these rates will remain in effect until new SPA rates are established under the national mail order program.
Effective January 1, 2019, the fee schedule amounts for mail order DTS (with KL modifier) are adjusted using the methodology for areas that were formerly CBAs during periods when there is a temporary lapse in the CBP. The National Mail-Order Recompete DTS SPAs of December 31, 2018, are increased by the projected percentage change in the CPI-U for the 12-month period on the date after the contract periods ended. For dates of service between January 1, 2019, and December 31, 2019, the National Mail-Order Recompete SPAs are updated by the projected change of 2.5%. The national mail order adjusted fee schedule amounts will be used in paying mail order diabetic testing supply claims in all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam and the American Samoa.

2019 Fee Schedule Update Factor of 2.3 Percent

For CY 2019, an update factor of 2.3 percent is applied to certain DMEPOS fee schedule amounts. Fee schedule amounts that are adjusted using information from CBPs are not be subject to the annual DMEPOS covered item update, but will be updated pursuant to the applicable adjustment methodologies outlined in 42 CFR Section 414.210(g).

In accordance with the statutory Sections 1834(a)(14) of the Act, certain DMEPOS fee schedule amounts are updated for 2019 by the percentage increase in the CPI-U for the 12-month period ending June 30, 2018, adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business Multi-Factor Productivity (MFP). The MFP adjustment is 0.6 percent and the CPI-U percentage increase is 2.9 percent. Thus, the 2.9 percentage increase in the CPI-U is reduced by the 0.6 percentage increase in the MFP resulting in a net increase of 2.3 percent for the update factor.

2019 Monthly Fee Schedule Amounts for Oxygen and Oxygen Equipment

As part of this update, CMS is implementing the 2019 monthly fee schedule payment amounts for stationary oxygen equipment (HCPCS codes E0424, E0439, E1390 and E1391), effective for claims with dates of service from January 1, 2019, through December 31, 2019. As required by statute, the CY 2006 addition of the separate payment classes for Oxygen Generating Portable Equipment (OGPE) and stationary and portable oxygen contents must be annually budget neutral.

For CY 2019, separate payment classes for portable gaseous oxygen equipment only, portable liquid oxygen equipment only, and high flow portable liquid oxygen contents only are established. Higher payments for the two new liquid oxygen classes are established. To implement this change, fees are added for new code E0447 Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 Liters Per Minute (LPM). The initial fee for E0447 is set at 150 percent of the fee for portable oxygen contents. This new high flow oxygen content class allows for the continuation of high flow oxygen volume adjustment payments beyond the initial 36 months of continuous use. In addition, the payment for portable liquid oxygen (code E0434) is set to be equivalent to the rental payment amount for portable concentrators and transfilling equipment (HCPCS codes E1392, K0738 or E0433).

Consistent with the requirements set forth in Section 1834(a) (9)(D)(ii) of the Act, a new methodology is established for ensuring that new payment classes for oxygen and oxygen
equipment are budget neutral.

The new methodology for ensuring the budget neutrality of the OGPE payment class and the two new classes related to liquid oxygen is to apply a budget neutrality off-set (percentage reduction) to all oxygen classes beginning January 1, 2019. This would spread the offset across all oxygen and oxygen equipment, thereby lowering the amount taken from the stationary oxygen payment to pay for the separate classes added via Section 1834(a)(9)(D) of the Act. The offset percentage varies by area and ranges from 6 to 9 percent.

Additional discussion of the addition of the new oxygen payment classes and the application of the annual budget neutrality across all classes of oxygen and oxygen equipment is available in the CY 2019 End-Stage Renal Disease (ESRD)/ DMEPOS final rule, CMS-1691-F, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

### 2019 Maintenance and Servicing Payment Amount for Certain Oxygen Equipment

The payment amount for maintenance and servicing for certain oxygen equipment is updated also for 2019. Payment for claims for maintenance and servicing of oxygen equipment was included in Transmittal 635, CR6792, dated February 5, 2010, and Transmittal 717, CR6990, dated June 8, 2010. To summarize, payment for maintenance and servicing of certain oxygen equipment can occur every 6 months beginning 6 months after the end of the 36th month of continuous use or end of the supplier’s or manufacturer’s warranty, whichever is later for either HCPCS code E1390, E1391, E0433 or K0738, billed with the “MS” modifier. Payment cannot occur more than once per beneficiary, regardless of the combination of oxygen concentrator equipment and/or transfilling equipment used by the beneficiary, for any 6-month period.

Per 42 CFR section 414.210(e)(5)(iii), the 2010 maintenance and servicing fee for certain oxygen equipment was based on 10 percent of the average price of an oxygen concentrator. For CY 2011 and subsequent years, the maintenance and servicing fee is adjusted by the covered item update for DME as set forth in §1834(a) (14) of the Act. Thus, the 2018 maintenance and servicing fee is adjusted by the 2.3 percent MFP-adjusted covered item update factor to yield a CY 2019 maintenance and servicing fee of $72.37 for oxygen concentrators and transfilling equipment.

### 2019 Update to the Labor Payment Rates

Included in the following table are the CY 2019 allowed payment amounts for HCPCS labor payment codes K0739, L4205 and L7520. Since the percentage increase in the CPI-U for the twelve-month period ending with June 30, 2019 is 2.9 percent, this change is applied to the 2019 labor payment amounts to update the rates for CY 2019.

The 2019 labor payment amounts in this table are effective for claims submitted using HCPCS codes K0739, L4205, and L7520 with dates of service from January 1, 2019, through December 31, 2019.

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<tr>
<td>TN</td>
<td>$15.70</td>
<td>$23.40</td>
<td>$31.77</td>
</tr>
<tr>
<td>TX</td>
<td>$15.70</td>
<td>$23.40</td>
<td>$31.77</td>
</tr>
<tr>
<td>UT</td>
<td>$15.74</td>
<td>$23.37</td>
<td>$49.46</td>
</tr>
<tr>
<td>VA</td>
<td>$15.70</td>
<td>$23.37</td>
<td>$31.77</td>
</tr>
</tbody>
</table>
### ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>January 22, 2019</td>
<td>We revised the article to reflect a revised CR 11064 that was issued on January 18. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same as the changes to the CR had no impact on the substance in the article.</td>
</tr>
<tr>
<td>December 14, 2018</td>
<td>Initial article released.</td>
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</table>

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Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens

MLN Matters Number: MM11146
Related Change Request (CR) Number: CR 11146
Related CR Release Date: January 11, 2019
Effective Date: January 1, 2019
Related CR Transmittal Number: R4199CP
Implementation Date: February 12, 2019 or sooner

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for specimen collection services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

CR11146 revises travel allowances payment amounts when billed on a per mileage basis using HCPCS code P9603 and when billed on a flat rate basis using HCPCS code P9604 for Calendar Year (CY) 2019. Make sure your billing staffs are aware of these changes.

BACKGROUND

Medicare Part B allows payment for a specimen collection fee and travel allowance, when medically necessary, for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under Section 1833(h)(3) of the Act. Medicare bases the payment for these services on the clinical laboratory fee schedule.

The travel codes allow for payment either on a per mileage basis (P9603) or on a flat rate per trip basis (P9604). Medicare makes payment of the travel allowance only if a specimen collection fee is also payable. The travel allowance is intended to cover the estimated travel costs of collecting a specimen including the laboratory technician’s salary and travel expenses. MAC discretion allows the MAC to choose either a mileage basis or a flat rate, and how to set each type of allowance. Because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary for a laboratory technician to travel for specimen collection, many MACs established local policy to pay based on a flat rate basis only.
Under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), Medicare prorates the travel payment component based on the number of specimens collected on that trip for both Medicare and non-Medicare patients, either at the time the laboratory submits the claim or when the flat rate is set by the MAC.

**Per Mile Travel Allowance (P9603),** the per mile travel allowance is used in situations where the average trip to the patients’ homes is longer than 20 miles round trip, and is prorated in situations where the technicians draw specimens from non-Medicare patients in the same trip.

The allowance per mile was computed using the Federal mileage rate of $0.58 per mile plus an additional $0.45 per mile to cover the technician’s time and travel costs. (The Internal Revenue Service determines the standard mileage rate for businesses based on periodic studies of the fixed and variable costs of operating an automobile.) MACs have the option of establishing a higher per mile rate in excess of the minimum $1.03 per mile if local conditions warrant it. The minimum mileage rate will be reviewed and updated throughout the year, as well as in conjunction with the Clinical Laboratory Fee Schedule (CLFS), as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable, or for miles that are not actually traveled by the laboratory technician.

**Per Flat-Rate Trip Basis Travel Allowance (P9604),** the per flat-rate trip basis travel allowance is $10.30.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).

**DOCUMENT HISTORY**

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>January 11, 2019</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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January 2019 Update of the Ambulatory Surgical Center (ASC) Payment System

MLN Matters Number: MM11108 Revised Related Change Request (CR) Number: 11108
Related CR Release Date: December 31, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4191CP Implementation Date: January 7,2019

This article was revised on January 16, 2019, to correct Table 2. The ASC PI for C9752, C9754 and C9755 should have been J8 (not G2). All other information is unchanged.

**PROVIDER TYPE AFFECTED**

This MLN Matters Article is intended for Ambulatory Surgical Centers (ASCs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**PROVIDER ACTION NEEDED**

CR 11108 informs MACs about updates to the ASC payment system for Calendar Year (CY) 2019. Be sure your billing staffs are aware of these changes.

**BACKGROUND**

CR 11108 describes changes to and billing instructions for various payment policies implemented in the January 2019 ASC payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

Included are CY 2019 payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), and the CY 2019 ASC payment rates for covered surgical and ancillary services (ASCFS file). The CY2019 ASC Code pair file is also included in CR 11108

ASC payment rates under the ASC payment system are generally established using payment rate information in the hospital Outpatient Prospective Payment System (OPPS) or the Medicare Physician Fee Schedule (MPFS). The payment files associated with CR 11108 reflect the most recent changes to the CY 2019 OPPS and CY 2019 MPFS payments.
KEY POINTS OF CR 11108

New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. This policy was implemented in the 2008 revised ASC payment system. Therefore, additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the OPPS.

Effective January 1, 2019, one new device pass-through category has been created; HCPCS code C1823, as described in Table 1.

Device Offset from Payment:

Section 1833(t)(6)(D)(ii) of the Act requires CMS, under the OPPS, to deduct from pass-through payments for devices an amount that reflects the portion of the Ambulatory Payment Classification (APC) payment amount. This policy was implemented in the 2008 revised ASC payment system. CMS has determined that a portion of the APC payment amount associated with the cost of HCPCS C1823 is reflected in APC 5464 (Level 4 Neurostimulator and Related Procedures). The C1823 device should always be billed with Current Procedural Terminology (CPT) Code 0424T (Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)), which is assigned to APC 5464 for CY 2019. The device offset from payment represents a deduction from pass-through payments for the device in category C1823. The descriptors and ASC payment indicator for C1823 is in table 1

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1823</td>
<td>Gen, neuro, trans sen/stim</td>
<td>Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads</td>
<td>J7</td>
</tr>
</tbody>
</table>

New Separately Payable Procedure Codes Effective January 1, 2019

Effective January 1, 2019, new HCPCS codes C9752, C9754, and C9755 are created as described in Table 2 below. Also, for CY 2019, we revised our definition of “surgery” in the ASC
payment system to account for certain “surgery-like” procedures that are assigned codes outside the Current Procedural Terminology (CPT) surgical range. As discussed in the CY 2019 OPPS/ASC final rule, CMS added separately payable cardiac catheterization procedures to the ASC covered procedures list. These codes are also included in table 2. Refer to ASC Addendum AA (see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html) for the ASC payment rate for these codes effective January 1, 2019.

Table 2. – New Separately Payable Procedure Codes Effective January 1, 2019

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9752</td>
<td>Intraosseous des lumb/sacrum</td>
<td>Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum</td>
<td>J8</td>
</tr>
<tr>
<td>C9754</td>
<td>Perc AV fistula, any site</td>
<td>Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)</td>
<td>J8</td>
</tr>
<tr>
<td>C9755</td>
<td>RF magnetic-guided AV fistula</td>
<td>Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed</td>
<td>J8</td>
</tr>
<tr>
<td>93451</td>
<td>Right heart cath</td>
<td>Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed</td>
<td>G2</td>
</tr>
<tr>
<td>93452</td>
<td>Left hrt cath w/ventriclgrphy</td>
<td>Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed</td>
<td>G2</td>
</tr>
<tr>
<td>93453</td>
<td>R&amp;L hrt cath w/ventriclgrphy</td>
<td>Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed</td>
<td>G2</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Short Descriptor</td>
<td>Long Descriptor</td>
<td>ASC PI</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>93454</td>
<td>Coronary artery angio s&amp;i</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;</td>
<td>G2</td>
</tr>
<tr>
<td>93455</td>
<td>Coronary art/grft angio s&amp;i</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography</td>
<td>G2</td>
</tr>
<tr>
<td>93456</td>
<td>R hrt coronary artery angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization</td>
<td>G2</td>
</tr>
<tr>
<td>93457</td>
<td>R hrt art/grft angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization</td>
<td>G2</td>
</tr>
<tr>
<td>93458</td>
<td>L hrt artery/ventricle angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed</td>
<td>G2</td>
</tr>
<tr>
<td>93459</td>
<td>L hrt art/grft angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography</td>
<td>G2</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Short Descriptor</td>
<td>Long Descriptor</td>
<td>ASC PI</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>93460</td>
<td>R&amp;l hrt art/ventricle angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed</td>
<td>G2</td>
</tr>
<tr>
<td>93461</td>
<td>R&amp;l hrt art/ventricle angio</td>
<td>Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography</td>
<td>G2</td>
</tr>
</tbody>
</table>

**Device Intensive Procedures**

Effective January 1, 2019, the OPPS modified the device-intensive criteria to lower the device offset percentage threshold from greater than 40 percent to greater than 30 percent and to allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. Refer to section IV.B (Device-Intensive Procedures) of the CY 2019 OPPS/ASC final rule that was published in the Federal Register on November 21, 2018 for more information on this policy. This policy is also implemented in the ASC payment system. Accordingly, effective January 1, 2019, all new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 31 percent (previously at least 41 percent), and thereby assigned device intensive status, until claims data are available. In certain rare instances, CMS may temporarily assign a higher offset percentage if warranted by additional information.

**MAC Use Only Effective January 1, 2019**

HCPCS C1890 and both its short and long descriptors are included in table 3. Additional information and requirements will be issued in a future CR release.
Table 3. Device Intensive Procedures that are Performed without a Device Effective January 1, 2019

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1890</td>
<td>No device w/dev-intensive px</td>
<td>No implantable/insertable device used with device-intensive procedures</td>
<td>J7</td>
</tr>
</tbody>
</table>

Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2019 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals

For CY 2019, several new HCPCS codes are created for reporting drugs and biologicals in the ASC payment system, where there have not previously been specific codes available. These new codes are listed in Table 4.

Table 4. — New CY 2019 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td>C9035</td>
<td>Injection, aristada initio</td>
<td>Injection, aripiprazole lauroxil (aristada initio), 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9036</td>
<td>Injection, patisiran</td>
<td>Injection, patisiran, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9037</td>
<td>Injection, risperidone</td>
<td>Injection, risperidone (perseris), 0.5 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9038</td>
<td>Inj mogamulizumab-kpkc</td>
<td>Injection, mogamulizumab-kpkc, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9039</td>
<td>Injection, plazomicin</td>
<td>Injection, plazomicin, 5 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9407</td>
<td>Iodine i-131 iobenguane, dx</td>
<td>Iodine i-131 iobenguane, diagnostic, 1 millicurie</td>
<td>K2</td>
</tr>
<tr>
<td>J0584</td>
<td>Injection, burosunab-twza 1m</td>
<td>Injection, burosunab-twza 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------</td>
<td>-------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>J0841</td>
<td>Inj crotalidae im f(ab')2 eq</td>
<td>Injection, crotalidae immune f(ab')2 (equine), 120 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J1746</td>
<td>Inj., ibalizumab-uiyk, 10 mg</td>
<td>Injection, ibalizumab-uiyk, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J2186</td>
<td>Inj., meropenem, vaborbactam</td>
<td>Injection, meropenem and vaborbactam, 10mg/10mg (20mg)</td>
<td>K2</td>
</tr>
<tr>
<td>J3397</td>
<td>Inj., vestronidase alfa-vjbk</td>
<td>Injection, vestronidase alfa-vjbk, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J7177</td>
<td>Inj., fibryga, 1 mg</td>
<td>Injection, human fibrinogen concentrate (fibryga), 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J7329</td>
<td>Inj, trivisc 1 mg</td>
<td>Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J9044</td>
<td>Inj, bortezomib, nos, 0.1 mg</td>
<td>Injection, bortezomib, not otherwise specified, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q4195</td>
<td>Puraply 1 sq cm</td>
<td>Puraply, per square centimeter</td>
<td>K2</td>
</tr>
<tr>
<td>Q4196</td>
<td>Puraply am 1 sq cm</td>
<td>Puraply am, per square centimeter</td>
<td>K2</td>
</tr>
<tr>
<td>Q5111</td>
<td>Injection, udenyca 0.5 mg</td>
<td>Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg</td>
<td>K2</td>
</tr>
</tbody>
</table>

### b. Other Changes to CY 2019 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS and CPT code descriptors that will be effective in CY 2019. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2018 and replaced with permanent HCPCS codes effective in CY 2019. ASCs should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the active CY 2019 HCPCS and CPT codes.

Table 5, notes those drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product’s CY 2018
HCPCS/CPT code and long descriptor are noted in the two left hand columns and the CY 2019 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.

Table 5. — Other CY 2019 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C9463</td>
<td>Injection, aprepitant, 1 mg</td>
<td>J0185</td>
<td>Injection, aprepitant, 1 mg</td>
</tr>
<tr>
<td>C9466</td>
<td>Injection, benralizumab, 1 mg</td>
<td>J0517</td>
<td>Injection, benralizumab, 1 mg</td>
</tr>
<tr>
<td>C9014</td>
<td>Injection, cerliponase alfa, 1 mg</td>
<td>J0567</td>
<td>Injection, cerliponase alfa, 1 mg</td>
</tr>
<tr>
<td>C9015</td>
<td>Injection, c-1 esterase inhibitor (human), (haegarda), 10 units</td>
<td>J0599</td>
<td>Injection, c-1 esterase inhibitor (human), (haegarda), 10 units</td>
</tr>
<tr>
<td>C9034</td>
<td>Injection, dexamethasone 9%, intraocular, 1 mcg</td>
<td>J1095</td>
<td>Injection, dexamethasone 9 percent, intraocular, 1 microgram</td>
</tr>
<tr>
<td>C9493</td>
<td>Injection, edaravone, 1 mg</td>
<td>J1301</td>
<td>Injection, edaravone, 1 mg</td>
</tr>
<tr>
<td>C9033</td>
<td>Injection, fosnetupitant 235 mg and palonosetron 0.25 mg</td>
<td>J1454</td>
<td>Injection, fosnetupitant 235 mg and palonosetron 0.25 mg</td>
</tr>
<tr>
<td>C9029</td>
<td>Injection, guselkumab, 1 mg</td>
<td>J1628</td>
<td>Injection, guselkumab, 1 mg</td>
</tr>
<tr>
<td>C9497</td>
<td>Loxapine, inhalation powder, 10 mg</td>
<td>J2062</td>
<td>Loxapine for inhalation, 1 mg</td>
</tr>
<tr>
<td>C9464</td>
<td>Injection, rolapitant, 0.5 mg</td>
<td>J2797</td>
<td>Injection, rolapitant, 0.5 mg</td>
</tr>
<tr>
<td>Q9993</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
<td>J3304</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
</tr>
<tr>
<td>C9016</td>
<td>Injection, triptorelin, extended-release, 3.75 mg</td>
<td>J3316</td>
<td>Injection, triptorelin, extended-release, 3.75 mg</td>
</tr>
<tr>
<td>-------------------</td>
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</tr>
<tr>
<td>C9032</td>
<td>Injection, voretigene neparvovec-rzyl, 1 billion vector genomes</td>
<td>J3398</td>
<td>Injection, voretigene neparvovec-rzyl, 1 billion vector genomes</td>
</tr>
<tr>
<td>Q9995</td>
<td>Injection, emicizumab-kxwh, 0.5 mg</td>
<td>J7170</td>
<td>Injection, emicizumab-kxwh, 0.5 mg</td>
</tr>
<tr>
<td>C9468</td>
<td>Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu</td>
<td>J7203</td>
<td>Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu</td>
</tr>
<tr>
<td>C9465</td>
<td>Hyaluronan or derivative, durolane, for intra-articular injection, per dose</td>
<td>J7318</td>
<td>Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>C9030</td>
<td>Injection, copanlisib, 1 mg</td>
<td>J9057</td>
<td>Injection, copanlisib, 1 mg</td>
</tr>
<tr>
<td>C9024</td>
<td>Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine</td>
<td>J9153</td>
<td>Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine</td>
</tr>
<tr>
<td>C9492</td>
<td>Injection, durvalumab, 10 mg</td>
<td>J9173</td>
<td>Injection, durvalumab, 10 mg</td>
</tr>
<tr>
<td>C9028</td>
<td>Injection, inotuzumab ozogamicin, 0.1 mg</td>
<td>J9229</td>
<td>Injection, inotuzumab ozogamicin, 0.1 mg</td>
</tr>
<tr>
<td>C9467</td>
<td>Injection, rituximab and hyaluronidase, 10 mg</td>
<td>J9311</td>
<td>Injection, rituximab 10 mg and hyaluronidase</td>
</tr>
<tr>
<td>J9310</td>
<td>Injection, rituximab, 100 mg</td>
<td>J9312</td>
<td>Injection, rituximab, 10 mg</td>
</tr>
</tbody>
</table>

c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2019

For CY 2019, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals continues to be made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug,
biological or therapeutic radiopharmaceutical. Also, in CY 2019, a single payment of ASP + 6 percent continues to be made for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective January 1, 2019, payment rates for many drugs and biologicals have changed from the values published in the CY 2019 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2018. In cases where adjustments to payment rates are necessary, CMS is not publishing the updated payment rates in CR11108. However, all ASC payable drugs and biologicals effective January 1, 2019, including those that were updated as a result of the new ASP calculations, are available in the January 2019 ASC Addendum BB at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

d. Drugs and Biologicals Based on ASP Methods with Restated Payment Rates

Some drugs and biologicals based on ASP methods may have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the first date of the quarter at http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html. Suppliers who think they may have gotten an incorrect payment for drugs and biologicals impacted by these corrections may request MAC adjustment of the previously processed claims.

e. Biosimilar Payment Policy

Effective January 1, 2019, the payment rate for biosimilars approved for payment in the ASC payment system will be the same as the payment rate in the OPPS and physician office setting, calculated as the average sales price (ASP) of the biosimilar(s) described by the HCPCS code + 6 percent of the ASP of the reference product. Payment will be made at the single ASP + 6 percent rate.

f. Payment of Drugs, Biologicals, and Radiopharmaceuticals If ASP Data Are Not Available

As in the OPPS, effective January 1, 2019, in the ASC payment setting, CMS will pay separately payable drugs and biological products that do not have pass-through payment status at Wholesale Acquisition Cost (WAC) + 3 percent instead of WAC + 6 percent, in cases where WAC-based payment applies.

g. Drugs and Biologicals with a Change in Status Indicator

HCPCS code Q2049, has a change in status indicator from “Y5” to “K2”, effective January 1, 2019, since we have pricing information for this drug code.
h. New Biosimilar HCPCS Code Effective October 1, 2018

HCPCS code Q5110, listed in table 6, is a biosimilar with the trade name Nivestym that will be paid separately in the ASC payment system. The code will be included in the ASC payment system with an effective date retroactive to October 1, 2018, per CR 10834, which states that HCPCS code is payable for Medicare for claims with a date of service on or after October 1, 2018.

Table 6. — New Biosimilar HCPCS Code Effective October 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5110</td>
<td>Nivestym</td>
<td>Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram</td>
<td>K2</td>
<td>10/01/2018</td>
</tr>
</tbody>
</table>

Skin Substitute Procedure Edits

The payment for skin substitute products that do not qualify for hospital OPPS pass-through status are packaged into the OPPS payment for the associated skin substitute application procedure. This policy is also implemented in the ASC payment system. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes. High cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278. All OPPS pass-through skin substitute products (ASC PI=K2) should be billed in combination with one of the skin application procedures described by CPT code 15271-15278. Table 7 lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable. Note that ASCs should not separately bill for packaged skin substitutes (ASC PI=N1) since packaged codes are not reportable under the ASC payment system.

Table 7.—Skin Substitute Assignments to High Cost and Low Cost Groups for CY 2019

<table>
<thead>
<tr>
<th>CY 2019 HCPCS Code</th>
<th>CY 2019 Short Descriptor</th>
<th>ASC PI</th>
<th>CY 2018 High/Low Assignment</th>
<th>CY 2019 High/Low Assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9363</td>
<td>Integra meshed bil wound mat</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>CY 2019 HCPCS Code</td>
<td>CY 2019 Short Descriptor</td>
<td>ASC PI</td>
<td>CY 2018 High/Low Assignment</td>
<td>CY 2019 High/Low Assignment</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------------------------------</td>
<td>--------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Q4100</td>
<td>Skin substitute, nos</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4101</td>
<td>Apligraf</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4102</td>
<td>Oasis wound matrix</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4103</td>
<td>Oasis burn matrix</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4104</td>
<td>Integra bmwd</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4105</td>
<td>Integra drt or omnigraft</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4106</td>
<td>Dermagraft</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4107</td>
<td>Graftjacket</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4108</td>
<td>Integra matrix</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4110</td>
<td>Primatrix</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4111</td>
<td>Gammagraft</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4115</td>
<td>Alloskin</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4116</td>
<td>Allograft</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4117</td>
<td>Hyalomatrix</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4121</td>
<td>Theraskin</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4122</td>
<td>Dermacell</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4123</td>
<td>Alloskin</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4124</td>
<td>Oasis tri-layer wound matrix</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4126</td>
<td>Memoderm/derma/tranz/integup</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4127</td>
<td>Talymed</td>
<td>N1</td>
<td>High</td>
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<tr>
<td>CY 2019 HCPCS Code</td>
<td>CY 2019 Short Descriptor</td>
<td>ASC PI</td>
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<td>CY 2019 High/Low Assignment</td>
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<tr>
<td>Q4128</td>
<td>Flexhd/allopatchhd/matrixhd</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4132</td>
<td>Grafix core, grafixpl core</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4133</td>
<td>Grafix stravix prime pl sqcm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4134</td>
<td>Hmatrix</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4135</td>
<td>Mediskin</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4136</td>
<td>Ezderm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4137</td>
<td>Amnioexcel biodexcel, 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4138</td>
<td>Biodfence dryflex, 1cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4140</td>
<td>Biodfence 1cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4141</td>
<td>Alloskin ac, 1cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4143</td>
<td>Repriza, 1cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4146</td>
<td>Tensix, 1cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4147</td>
<td>Architect ecm px fx 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4148</td>
<td>Neox neox rt or clarix cord</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4150</td>
<td>Allowrap ds or dry 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4151</td>
<td>Amnioband, guardian 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4152</td>
<td>Dermapure 1 square cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4153</td>
<td>Dermavest, plurivest sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4154</td>
<td>Biovance 1 square cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4156</td>
<td>Neox 100 or clarix 100</td>
<td>N1</td>
<td>High</td>
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<tr>
<td>Q4157</td>
<td>Revitalon 1 square cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4158</td>
<td>Kerecis omega3, per sq cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4159</td>
<td>Affinity1 square cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4160</td>
<td>Nushield 1 square cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4161</td>
<td>Bio-connekt per square cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4163</td>
<td>Woundex, bioskin, per sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4164</td>
<td>Helicoll, per square cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4165</td>
<td>Keramatrix, per square cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
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<tr>
<td>Q4166</td>
<td>Cytal, per square centimeter</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
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<tr>
<td>Q4167</td>
<td>Truskin, per sq centimeter</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
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<tr>
<td>Q4169</td>
<td>Artacent wound, per sq cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4170</td>
<td>Cygnus, per sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
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<tr>
<td>Q4173</td>
<td>Palingen or palingen xplus</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4175</td>
<td>Miroderm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4176</td>
<td>Neopatch, per sq centimeter</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4178</td>
<td>Floweramniopatch, per sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Q4179</td>
<td>Flowerderm, per sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4180</td>
<td>Revita, per sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4181</td>
<td>Amnio wound, per square cm</td>
<td>N1</td>
<td>High</td>
<td>High*</td>
</tr>
<tr>
<td>Q4182</td>
<td>Transcyte, per sq centimeter</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
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<td>CY 2019 HCPCS Code</td>
<td>CY 2019 Short Descriptor</td>
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<td>CY 2018 High/Low Assignment</td>
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<tr>
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<td>----------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Q4183</td>
<td>Surgigraft, 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4184</td>
<td>Cellesta, 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4186</td>
<td>Epifix 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4187</td>
<td>Epicord 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4188</td>
<td>Amnioarmor 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4190</td>
<td>Artacent ac 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4191</td>
<td>Restorigin 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4193</td>
<td>Coll-e-derm 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4194</td>
<td>Novachor 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4195*</td>
<td>Puraply 1 sq cm</td>
<td>K2</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4196*</td>
<td>Puraply am 1 sq cm</td>
<td>K2</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4197</td>
<td>Puraply xt 1 sq cm</td>
<td>N1</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Q4198</td>
<td>Genesis amnio membrane 1sqcm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4200</td>
<td>Skin te 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4201</td>
<td>Matrion 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4203</td>
<td>Derma-gide, 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Q4204</td>
<td>Xwrap 1 sq cm</td>
<td>N1</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

* These products do not exceed either the MUC or PDC threshold for CY 2019, but are assigned to the high cost group because they were assigned to the high cost group in CY 2018.

+ OPPS Pass-through payment status in CY 2019.
CY 2019 ASC Wage Index

In the CY2019 OPPS/ASC final rule with comment period, CMS informed readers that generally, the Office of Management and Budget (OMB) issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provides updates to and supersedes OMB Bulletin No. 15–01 that was issued on July 15, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. Please refer to page 59074 of the CY2019 OPPS/ASC final rule for more details. OMB Bulletin No. 17–01 made the following change that is relevant to the ASC wage index: The new urban Core Based Statistical Area (CBSA) is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The final CY2019 ASC wage indices are included in Attachment B of CR11108.

Coverage Determinations

The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the ASC payment system does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
DOCUMENT HISTORY

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<td>January 16, 2019</td>
<td>This article was revised to correct Table 2. The ASC PI for C9752, C9754 and C9755 should have been J8 (not G2).</td>
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Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2019 Update

MLN Matters Number: MM11163
Related Change Request (CR) Number: 11163
Related CR Release Date: February 1, 2019
Effective Date: January 1, 2019
Related CR Transmittal Number: R4234CP
Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you that the Centers for Medicare & Medicaid Services (CMS) has issued payment files to the MACs based upon the 2019 Medicare Physician Fee Schedule (MPFS) Final Rule. CR 11163 amends those payment files. Please be sure your billing staffs are aware of these changes.

BACKGROUND


Below is a summary of the changes for the April update to the 2019 Medicare Physician Fee Schedule Database (MPFSD). These changes are effective for dates of service on and after January 1, 2019. CMS has added new HCPCS codes (G2001-G2009 and G2013-G2015) to the 2019 MPFSDB and updated another code (G9987) as shown in the table below. CMS communicated instructions for these new codes (G2001-G2009 and G2013-G2015) through a separate CR (CR 10907). Please consult MLN Matters article MM10907 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10907.pdf for these instructions and other information.
Table: April Updates to the 2019 MPFSD

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<td>G9987</td>
<td>Assistant Surgery, Co-Surgeon, &amp; Team Surgeon indicator = 9</td>
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<td>G2001</td>
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<td>All MPFS indicators and RVUs = 99339</td>
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<tr>
<td>G2015</td>
<td>All MPFS indicators and RVUs = 99340</td>
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</table>

Note: MACs will not search their files to retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims that you bring to their attention.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).
Summary of Policies in the Calendar Year (CY) 2019 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List

MLN Matters Number: MM11063  Related Change Request (CR) Number: 11063
Related CR Release Date: November 30, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4176CP  Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians and other providers who submit claims to Medicare Administrative Contractors (MACs) for services paid under the Medicare Physician Fee Schedule (MPFS) and provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11063 provides a summary of policies in the Calendar Year (CY) 2019 MPFS Final Rule and announces the Telehealth Originating Site Facility Fee payment amount and makes other policy changes related to Medicare Part B payment. These changes are applicable to services furnished in CY 2019. Make sure your billing staffs are aware of these updates.

BACKGROUND

Section 1848(b)(1) of the Social Security Act (the Act) requires the Secretary to establish by regulation a fee schedule of payment amounts for physicians’ services for the subsequent year. The Centers for Medicare & Medicaid Services (CMS) final rule (Regulation number CMS-1693-F) that updates payment policies and Medicare payment rates for services furnished by physicians and Nonphysician Practitioners (NPPs) that are paid under the MPFS in CY 2019 went on display on November 1, 2018. The final rule also addresses public comments on Medicare payment policies proposed earlier this year. The following summarizes the key provisions of this final rule.
Streamlining Evaluation and Management (E/M) Payment and Reducing Clinician Burden

For CY 2019 and CY 2020, CMS will continue the current coding and payment structure for E/M office/outpatient visits and practitioners should continue to use either the 1995 or 1997 E/M documentation guidelines to document E/M office/outpatient visits billed to Medicare. For CY 2019 and beyond, CMS is finalizing the following policies:

- Elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit
- For established patient office/outpatient visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. Practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so.
- CMS is clarifying that for E/M office/outpatient visits, for new and established patients for visits, practitioners need not re-enter in the medical record information on the patient’s chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information.
- Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians.

Beginning in CY 2021, CMS will further reduce burden with the implementation of payment, coding, and other documentation changes. Payment for E/M office/outpatient visits will be simplified and payment would vary primarily based on attributes that do not require separate, complex documentation. Specifically for CY 2021, CMS is finalizing the following policies:

- Reduction in the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients while maintaining the payment rate for E/M office/outpatient visit level 5 in order to better account for the care and needs of complex patients
- Permitting practitioners to choose to document E/M office/outpatient level 2 through 5 visits using Medical Decision Making (MDM) or time instead of applying the current 1995 or 1997 E/M documentation guidelines, or alternatively practitioners could continue using the current framework
- Beginning in CY 2021, for E/M office/outpatient levels 2 through 5 visits, CMS will allow for flexibility in how visit levels are documented—specifically a choice to use the current framework, MDM, or time. For E/M office/outpatient level 2 through 4 visits, when using MDM or current framework to document the visit, CMS will also apply a minimum supporting documentation standard associated with level 2 visits. For these cases, Medicare would require information to support a level 2 E/M office/outpatient visit code for history, exam and/or MDM.
- When time is used to document, practitioners will document the medical necessity of the visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary.
- Implementation of add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care, though they would not be restricted by physician specialty. These codes would only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally would not impose new per-visit documentation requirements.
- Adoption of a new “extended visit” add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient.

CMS believes these policies will allow practitioners greater flexibility to exercise clinical judgment in documentation, so they can focus on what is clinically relevant and medically necessary for the beneficiary. CMS intends to engage in further discussions with the public to potentially further refine the policies for CY 2021.

After consideration of concerns raised by commenters in response to the proposed rule, CMS is not finalizing aspects of the proposal that would have:

1. Reduced payment when E/M office/outpatient visits are furnished on the same day as procedures
2. Established separate coding and payment for podiatric E/M visits
3. Standardized the allocation of practice expense Relative Value Unit (RVUs) for the codes that describe these services

**Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**

CMS is finalizing its proposals to pay separately for two newly defined physicians’ services furnished using communication technology:

- Brief communication technology-based service, for example, virtual check-in (Healthcare Common Procedure Coding System (HCPCS) code G2012)
- Remote evaluation of recorded video and/or images submitted by an established patient (HCPCS code G2010)

CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (Current Procedural Terminology (CPT) codes 99453, 99454, and 99457) and interprofessional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449).

**Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders**

Through an interim final rule with comment period, CMS is implementing a provision from the
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act that removes the originating site geographic requirements and adds the home of an individual as a permissible originating site for telehealth services furnished for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for services furnished on or after July 1, 2019.

**Providing Practice Flexibility for Radiologist Assistants**

CMS is revising the physician supervision requirements so that diagnostic tests performed by a Radiologist Assistant (RA) that meets certain requirements, that would otherwise require a personal level of physician supervision as specified in its regulations, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

**Discontinue Functional Status Reporting Requirements for Outpatient Therapy**

CMS is finalizing its proposal to discontinue the functional status reporting requirements for services furnished on or after January 1, 2019.

**Outpatient Physical Therapy and Occupational Therapy Services Furnished by Therapy Assistants**

The Bipartisan Budget Act of 2018 requires payment for services furnished in whole or in part by a therapy assistant at 85 percent of the applicable Part B payment amount for the service effective January 1, 2022. In order to implement this payment reduction, the law requires CMS to establish a new modifier by January 1, 2019, and CMS to detail its plans to accomplish this in the final rule.

CMS is finalizing its proposal to establish two new modifiers – one for Physical Therapy Assistants (PTA) and another for Occupational Therapy Assistants (OTA) – when services are furnished in whole or in part by a PTA or OTA. However, CMS is finalizing the new modifiers as “payment” rather than as “therapy” modifiers, based on comments from stakeholders. These will be used alongside of the current PT and OT modifiers, instead of replacing them, which retains the use of the three existing therapy modifiers to report all PT, OT, and Speech Language Pathology (SLP) services, that have been used since 1998 to track outpatient therapy services that were subject to the therapy caps.

CMS is also finalizing a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, instead of the proposed definition that applied when a PTA or OTA furnished any minute of a therapeutic service. The new therapy modifiers for services furnished by PTAs and OTAs are not required on claims until January 1, 2020.

**Practice Expense (PE): Market-Based Supply and Equipment Pricing Update**

CMS is finalizing the proposal to adopt updated direct PE input prices for supplies and
equipment. While CMS is adopting most of the prices for supplies and equipment as recommended by the contractor and included in the proposed rule, in the case of particular items, CMS is finalizing refinements to the proposed prices based on feedback from commenters. CMS is also finalizing its proposal to phase-in use of these new prices over a 4-year period beginning in CY 2019 to ensure a smooth transition.

**Payment Rates for Non-excepted Off-campus Provider-Based Hospital Departments Paid Under the PFS**

Section 603 of the Bipartisan Budget Act of 2015 requires that certain items and services furnished by certain off-campus hospital outpatient provider-based departments are no longer paid under the Hospital Outpatient Prospective Payment System (OPPS) and are instead paid under the applicable payment system. In CY 2017, CMS finalized the PFS as the applicable payment system for most of these items and services.

Since CY 2017, payment for these items and services furnished in non-excepted off-campus provider-based departments has been made under the PFS using a PFS Relativity Adjuster based on a percentage of the OPPS payment rate. The PFS Relativity Adjuster in CY 2018 is 40 percent, meaning that non-excepted items and services are paid 40 percent of the amount that would have been paid for those services under the OPPS. CMS is finalizing that the PFS Relativity Adjuster remain at 40 percent for CY 2019. CMS believes that this PFS Relativity Adjuster encourages fairer competition between hospitals and physician practices by promoting greater payment alignment between outpatient care settings.

**Medicare Telehealth Services**

For CY 2019, CMS is finalizing its proposals to add HCPCS codes G0513 and G0514 (Prolonged preventive service(s)) to the list of telehealth services.

CMS is also finalizing policies to implement the requirements of the Bipartisan Budget Act of 2018 for telehealth services related to beneficiaries with End-Stage Renal Disease (ESRD) receiving home dialysis and beneficiaries with acute stroke effective January 1, 2019. CMS is finalizing the addition of renal dialysis facilities and the homes of ESRD beneficiaries receiving home dialysis as originating sites, and to not apply originating site geographic requirements for hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, and beneficiary homes, for purposes of furnishing the home dialysis monthly ESRD-related clinical assessments.

CMS is also finalizing policies to add mobile stroke units as originating sites and not to apply originating site type or geographic requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

**Telehealth origination site facility fee payment amount update**

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through
December 31, 2002, at $20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in Section 1842(i)(3) of the Act. The MEI increase for 2019 is 1.5 percent. Therefore, for CY 2019, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge, or $26.15. (The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.)

ADDITIONAL INFORMATION


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DOCUMENT HISTORY

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<td>December 3, 2018</td>
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