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Fall 2018
October – November – December
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- Communiqué newsletters
- Specialty- and service-specific educational articles
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Common Working File (CWF) Provider Queries National Provider Identifier (NPI) and Submitter Identification (ID) Verification

MLN Matters Number: MM10983  Related CR Release Date: November 9, 2018
Related CR Transmittal Number: R2198OTN  Related Change Request (CR) Number: 10983
Effective Date: April 1, 2019 for NPI Verification, July 1, 2019 for Submitter ID Verification
Implementation Date: April 1, 2019 for NPI Verification, July 1, 2019 for Submitter ID Verification

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for Medicare Part A providers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10983 announces that the Common Working File (CWF) will require verification of the National Provider Identifier (NPI) and Submitter Identification (ID) similar to the Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) when Medicare Part A providers request Medicare beneficiary eligibility and entitlement data via the CWF provider inquiry screens. Make sure your billing staffs are aware of this update.

BACKGROUND

Medicare Part A providers, clearinghouses and billing agents can request Part A Medicare beneficiary eligibility information from CWF. There are five Part A eligibility queries available through the CWF.

The Centers for Medicare & Medicaid Services (CMS) is directing CWF to modify each Part A eligibility inquiry and establish verification processes similar to those established in HETS. This change will align the verification process for Part A eligibility data across the CMS systems. Thus, with the implementation of this change request, the CWF host will verify the status of the NPI and the Submitter ID against information provided by the Provider Enrollment, Chain and Ownership System (PECOS) and HETS, respectively.
ADDITIONAL INFORMATION

Currently, Medicare Part A providers have access to Medicare beneficiary eligibility and entitlement data through 1) MACs portals, 2) HETS, and/or 3) CWF provider inquiry screens.

With implementation of CR 10983, Medicare Part A providers must have HETS Submitter ID to access CWF provider inquiry screens. All HETS submitters have HETS Submitter IDs issued and maintained by Medicare Customer Assistance Re: Eligibility (MCARE). However, Medicare Part A providers not having HETS Submitter IDs shall either continue to access MACs portals without any changes or establish a Submitter ID with HETS.


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 Chapter 15, Pub. 100-08, Certification Statement Policies

MLN Matters Number: MM10845 Revised  Related Change Request (CR) Number: 10845
Related CR Release Date: September 5, 2018  Effective Date: October 1, 2018
Related CR Transmittal Number: R824PI  Implementation Date: October 1, 2018

Note: This article was revised on September 5, 2018, to reflect a revised CR10845 issued the same day. The revised CR did not change any substantive information in the article. Within the article, there is a revised transmittal number, CR release date, and Web address for accessing the CR. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians and providers, including Home Health Agencies (HHAs), submitting certain Internet-based applications to Medicare Administrative Contractors (MACs) via the Provider Enrollment Chain and Ownership System (PECOS).

PROVIDER ACTION NEEDED

Change Request (CR) 10845 makes modifications to certain provider enrollment certification statement policies. Specifically, you may upload provider enrollment certification statements using PECOS functionality.

CR10845 makes these modifications via changes to the Medicare Program Integrity Manual, Chapter 15, Section 15.5.14.4. The revised manual section is attached to CR10845. Make sure your billing staff are aware of these changes.

BACKGROUND

PECOS functionality provides an option to upload paper certification statements. CR10845 aligns the provider enrollment certification statement policy with this PECOS functionality.

CR10845 and the accompanying revised portion of the manual requires your MACs to:
- Accept all handwritten signatures for paper forms CMS-855, CMS-20134, CMS-460 and CMS-588 application submissions
- Accept e-signed or uploaded signatures for web-based application submissions. MACs will no longer accept paper certification statements for web-based application submissions (CMS-855 and CMS-20134 only) via mail. If the provider chooses to
submit its certification statement via paper rather than through e-signature, it shall do so via PECOS upload functionality

- Not accept stamped signatures
- Accept uploaded, faxed and emailed paper certification statements in response to a development request.
- Begin processing ALL applications upon receipt and shall develop for missing certification statements and all other missing information, including application fee, upon review
- Consider the web-based application date of receipt as the date of the web-based application submission

Note: There is no legislative or regulatory impact associated with CR10845.

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 Medicare Deductible, Coinsurance and Premium Rates for 2019

MLN Matters Number: MM11025
Related Change Request (CR) Number: CR 11025
Related CR Release Date: November 2, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R119GI
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice MACs and Durable Medical Equipment MACs for services to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11025 provides instruction for MACs to update the claims processing system with the new Calendar Year (CY) 2019 Medicare deductible, coinsurance, and premium rates. Make sure your billing staffs are aware of these changes.

BACKGROUND

Beneficiaries who use covered Part A services may be subject to deductible and coinsurance requirements. A beneficiary is responsible for an inpatient hospital deductible amount, which is deducted from the amount payable by the Medicare program to the hospital, for inpatient hospital services furnished in a spell of illness. When a beneficiary receives such services for more than 60 days during a spell of illness, he or she is responsible for a coinsurance amount equal to one-fourth of the inpatient hospital deductible per-day for the 61st - 90th day spent in the hospital.

An individual has 60 lifetime reserve days of coverage, which they may elect to use after the 90th day in a spell of illness. The coinsurance amount for these days is equal to one-half of the inpatient hospital deductible. A beneficiary is responsible for a coinsurance amount equal to one-eighth of the inpatient hospital deductible per day for the 21st through the 100th day of Skilled Nursing Facility (SNF) services furnished during a spell of illness.

Most individuals age 65 and older, and many disabled individuals under age 65, are insured for Health Insurance (HI) (Part A) benefits without a premium payment. The Social Security Act
provides that certain aged and disabled persons who are not insured may voluntarily enroll, but are subject to the payment of a monthly premium. Since 1994, voluntary enrollees may qualify for a reduced premium if they have 30 - 39 quarters of covered employment. When voluntary enrollment takes place more than 12 months after a person’s initial enrollment period, a 10 percent penalty is assessed for 2 years for every year they could have enrolled and failed to enroll in Part A.

Under Part B of the Supplementary Medical Insurance (SMI) program, all enrollees are subject to a monthly premium. Most SMI services are subject to an annual deductible and coinsurance (percent of costs that the enrollee must pay), which are set by statute. When Part B enrollment takes place more than 12 months after a person’s initial enrollment period, there is a permanent 10 percent increase in the premium for each year the beneficiary could have enrolled and failed to enroll.

2019 PART A - HOSPITAL INSURANCE (HI)

- **Part A Deductible**: $1,364.00
- **Part A Coinsurance**
  - $341.00 a day for 61st-90th day
  - $682.00 a day for 91st-150th day (lifetime reserve days)
  - $170.50 a day for 21st-100th day (SNF) coinsurance
- **Base Premium (BP)**: $437.00 a month
- **BP with 10% surcharge**: $480.70 a month
- **BP with 45% reduction**: $240.00 a month (for those who have 30-39 quarters of coverage)
- **BP with 45% reduction and 10% surcharge**: $264.00 a month

2019 PART B - SUPPLEMENTARY MEDICAL INSURANCE (SMI)

- **Standard Premium**: $135.50 a month
- **Deductible**: $185.00 a year
- **Pro Rata Data Amount**:
  - $133.57 1st month
  - $51.43 2nd month
- **Coinsurance**: 20 percent

Note that the Part B premium may vary based on beneficiary income above certain levels. CR11025 has additional information showing Part B premium rates as adjusted for income.

**ADDITIONAL INFORMATION**

and Payment Limitations), Sections 10.3 (Basis for Determining the Part A Coinsurance Amounts), 20.2 (Part B Annual Deductible), and 20.6 (Part B Premium) is attached to that CR.

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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Updating Language to Clarify for Providers Chapter 3, Section 20 and Chapter 5, Section 70 of the Medicare Secondary Payer Manual

MLN Matters Number: MM10863 Related Change Request (CR) Number: CR 10863
Related CR Release Date: August 17, 2018 Effective Date: November 20, 2018
Related CR Transmittal Number: Implementation Date: November 20, 2018
R123MSP

PROVIDER TYPE AFFECTED

This MLN Matters article is intended for provider and hospital-affiliated services billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10863 furnishes providers and hospitals with additional clarification regarding when and where to obtain information from Medicare beneficiaries, or authorized representatives, for inpatient admissions or outpatient encounters. Make your staff aware of this clarification.

BACKGROUND

Prior to submitting a bill to Medicare, you must determine whether Medicare is the primary or secondary payer for each beneficiary’s inpatient admission or outpatient encounter by asking the beneficiary about any other insurance coverage that may be primary to Medicare.

Specifically, Section 1862(b)(6) of the Social Security Act (The Act), (https://www.ssa.gov/OSSHome/ssact/title18/1862.htm, (42 USC 1395y(b)(6)), https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partE-sec1395y.pdf) requires all entities seeking payment for any item or service furnished under Medicare Part B to complete (based on information obtained from the individual to whom the item or service is furnished) that portion of the claim form related to the availability of other health insurance.

Additionally, 42 CFR 489.20(g) (https://www.govregs.com/regulations/expand/title42_chapterIV_part489_subpartB_section489).
20#title42_chapterIV_part489_subpartB_section489.20) requires all providers agree to bill other primary payers before billing Medicare.

CR10863 provides clarification to this process:

1. The Medicare Secondary Payer (MSP) Manual, Chapter 3 (MSP Provider, Physician, and Other Supplier Billing Requirements), Section 20.2.1(Model Admission Questions to Ask Medicare Beneficiaries) provides a model questionnaire listing the type of questions hospitals may use to determine the correct primary payers of claims for all beneficiary services that you furnish. This updated manual is an attachment to CR10863.

2. If you have access to the Common Working File (CWF), your admission staff may ask the beneficiary if any insurance information it contains has changed. If there are no changes to the beneficiary’s insurance, then there is no need to ask the questions. However, if insurance information has changed, you must ask the MSP questions. Further, you need to notate (for auditing purposes) that all the questions were not asked upon admission based on the beneficiary’s statement that their insurance information has not changed. Notations may be cited on the CWF screen print verifying the MSP information in the system is correct or the notations may be attached to the CWF print out. Your MAC may request this notation and confirmation during its hospital review.

3. The HIPAA Eligibility Transaction System (HETS) Health Care Eligibility Benefit Inquiry and Response (270/271) Transaction Set is used to transmit Health Care Eligibility Benefit Inquiries from health care providers, insurers, clearinghouses and other health care adjudication processors. You can use the HETS 270/271 transaction set to make an inquiry about the Medicare eligibility of an individual and to identify insurance that is primary or secondary to Medicare.

Similar to the CWF process, if you have the ability to submit and receive a HETS 270/271 transaction set and, upon review, there are no changes to the beneficiary’s insurance then there is no need to ask the questions. However, if there are changes, you must ask the MSP questions. Further, you need to notate (for auditing purposes) that all the questions were not asked upon admission based on the beneficiary’s statement that their insurance information has not changed as your MAC may request this notation and confirmation during its hospital review. Notations may be cited on the 270/271 screen print verifying the MSP information in the system is correct or the notations may be attached to the HETS 270/271 print out.

4. Some hospitals offer provider-based services, such as a provider affiliated transfer ambulance service. The affiliated hospital-based service does not need to ask the MSP questions if the hospital admission staff has already asked the questions or verified the beneficiary’s insurance information. The admissions staff would then bill the appropriate insurer for the ambulance service.

However, if the ambulance service is not affiliated with the hospital, then the ambulance service is responsible for collecting and/or verifying the correct insurance information prior to billing for services.
ADDITIONAL INFORMATION

The official instruction, CR10863, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R123MSP.pdf. You will find the updated MSP Manual, Chapter 3, Sections 20 and Chapter 5, Section 70 as attachments to this CR.

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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PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice (HH&H) MACs and Durable Medical Equipment (DME) MACs, for services provided to Medicare beneficiaries who are in a Part A covered Skilled Nursing Facility (SNF) stay.

PROVIDER ACTION NEEDED

CR 10981 makes changes to HCPCS codes and Medicare Physician Fee Schedule (MPFS) designations that will be used to revise Common Working File (CWF) edits to allow MACs to make appropriate payments in accordance with policy for SNF CB in Chapter 6, Section 110.4.1 and Chapter 6, Section 20.6 in the Medicare Claims Processing Manual (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c06.pdf). Make sure your billing staff are aware of these changes.

BACKGROUND

The CWF currently has edits in place for claims received for beneficiaries in a Part A covered SNF stay, as well as for beneficiaries in a non-covered stay. These edits allow only those services that are excluded from SNF CB to be paid separately. Barring any delay in the MPFS, Medicare will provide the new code files CWF by November 1, 2018.

By the first week in December 2018, Medicare will post the new code files at https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html. The files will be applicable to claims with dates of service on or after January 1, 2019, through December 31, 2019. It is important and necessary for the provider community to view the “General Explanation of the Major Categories” file located at the bottom of each year’s update in order to understand the Major Categories including additional exclusions not driven by HCPCS codes.
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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Correction to Common Working File (CWF) Informational Unsolicited Response (IUR) 7272 for Intervening Stay

MLN Matters Number: MM10960  Related Change Request (CR) Number: 10960
Related CR Release Date: October 26, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R2174OTN  Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for providers (hospitals and home health agencies) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 10960 informs MACs about the changes to ensure Medicare’s CWF bypasses the IUR 7272 edit when there is an Inpatient Prospective Payment System (IPPS) hospital claim in history with patient discharge status code ‘61’ (Discharged/transferred within this institution to a hospital-based Medicare approved swing bed) and a home health claim is received with an admission date equal to or within 3 days of the history IPPS claim’s discharge date and there is an intervening swing bed claim in history. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) was recently made aware that CWF IUR 7272 is setting on an IPPS hospital claim in history with patient discharge status code ‘61’ (Discharged/transferred within this institution to a hospital-based Medicare approved swing bed) when a home health claim is received with an admission date equal to or within 3 days of the history IPPS claim’s discharge date and there is an intervening swing bed claim in history. This CR ensures CWF bypasses IUR 7272 for this scenario.

CR 10960 contains no new policy and the CR applies to all dates of service processed on or after the implementation date of April 1, 2019.
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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Ensuring Occurrence Code 22 is Billed Correctly on Skilled Nursing Facility Inpatient Claims

MLN Matters Number: MM10922  Related Change Request (CR) Number: 10922
Related CR Release Date: October 5, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R2146OTN  Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

This article is based on Change Request (CR) 10922 which describes systems changes necessary to ensure SNFs bill Occurrence Code (OC) 22 correctly. Please make sure your billing staffs are aware of these changes.

BACKGROUND

Medicare’s Common Working File (CWF) Maintainer recently discovered that an incoming inpatient claim was applied to the wrong benefit period when OC ‘22’ was submitted incorrectly on a SNF claim in history.

CR10922 will ensure OC ‘22’ is billed correctly so that the CWF can apply the appropriate benefit period.

Note that CR10922 contains no policy changes or new policies, and it improves the implementation of the existing policy in the Medicare Claims Processing Manual, Chapter 6 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf). As a result of CR10922, your MAC will Return to Provider (RTP) an inpatient SNF claim (Type of Bill (TOB) 21X or swing bed claim with TOB 18X) when all of the following are present on the claim:

- OC ‘22’ and
- OC ‘22’ date is equal to the through date of the claim and
- Patient discharge status code is other than ‘30’. 
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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Healthcare Provider Taxonomy Codes (HPTCs) October 2018 Code Set Update

MLN Matters Number: MM10857 Related Change Request (CR) Number: 10857
Related CR Release Date: August 24, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4116CP Implementation Date: No later than January 7, 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) 10857 directs MACs to obtain the most recent Healthcare Provider Taxonomy Codes (HPTCs) code set and use it to update their internal HPTC tables and/or reference files. Make sure your billing staffs are aware of these updates.

BACKGROUND

The HPTC set is maintained by the National Uniform Claim Committee (NUCC) for standardized classification of health care providers. The NUCC updates the code set twice per year with changes effective April 1 and October 1. The HPTC list is available for view or for download at www.nucc.org/index.php/code-sets-mainmenu-41/provider-taxonomy-mainmenu-40.

The Health Insurance Portability and Accountability Act (HIPAA) requires that covered entities comply with the requirements in the electronic transaction format implementation guides adopted as national standards. Institutional and professional claim electronic standard implementation guides (X12 837-I and 837-P) each require use of valid codes contained in the HPTC set when there is a need to report provider type or physician, practitioner, or supplier specialty for a claim.

You should note that:

1. Valid HPTCs are those codes approved by the NUCC for current use.
2. Terminated codes are not approved for use after a specific date.
3. Newly approved codes are not approved for use prior to the effective date of the code set update in which each new code first appears.
4. Specialty and/or provider type codes issued by any entity other than the NUCC are not valid.
5. Medicare would be guilty of non-compliance with HIPAA if MACs accepted claims that contain invalid HPTCs.

Although the NUCC generally posts their updates on the Washington Publishing Company (WPC) website 3 months prior to the effective date, changes are not effective until April 1 or October 1 as indicated in each update. The changes to the code set include the addition of a new code and addition of definitions to existing codes. When reviewing the Health Care Provider Taxonomy code set online, revisions made since the last release are identified.

**Note:** MACs having the capability to do so will update the HPTC table, such that claims received on and after October 1, 2018, will be validated against the October 1, 2018, HPTC set. MACs lacking the capability to implement the updated October 2018 HPTC set, for claims received on or after October 1, 2018, will implement the October 2018 HPTC update as soon as possible after October 1, 2018, but no later than January 7, 2019.

**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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Hospital and Critical Access Hospital (CAH) Swing-Bed Manual Revisions

MLN Matters Number: MM10962  Related Change Request (CR) Number: 10962
Related CR Release Date: November 2, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R4157CP  Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for hospitals, including Critical Access Hospitals (CAHs), billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 10962 clarifies policies related to hospitals and CAHs with respect to services furnished to swing-bed patients, including policies related to pass-through reimbursement for Certified Registered Nurse Anesthetist (CRNA) services. Make sure your billing staffs are aware of these changes.

BACKGROUND

CAH swing-bed services are not subject to the Skilled Nursing Facility (SNF) prospective payment system. Instead, CAHs are paid based on 101 percent of reasonable cost for swing-bed services. As is the case with CAH inpatient services, CAH swing-bed services are subject to the hospital bundling requirements at section 1862(a)(14) of the Social Security Act and in the regulations at 42 CFR § 411.15(m). Therefore, because CAH swing-bed services are subject to the hospital bundling requirements, the Centers for Medicare & Medicaid Services (CMS) is clarifying that nonprofessional services provided to a CAH swing-bed patient must be included on the CAH’s swing-bed bill.

In addition, CRNA pass-through payments (42 CFR § 412.113 (c)) provide qualifying hospitals and CAHs with reasonable cost-based payments for CRNA services. CMS is clarifying that qualifying hospitals and CAHs are eligible to receive pass-through payments for CRNA services provided to hospital and CAH swing-bed patients since these patients are considered inpatients for Medicare payment purposes. CRNA pass-through services provided to swing-bed patients must be included on the hospital’s or CAH’s swing-bed bill.
As a result of CR 10962:

- MACs will allow CAHs to bill for: (1) bed and board; (2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and (3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements; which are rendered in a CAH swing-bed on Type of bill (TOB) 18x where the Provider number range begins with Z300 through Z399.

- MACs will allow for services rendered by a CRNA in a CAH swing-bed, where the CAH has CRNA pass-through using TOB 18x; Revenue Code (REV) 0964 professional service; REV: 037x technical; and a Provider Number range beginning with Z300 through Z399.

- MACs will allow for services rendered by a CRNA in a hospital swing-bed, where the short-term acute care hospital has CRNA pass-through, using TOB 18x; REV 0964 professional service; REV: 037x technical; and a Provider Number range beginning with U001 through U879.

ADDITIONAL INFORMATION

The official instruction, CR 10962, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4157CP.pdf. CR 10962 updates Chapters 3, 4, and 6 of the Medicare Claims Processing Manual. These updated chapters are attached to the CR.

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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Implementation of Healthcare Common Procedure Coding System (HCPCS) Code J3591 and Additional Changes for End Stage Renal Disease (ESRD) Claims

MLN Matters Number: MM10851
Related Change Request (CR) Number: 10851
Related CR Release Date: November 2, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R2192OTN
Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for End-Stage Renal Disease (ESRD) facilities that submit claims to Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

The purpose of Change Request (CR) 10851 is to implement a new unclassified drug or biological for End Stage Renal Disease (ESRD) and to make additional changes for the 72X Type of Bill (TOB). Make sure your billing staffs are aware of these changes.

BACKGROUND

The Medicare Improvements for Patients and Providers Act (MIPPA; Section 153(b); https://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf) required the implementation of an End Stage Renal Disease Prospective Payment System (ESRD PPS), effective January 1, 2011. The ESRD PPS provides a per treatment payment amount to ESRD facilities that covers all of the resources used in furnishing an outpatient dialysis treatment.

CR7064 implemented the ESRD PPS (Transmittal 2134; see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7064.pdf) entitled End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services.

The ESRD PPS provides outlier payments, if applicable, for high cost patients due to unusual variations in the type or amount of medically necessary care. Medicare regulations at 42 CFR §413.237(a)(1)(i) (https://www.gpo.gov/fdsys/pkg/CFR-2012-title42-vol2/pdf/CFR-2012-title42-vol2-sec413-237.pdf) provide that ESRD PPS outlier services are those ESRD-related services
that were or would have been considered separately billable under Medicare Part B or would have been separately payable drugs under Medicare Part D (excluding renal dialysis oral-only drugs), for renal dialysis services furnished prior to January 1, 2011. Information regarding the ESRD PPS outlier policy is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html.

Under the ESRD PPS drug designation process, the Centers for Medicare & Medicaid Services (CMS) provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new renal dialysis drugs and biologicals that qualify under 42 CFR 413.234(c) (https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol2/pdf/CFR-2016-title42-vol2-sec413-234- .pdf). While these drugs are eligible for the TDAPA, they do not qualify toward outlier calculation. Until January 1, 2019, calcimimetics were the only drugs that qualify for payment using the TDAPA. CR10065 (Transmittal 1999; see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLNMattersArticles/Downloads/MM10065.pdf) entitled Implementation of the Transitional Drug Add-On Payment Adjustment implemented TDAPA, and information regarding TDAPA is available https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html.

New United States Food and Drug Administration approved renal dialysis drugs and biologicals can come to market at any point of the year, and the Healthcare Common Procedure Coding System (HCPCS) process has an annual release schedule. There is often a timeframe wherein a drug manufacturer has submitted a HCPCS application yet still awaiting a permanent code to be used by providers for billing Medicare. New drugs and biologicals could potentially be eligible for TDAPA, and this policy could also be applicable for outlier eligible services. CMS provides more information regarding the HCPCS process at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html.

In order to accurately capture all treatments provided to a beneficiary, CMS implemented the CG modifier in CR9989 (see related article at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLNMattersArticles/downloads/MM9989.pdf). Modifier CG – Policy Criteria Applied for the 72x type of bill is used to identify dialysis treatments (CPT 90999) in excess of 13 or 14 per month that do not meet medical justification requirements as defined by the MACs.

Effective January 1, 2019, for new renal dialysis drugs and biologicals that are eligible for outlier or TDAPA, CMS is implementing the following new HCPCS code:

- J3591 - Unclassified drug or biological (for ESRD on dialysis)

End Stage Renal Disease Prospective Payment System (ESRD PPS) Outlier Policy

For new injectable renal dialysis drugs and biologicals that are eligible outlier services, ESRD facilities should report J3591 with the National Drug Code (NDC) in the 11-digit format 5-4-2. The Medicare claims processing system will flag the code for manual pricing by the MAC. The MAC will set the payment rate based on pricing methodologies under 1847A of the Social Security Act using guidance in the Medicare Claims Processing Manual, Chapter 17, Section
20.1.3. The final pricing information will be passed to value code 79 to be included in the outlier calculation. Oral equivalent renal dialysis drugs and biologicals that are eligible outlier services will follow the existing processes.

CMS will issue guidance to advise when to use the code for an outlier drug.

**Acute Kidney Injury (AKI) Claims**

Outlier payment eligibility are payment policies under the ESRD PPS that are only applicable to ESRD beneficiaries. Therefore, J3591 is not billable on an AKI claim.

J3591 is used to facilitate potential outlier payment or the TDAPA to ESRD facilities when a new renal dialysis service is available but before it has been assigned its own HCPCS code (if applicable). The outlier and TDAPA policies are for renal dialysis services (drugs and biologicals used for the treatment of ESRD) only.

Since ESRD facilities use the AY modifier when an item or service is furnished for reasons other than the treatment of ESRD to facilitate separate payment under Medicare Part B, ESRD facilities should not receive separate payment for J3591 either with or without the AY modifier and the MACs shall process the line item as covered with no separate payment under the ESRD PPS.

**Calculation of the Transitional Drug Add-on Payment Adjustment (TDAPA) and Outlier**

Dialysis treatments reported with the CG modifier and non-covered dialysis treatments should not be used for purposes of the TDAPA or outlier calculations. For purposes of the number of dialysis treatments for the month used in the TDAPA and outlier calculations, MACs should only consider those treatments that are reported and covered. MACs should mass adjust outlier claims reported with the CG modifier beginning with dates of service October 1, 2017. MACs should also mass adjust TDAPA claims reported with the CG modifier beginning with dates of service January 1, 2018 to ensure appropriate Medicare payment.

**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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Incomplete Colonoscopies Billed with Modifier 53 for Critical Access Hospital (CAH) Method II Providers

MLN Matters Number: MM10937  Related Change Request (CR) Number: 10937
Related CR Release Date: October 26, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R4153CP  Implementation Date: April 1, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Critical Access Hospital (CAH) Method II providers submitting claims to Medicare Administrative Contractors (MACs) for colonoscopy services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10937 implements the payment methodology for incomplete colonoscopy procedures (Healthcare Common Procedure Coding System (HCPCS) codes 44388, 45378, G0105, and G0121 with a modifier 53) for CAH Method II providers. Please make sure your billing staffs are aware of these changes.

BACKGROUND

Physicians and non-physician practitioners billing on Type of Bill (TOB) 85X for professional services rendered in a Method II CAH have the option of reassigning their billing rights to the CAH. When the billing rights are reassigned to the Method II CAH, payment is made to the CAH for professional services (revenue code (REV) 96X, 97X, or 98X) based on the Medicare Physician Fee Schedule (MPFS) supplemental file.

According to Current Procedural Terminology (CPT) instruction, prior to Calendar Year (CY) 2015, an incomplete colonoscopy was defined as a colonoscopy that did not evaluate the colon past the splenic flexure (the distal third of the colon). Physicians were previously instructed to report an incomplete colonoscopy with 45378 and append modifier 53 (discontinued procedure), which is paid at the same rate as a sigmoidoscopy.

In CY 2015, the CPT instruction changed the definition of an incomplete colonoscopy to a colonoscopy that does not evaluate the entire colon. The 2015 CPT Manual states,

“When performing a diagnostic or screening endoscopic procedure on a patient who is scheduled and prepared for a total colonoscopy, if the physician is unable to advance the..."
colonoscope to the cecum or colon-small intestine anastomosis due to unforeseen circumstances, report 45378 (colonoscopy) or 44388 (colonoscopy through stoma) with modifier 53 and provide appropriate documentation.”

Therefore, in accordance with the change in CPT Manual language, the Centers for Medicare & Medicaid Services (CMS) has applied specific values in the Medicare physician fee schedule for the following codes:

- 44388-53, [44388 (colonoscopy through stoma) with modifier 53]
- 45378-53, [45378 (colonoscopy) with modifier 53]
- G0105-53, [G0105 (colorectal cancer screening, colonoscopy on individual at high risk) with modifier 53] and
- G0121-53 [G0121 (colorectal cancer screening, colonoscopy on individual not meeting criteria for high risk) with modifier 53]

Effective for services performed on or after April 1, 2019, the MPFS database will have specific values for the codes listed above. Given that the new CPT definition of an incomplete colonoscopy also includes colonoscopies where the colonoscope is advanced past the splenic flexure but not to the cecum, CMS has established new values for incomplete diagnostic and screening colonoscopies performed on or after January 1, 2016. Incomplete colonoscopies are reported with the 53 modifier. Medicare will pay for the interrupted colonoscopy at a rate that is calculated using one-half the value of the inputs for the codes.

In situations where a CAH has elected payment Method II for CAH patients, payment will be consistent with payment methodologies currently in place as outlined in the Medicare Claims Processing Manual (Publication 100-04, Chapter 12, Section 30.1 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf), and Chapter 18, Section 60.2 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c18.pdf).

As such, CAHs that elect Method II payment must use modifier “53” to identify an incomplete screening colonoscopy (physician professional service(s) billed in revenue code 096X, 097X, and/or 098X.

Such CAHs will also bill the technical or facility component of the interrupted colonoscopy in revenue code 075X (or other appropriate revenue code) using the “-73” or “-74” modifier as appropriate.

When MACs apply the adjusted payment for incomplete colonoscopies, they will return the following remittance codes:

- Claim Adjustment Reason Code 59 - Processed based on multiple or concurrent procedure rules. (For example, multiple surgery or diagnostic imaging, concurrent anesthesia.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present
- Group code “CO” - contractual obligation
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>October 26, 2018</td>
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Next Generation Accountable Care Organization (NGACO) Model Post Discharge Home Visit HCPCS

MLN Matters Number: MM10907 Related Change Request (CR) Number: 10907
Related CR Release Date: October 26, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R213DEMO Implementation Date: April 1, 2019

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 CR1907. 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: G0064; G0065; G0066; G0067; G0068; G0069; G0070; G0071; G0072; G0073; G0074; and G0075. 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).
DOCUMENT HISTORY

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<td>October 29, 2018</td>
<td>Initial article released.</td>
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October 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.3

MLN Matters Number: MM10900 Related Change Request (CR) Number: 10900
Related CR Release Date: August 24, 2018 Effective Date: October 1, 2018
Related CR Transmittal Number: R4122CP Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for providers and suppliers billing Medicare Administrative Contractors (MACs), including the Home Health and Hospice MACs, for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10900 informs MACs about the changes to the Integrated Outpatient Code Editor (I/OCE) instructions and specifications for the Integrated OCE that will be utilized under the Outpatient Prospective Payment System (OPPS) and non-OPPS for hospital outpatient departments, community mental health centers, all non-OPPS providers, and for limited services when provided in a home health agency not under the Home Health Prospective Payment System or to a hospice patient for the treatment of a non-terminal illness. Make sure your billing staffs are aware of these changes.

BACKGROUND

CR10900 informs the A/B MACs, RHHIs, and the Fiscal Intermediary Shared System (FISS) that the I/OCE is being updated for October 1, 2018. The I/OCE routes all institutional outpatient claims (which includes non-OPPS hospital claims) through a single integrated OCE.

The modifications of the IOCE for the October 2018 V19.3 release are summarized in the table below. Readers should also read through the entire specifications document and note the highlighted sections, which should also indicate changes from the prior release of the software. Some I/OCE modifications in the update may be retroactively added to prior releases. If so, the retroactive date appears in the 'Effective Date' column. The I/OCE specifications will be posted at http://www.cms.gov/OutpatientCodeEdit/.
<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Edits Affected</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/1/2018</td>
<td>1, 2, 3, 5, 86</td>
<td>Updated diagnosis code editing for validity, age, gender and manifestation based on the FY 2019 ICD-10-CM code revisions to the Medicare Code Editor (MCE).</td>
</tr>
<tr>
<td>10/1/2018</td>
<td>29</td>
<td>Updated the mental health diagnosis list based on the FY 2019 ICD-10-CM code revisions.</td>
</tr>
<tr>
<td>4/1/2018</td>
<td>106, 107, 108</td>
<td>Update Critical Care exception under Add-on Code Editing to only be applicable to bill type 85x submitting professional services with revenue codes 96x, 97x, and 98x.</td>
</tr>
<tr>
<td>4/1/2018</td>
<td>107</td>
<td>Update the logic for Add-on Code Edit 107 to be applied only for claims with bill type 85x (Critical Access Hospital (CAH)) and only for professional services reported with revenue codes 96x, 97x and 98x. See also the Edits Applied by Bill Type tables.</td>
</tr>
<tr>
<td>4/1/2018</td>
<td>106, 107, 108</td>
<td>Update logic for Add-on Code Editing to implement the edit processing at the claim level rather than line level (line item date of service (LIDOS)). Exception: Claims with 85x bill type reporting professional services with revenue codes 96x, 97x, and 98x continue to process add-on edits at the day level (LIDOS).</td>
</tr>
<tr>
<td>1/1/2012</td>
<td>20, 40</td>
<td>Update logic for NCCI Editing to not apply edits 20 or 40 across professional revenue codes (96x, 97x, or 98x) and facility revenue codes submitted on an 85x bill type for CAH. (Note: This change will be made retroactively to both edits inception)</td>
</tr>
<tr>
<td>10/1/2018</td>
<td></td>
<td>Update Add-on Code Editing section to include additional conditions for editing.</td>
</tr>
<tr>
<td>Effective Date</td>
<td>Edits Affected</td>
<td>Modification</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>10/1/2018</td>
<td></td>
<td>Update Partial Hospitalization section to note that PHP/DMH processing logic does not occur if there is an inpatient only procedure on the same claim. This is already existing logic that just needed to be documented within the respective processing section.</td>
</tr>
<tr>
<td>10/1/2018</td>
<td></td>
<td>Update National Correct Coding Initiative (NCCI) section to include the new condition for editing for Critical Access Hospitals (85x) submitting both professional and facility services on the same day/claim.</td>
</tr>
<tr>
<td>10/1/2018</td>
<td></td>
<td>Update the following lists for the release (see quarterly data files):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Add on Type I (edit 106) Add on Type III (edit 108)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Comprehensive Ambulatory Payment Classification (APC) list</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Device Procedure list (edit 92)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Terminated device procedures for offset</td>
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<tr>
<td></td>
<td></td>
<td>- Pass-through radiopharmaceutical HCPCS for offset APC (edit 99)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pass-through skin substitute product HCPCS (edit 99)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Pass-through contrast HCPCS for offset APC (edit 99)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Radiological HCPCS reported with FX or FY modifier</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Skin Substitute Product (edit 87)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Edit 99 Exclusion (edit 99)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Contrast HCPCS</td>
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<tr>
<td>10/1/2018</td>
<td></td>
<td>Make all HCPCS/APC/SI changes as specified by CMS (quarterly data files).</td>
</tr>
<tr>
<td>10/1/2018</td>
<td>20, 40</td>
<td>Implement version 24.3 of the NCCI (as modified for applicable outpatient institutional providers).</td>
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ADDITIONAL INFORMATION


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October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)

MLN Matters Number: MM10923
Related CR Number: 10923
MLN Matters Number: MM10923
Related CR Release Date: August 24, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R4123CP
Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR10923 describes changes to and billing instructions for various payment policies implemented in the October 2018 Outpatient Prospective Payment System (OPPS) update. The October 2018 Integrated Outpatient Code Editor (I/OCE) will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR10923. Make sure your billing staffs are aware of these updates.

BACKGROUND

CR 10923 informs you of the following changes to billing instructions for various payment policies implemented in the October 2018 OPPS update.

Key changes are as follows:

1. **New Separately Payable Procedure Code**

   Effective October 1, 2018, HCPCS code C9750 is created, as described in Table 1, and assigned to APC 5223 (Level 3 Pacemaker and Similar Procedures) with a payment rate of $9,747.99. This procedure was previously described by Category III Current Procedural Terminology (CPT) code 0302T, which was deleted December 31, 2017.
Table 1 — New Separately Payable Procedure Code, Effective October 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
<th>Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9750</td>
<td>Ins/rem-replace compl iims</td>
<td>Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation and peri-operative interrogation and programming; complete system (includes device and electrode)</td>
<td>J1</td>
<td>5223</td>
<td>$9,747.99</td>
</tr>
</tbody>
</table>

2. Drugs, Biologicals, and Radiopharmaceuticals

a. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2018

For Calendar (CY) 2018, payment for separately payable, non-pass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP - 22.5 percent if acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2018, a single payment of ASP + 6 percent 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. Updated payment rates effective October 1, 2018, and drug price restatements are in the October 2018 update of the OPPS Addendum A and Addendum B on the Centers for Medicare & Medicaid Services (CMS) website at http://www.cms.gov/HospitalOutpatientPPS/.

b. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Some drugs and biologicals based on ASP methodology will 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 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html.

c. Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2018

Eight drugs and biologicals have been granted OPPS pass-through status, effective October 1, 2018. These drugs and biologicals are described in Section 2b and 2c of this article and are in Tables 2 and 3.

Four drugs and biologicals have been granted new OPPS pass-through status, effective October 1, 2018. CMS received a completed pass-through application for these drugs, which
passed both the newness and cost criteria to receive pass-through payment. These items, along with their descriptors and APC assignments, are identified in Table 2.

Providers may resubmit claims that were impacted by adjustments to previous quarter’s payment files.

### Table 2 – Drugs and Biologicals with OPPS Pass-Through Status Effective October 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9033</td>
<td>Injection, fosnetupitant 235 mg and palonosetron 0.25 mg</td>
<td>G</td>
<td>9099</td>
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<tr>
<td>C9034</td>
<td>Injection, dexamethasone 9%, intraocular, 1 mcg</td>
<td>G</td>
<td>9172</td>
</tr>
<tr>
<td>Q5105</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units</td>
<td>G</td>
<td>9096</td>
</tr>
<tr>
<td>Q5106</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units</td>
<td>G</td>
<td>9097</td>
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### Table 3 – Drugs and Biologicals Receiving Pass-Through Status in Accordance with Public Law 115-141 Effective October 1, 2018

<table>
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<th>HCPCS Code</th>
<th>Long Descriptor</th>
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<th>APC</th>
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<tr>
<td>A9586</td>
<td>Florbetapir f18, diagnostic, per study dose, up to 10 millicuries</td>
<td>G</td>
<td>9084</td>
</tr>
<tr>
<td>C9447</td>
<td>Injection, phenylephrine and ketorolac, 4 ml vial</td>
<td>G</td>
<td>9083</td>
</tr>
<tr>
<td>Q4172</td>
<td>PuraPly, and PuraPly Antimicrobial, any type, per square centimeter</td>
<td>G</td>
<td>9082</td>
</tr>
<tr>
<td>Q9950</td>
<td>Injection, sulfur hexafluoride lipid microsphere, per ml</td>
<td>G</td>
<td>9085</td>
</tr>
</tbody>
</table>

d. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Public Law 115-141)

Section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115-141) amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(G), which provides that, for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017, and for which payment was packaged into a covered hospital outpatient
service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018, through September 30, 2020. There are four products whose period of drug and biological pass-through payment status ended on December 31, 2017; these four drugs and biologicals will have pass-through status reinstated effective October 1, 2018. These products are listed in Table 3.

Beginning in CY 2019, CMS proposed to continue pass-through payment status for these drugs and biologicals (83 FR 37114).

Section 1301(a)(1) of Pub. L. 115-141 also added a new subparagraph (H) to section 1833(t)(6) to the Act, which provides for a temporary payment rule for drugs and biologicals whose period of pass-through payment ended on December 31, 2017. Under this provision, the payment amount for such drugs or biologicals furnished during the period beginning on October 1, 2018 and ending on March 31, 2019, shall be the greater of the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological or the payment amount that applied under subparagraph (D)(i) for such drug or biological on December 31, 2017. In addition, section 1301(a)(1) of Pub. L. 115-141 added a new subparagraph (I) to section 1833(t)(6) to require that, for any drug or biological whose period of pass-through payment ended on December 31, 2017, and for which payment under this subsection is packaged into a payment amount for a covered hospital Outpatient Department (OPD) service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018, the Secretary shall remove the packaged costs of such drug or biological from the payment amount for the covered OPD service with which it is packaged. Finally, section 1301(a)(3) of Pub. L. 115-141 permits the Secretary to implement the amendments made by section 1301(a)(1) and (2) by program instruction or otherwise. CR10923 implements the requirement in section 1833(t)(6)(I)(i) to remove the packaged costs of the drugs or biologicals listed in Table 3 from the payment amounts for the covered OPD services (or groups of services) with which they are packaged.

As explained above, these drugs and biologicals will be receiving separate payment under the OPPS instead of having their costs packaged into the payment amount for associated procedures for the period beginning October 1, 2018 through December 31, 2018. Therefore, CMS updated the CY 2018 payment rates to reflect the separate payment for the drugs and biologicals listed in Table 3 and found the payment rates for the 10 APCs listed in Table 4 were affected by the separate payment for these drugs and biologicals, and therefore, CMS removed the costs of the drugs and biologicals from the payment amounts for these APCs. The updated payment rates for these APCs, which are effective October 1, 2018 through December 31, 2018, are in the October 2018 update of the OPPS Addendum A and Addendum B at http://www.cms.gov/HospitalOutpatientPPS/.
Table 4 – APCs with New Payment Rates because of the Separate Payment for Certain Drugs and Biologicals Receiving Pass-Through Status in Accordance with Public Law 115-141 Effective October 1, 2018, through December 31, 2018

<table>
<thead>
<tr>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 5 Intraocular Procedures</td>
<td>J1</td>
<td>5495</td>
</tr>
<tr>
<td>Level 1 Intraocular Procedures</td>
<td>J1</td>
<td>5491</td>
</tr>
<tr>
<td>Level 3 Imaging with Contrast</td>
<td>S</td>
<td>5573</td>
</tr>
<tr>
<td>Level 4 Nuclear Medicine and Related Services</td>
<td>S</td>
<td>5594</td>
</tr>
<tr>
<td>Level 3 Intraocular Procedures</td>
<td>J1</td>
<td>5493</td>
</tr>
<tr>
<td>Level 2 Intraocular Procedures</td>
<td>J1</td>
<td>5492</td>
</tr>
<tr>
<td>Level 3 ENT Procedures</td>
<td>T</td>
<td>5163</td>
</tr>
<tr>
<td>Level 2 Imaging with Contrast</td>
<td>S</td>
<td>5572</td>
</tr>
<tr>
<td>Pulmonary Treatment</td>
<td>S</td>
<td>5791</td>
</tr>
<tr>
<td>Level 4 Extraocular, Repair, and Plastic Eye Procedures</td>
<td>J1</td>
<td>5504</td>
</tr>
</tbody>
</table>

e. New Biosimilar HCPCS Code

HCPCS code Q5108, listed in table 5, is a biosimilar with the trade name Fulphila that will be paid separately in the OPPS. The code will be included in the OPPS with an effective date retroactive to July 12, 2018, per CR10834, which states that HCPCS code is payable for Medicare for claims with a date of service on or after July 12, 2018.

Table 5 — New Biosimilar HCPCS Code Effective July 12, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5108</td>
<td>Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg</td>
<td>K</td>
<td>9173</td>
<td>07/12/2018</td>
</tr>
</tbody>
</table>
3. Reassignment of Skin Substitute Product from the Low-Cost Group to the High-Cost Group

One skin substitute product, HCPCS code Q4181, is reassigned from the low-cost skin substitute group to the high-cost skin substitute group based on updated pricing information. The product is listed in Table 6.

**Table 6 – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective October 1, 2018**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>SI</th>
<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4181</td>
<td>Amnio wound, per square cm</td>
<td>N</td>
<td>High</td>
</tr>
</tbody>
</table>

4. Changes to OPPS Pricer Logic

   a. New OPPS payment rates and copayment amounts will be effective October 1, 2018. All copayment amounts will be limited to a maximum of 40 percent of the APC payment rate. Copayment amounts for each service cannot exceed the CY 2018 inpatient deductible of $1,340. For most OPPS services, copayments are set at 20 percent of the APC payment rate.

   b. Effective October 1, 2018, there will be one contrast agent, Q9950, receiving pass-through payment in the OPPS Pricer logic. For APCs containing nuclear medicine procedures, the I/OCE will send the off-set amount of the pass-through for the contrast agent, then Pricer will reduce the amount of the pass-through contrast agent payment by the wage-adjusted offset for the APC with the highest offset amount when the contrast agent with pass-through appears on a claim with a nuclear procedure. The offset will cease to apply when the contrast agent expires from pass-through status. The offset amounts for diagnostic radiopharmaceuticals are the “policy-packaged” portions of the CY 2018 APC payments for nuclear medicine procedures and are on the CMS website at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html).

5. Coverage Determinations

As a reminder, the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS 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.

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Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes – October 2018 Update

MLN Matters Number: MM10834 Revised Related Change Request (CR) Number: 10834
Related CR Release Date: September 13, 2018 Effective Date: July 12, 2018, for Q5108; October 1, 2018, for Q5110
Related CR Transmittal Number: R4134CP Implementation Date: October 1, 2018

Note: This article was revised on September 20, 2018, to delete the note that stated MACs should hold claims for Q5108 and Q5110 until CR10834 is implemented, since that is no longer a requirement. 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

The HCPCS code set is updated on a quarterly basis. CR 10834 informs MACs of the October 2018 addition of new HCPCS codes, Q5108 and Q5110. The codes are payable by Medicare effective with dates of service on or after July 12, 2018, for Q5108 and effective with dates of service on or after October 1, 2018, for Q5110.

The short descriptor for Q5108 is Injection, fulphila, and the long descriptor is Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg. The Type of Service (TOS) Codes for Q5108 are 1, P.

The short descriptor for Q5110 is Nivestym, and the long descriptor is Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram. The TOS Codes for Q5110 are 1, P. The Medicare Physician Fee Schedule Database (MPFSDB) Status Indicator for both codes is E.

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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<td>This article was revised on September 13, 2018, due to a revised CR 10834 that added a new HCPCS code, Q5110 (Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram). The CR release date, transmittal number and link to the transmittal also changed.</td>
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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 5, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4127CP
Implementation Date: January 7, 2019

Note: This article was revised on September 6, 2018 to reflect the revised CR10871 issued on September 5. 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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Revision of SNF CB Edits for Ambulance Services Rendered to Beneficiaries in a Part A Skilled Nursing Facility Stay

MLN Matters Number: MM10955
Related Change Request (CR) Number: 10955
Related CR Release Date: November 2, 2018
Effective Date: April 1, 2019
Related CR Transmittal Number: R2176OTN
Implementation Date: April 1, 2019

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10955 revises the SNF Consolidated Billing (CB) edits to ensure accurate payment of ambulance services rendered to beneficiaries in a covered Part A SNF stay. CR10955 does not contain any new policy and only further revises existing claim system edits to ensure accurate payment of ambulance transports that are included in or excluded from SNF CB. Make sure your billing staffs are aware of these revisions.

BACKGROUND

CR6700 (Transmittal 595, issued Nov. 6, 2009) implemented certain claim system edits intended to deny claims for Part B ambulance services that should be bundled under SNF CB rules. In 2017, the Inspector General conducted a follow-up audit of Medicare payments for Part B ambulance services furnished to beneficiaries in a Part A covered SNF stay. The Inspector General found that the current claim system editing is insufficient to prevent overpayments to ambulance providers and suppliers for transports that should have been bundled under SNF CB.

Generally, ambulance services are bundled when furnished to a beneficiary who has the status of a SNF “resident” for CB purposes. This general principle is one that the SNF PPS basically inherited from the Inpatient Prospective Payment System (IPPS), which has a similar rule for hospital bundling of ambulance transports.

One exception to this general SNF CB rule on ambulance services is when such transports are furnished in connection with the receipt of offsite Part B dialysis services. Even though the receipt of offsite dialysis doesn’t affect the beneficiary’s SNF “resident” status, dialysis-related
ambulance services are nevertheless excluded from CB per Section 103 of the Balanced Budget Refinement Act (BBRA) of 1999, which amended Section 1888(e)(2)(A)(iii)(I) of the Social Security Act (the Act) specifically to carve out dialysis-related ambulance transports from the SNF CB bundle.

Under the general rule set forth above, the initial ambulance trip that first brings a beneficiary to the SNF is not subject to CB because the beneficiary has not yet been admitted to the SNF as a resident at that point. Similarly, an ambulance transport that conveys a beneficiary from the SNF at the end of a stay is not subject to CB when it occurs in connection with one of the following events specified in subclauses (i) through (iv) of 42 CFR 411.15(p)(3) as ending the beneficiary’s SNF “resident” status:

- A trip for an inpatient admission to a Medicare-participating hospital or Critical Access Hospital (CAH)
  - Note: See the discussion below on “Transfers Between Two SNFs,” regarding an ambulance trip that conveys a beneficiary from the discharging SNF for a same-day inpatient admission to another SNF.
- A trip to the beneficiary’s home to receive services from a Medicare participating home health agency under a plan of care
- A trip to a Medicare participating hospital or CAH for the specific purpose of receiving emergency services or certain other exceptionally intensive outpatient services (Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scans, cardiac catheterizations, ambulatory surgery that requires the use of an operating room or comparable facilities, and so forth) that the Centers for Medicare & Medicaid Services (CMS) has designated as being beyond the general scope of SNF comprehensive care plans
- A formal discharge (or other departure) from the SNF, unless the beneficiary returns to that or another SNF before the following midnight.

Transfers Between Two SNFs: When a beneficiary is discharged from a covered stay in SNF 1 and then transfers to SNF 2 before the following midnight, that day is a covered Part A day for the beneficiary, to which CB applies. Accordingly, the ambulance trip that conveys the beneficiary would be bundled back to SNF 1 since, under Section 411.15(p)(3)(i), the beneficiary would continue to be considered a “resident” of SNF 1 (for CB purposes) up until the actual point of admission to SNF 2. By contrast, when an individual leaves an SNF via ambulance and does not return to that or another SNF before the following midnight, the day is not a covered Part A day. Accordingly, CB would not apply to that ambulance trip.

Roundtrip to Physician’s Office: Confusion sometimes arises over the issue of an ambulance roundtrip that transports a SNF resident to a physician’s office, since this is a type of destination that the Part B ambulance benefit doesn’t normally cover. It’s important to note that the regulations at 42 CFR 409.27(c) on coverage of ambulance transports under the SNF benefit provide that such transports must meet the general medical necessity requirement, described in 42 CFR 410.40(d)(1), that applies under the separate Part B ambulance benefit (that is, the beneficiary’s condition must be such that transportation by any means other than ambulance would be medically contraindicated). However, while the Part A SNF regulations incorporate this
general requirement, they don't incorporate the more detailed coverage restrictions that apply to the Part B ambulance benefit—such as the limitation of coverage under Part B to include only those trips that transport a beneficiary to certain specified destinations (42 CFR 410.40(e)). Thus, if a SNF's Part A resident requires transportation to a physician's office and meets the general medical necessity requirement for transport by ambulance (using any other means of transport would be medically contraindicated), then the ambulance roundtrip is subject to CB and included in the SNF bundle.

Non-ambulance Forms of Transport: In contrast to the ambulance coverage discussed above, Medicare simply doesn’t provide any coverage at all – under Part A or B – for any non-ambulance forms of transportation, such as ambulette, wheelchair van, or litter van. Thus, in those situations where it’s medically feasible to convey a SNF resident by some means other than an ambulance, the transportation of such a resident (regardless of the type of vehicle used) would neither be included within the SNF bundle nor coverable under the separate Part B ambulance benefit but would simply be altogether noncovered by Medicare. As with any other noncovered service for which a resident may be financially liable, the SNF is required under the regulations at 42 CFR 483.10(g)(18) to, “… inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare and/or Medicaid, or by the facility’s per diem rate.”

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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Revisions to the Telehealth Billing Requirements for Distant Site Services

MLN Matters Number: MM10583 Revised
Related CR Release Date: June 21, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R2095OTN
Implementation Date: October 1, 2018

Note: This article was revised on September 6, 2018, to correct the effective date of the GT modifier (annotated in red). That date should be October 1, 2018. All other information remains the same.

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for providers who submit claims to Medicare Administrative Contractors (MACs) for telehealth services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) implements requirements for billing modifier GT for Telehealth Distant Site Services. As of October 1, 2018, the GT modifier is only allowed on institutional claims billed by a Critical Access Hospital (CAH) Method II. Make sure your billing staffs are aware of this requirement.

BACKGROUND

Previous guidance instructed providers to submit claims for telehealth services using the appropriate procedure code along with the telehealth modifier GT (via interactive audio and video telecommunications systems). In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) final rule, payment policies regarding Medicare’s use of a new Place of Service (POS) Code describing services furnished via telehealth (POS 02) were finalized and implemented through CR9726. The new POS code became effective January 1, 2017.

In the CY 2018 PFS final rule, the requirement to use the GT modifier was eliminated for all professional claims. CR10152, which implemented that policy, included a business requirement instructing MACs to be aware that the GT modifier is only allowed for distant site services billed when the type of bill is a Method II CAH with a revenue code 96X, 97X, or 98X or with a service line that contains HCPCS code Q3014 or the type of bill is a Method II CAH with revenue code 942 and contains G0420 or G0421. As of October 1, 2018, the GT modifier is only allowed on
institutional claims billed under CAH Method II. If the GT modifier is billed under any circumstances, except as just outlined for Method II CAHs, the claim line will be rejected with the following remittance codes:

- Group Code CO - Contractual obligation
- Claim Adjustment Reason Code 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. Start: 01/01/1995 | Last Modified: 07/01/2017

### 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

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<tr>
<td>September 6, 2018</td>
<td>This article was revised to correct the effective date of the GT modifier. That date should be October 1, 2018.</td>
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<tr>
<td>June 21, 2018</td>
<td>This article was revised to reflect a revised CR10583 issued on June 20. In the article, the criteria that allows the GT modifier to be present on Method II CAH claim lines is revised. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.</td>
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<tr>
<td>April 27, 2018</td>
<td>Initial article released.</td>
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MLN Matters Number: MM10959
Related CR Release Date: October 26, 2018
Effective Date: April 1, 2 PROVIDER TYPE AFFECTED
This MLN Matters Article is intended for approved teaching hospitals submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries enrolled in a Medicare Advantage (MA) plan.

PROVIDER ACTION NEEDED
CR10959 instructs the Common Working File (CWF) to bypass edit 5233 on claims billed with an Investigational Device Exemption (IDE) study or a clinical study approved under Coverage with Evidence Development (CED) so that the Fiscal Intermediary Shared System (FISS) can make the IME only payment on approved teaching hospital claims for MA-enrolled beneficiaries. MACs will assist hospitals in resubmitting the rejected inpatient information only claims with condition codes 04, 69, and 30, one of the approved IDE or CED study numbers listed in the most updated list MACs received from CMS and an admission date on or after April 1, 2015, through the implementation date of CR10959 upon request from the hospital. The only claims that need to be resubmitted are IME only claims that were rejected. Make sure your billing staffs are aware of these changes.

BACKGROUND
The Centers for Medicare & Medicaid Services (CMS) recently learned that approved teaching hospitals are not receiving the IME adjustment on claims billed on Type of Bill 11X with Condition Codes (CC) 04, 69 and 30 and Value Code (VC) ‘D4’ with a national clinical trial number for an IDE study or a clinical study approved under CED. This issue is an unintended consequence of the implementation of CR10238, Transmittal 3943 issued on December 22, 2017. (Related MLN article MM10238, is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10238.pdf.)
CR10959 instructs the MACs to bypass edit 5233 on inpatient information only claims with:

- Type of Bill 11X
- CC - ‘04’, ‘69’ and ‘30’ present
- VC - ‘D4’ present with a valid IDE or CED study number
- Any date of service processed on or after April 1, 2019

MACs shall ensure that only the IME payment is made when the inpatient claim contains a CC of 04 or 69.

MACs will assist hospitals in resubmitting the rejected inpatient information only claims with condition codes 04, 69, and 30, one of the approved IDE or CED study numbers listed in the most updated list MACs received from CMS and an admission date on or after April 1, 2015, through the implementation date of CR10959 upon request from the hospital.

**ADDITIONAL INFORMATION**


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User CR: Fiscal Intermediary Shared System (FISS) - Implementation of the Molecular Diagnostic Services (MolDX)

MLN Matters Number: MM10760  Related Change Request (CR) Number: 10760
Related CR Release Date: November 9, 2018  Effective Date: April 1, 2019
Related CR Transmittal Number: R2201OTN  Implementation Date: April 1, 2019

PROVIDER TYPE AFFECTED
This MLN Matters Article is intended for providers who submit claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice MACs, for Molecular Diagnostic Services (MolDX) services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED
CR 10760 adds a MolDX test identification (ID) field to FISS. The MolDX program requires that providers be able to input a unique test ID into their claims at the detail line level. Providers will now be able to manually enter or correct the MolDX test ID field through Direct Data Entry (DDE) processing. This will assist the MACs in more accurate adjudication of Part A claims involved with the MolDX program. This feature will be available on April 1, 2019. Make sure your billing staff is aware of this change.

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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L34592 VERTEBROPLASTY (PERCUTANEOUS) & VERTEBRAL AUGMENTATION INCLUDING CAVITY CREATION, KYPHOPLASTY MASS ADJUSTMENT

WPS GHA will be implementing a mass adjustment of previously denied claims for kyphoplasty (CPT codes 22510-22515) for Place of Service (POS) 11 (office setting) for dates of service January 1, 2017, to September 13, 2018. We believe that best practice is for the physician providing the service to document the use of x-ray guidance, either fluoroscopy or CT scan in all settings, including an office setting. The edit that had been in place is no longer operational. Affected providers do not need to take any action; the provider’s remittance advice will serve as notification that the mass adjustment has occurred. We anticipate all adjustments will be completed by October 19, 2018.

This pertains to Local Coverage Determination (LCD) Vertebroplasty (Percutaneous) & Vertebral Augmentation including cavity creation, L34592 (https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34592). The policy will be clarified to reflect these documentation recommendations with the next available update which is planned for November 1, 2018.

It is important to point out that claims can deny for many reasons. All services must be reasonable and necessary, documents must be properly signed, and other documentation requirements must be met. If you need further information regarding this notification or if you find that your claim(s) meeting this criteria haven’t been appropriately adjusted by October 31, 2018, please feel free to contact Customer Service at:

J5 (866) 518-3285
J8 (866) 234-7331

MEDICARE BENEFICIARIES AND HOSPICE BENEFITS

Medicare beneficiaries who have a terminal illness with a life expectancy of six months or less and who are entitled to Hospital Insurance (Part A) have the option of electing hospice benefits in lieu of standard Medicare coverage for treatment and management of their terminal condition. The hospice provisions only cover care provided by a Medicare-certified hospice. The coverage is available for two 90-day periods and an unlimited number of 60-day periods during the hospice patient's lifetime. The coverage of the hospice benefit is discussed in the Centers for Medicare & Medicaid Services (CMS) Internet-Only Manual (IOM) Publication 100-04, Chapter 11. You can access this publication on the following CMS website: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf

When the patient elects hospice care, the beneficiary waives all rights to Medicare Part B payments for services related to the treatment and management of the terminal illness during any period the beneficiary's hospice benefit is in force, except for the professional services of an "attending physician." Payment for all services related to the patient's terminal illness is made through the hospice under Medicare Part A benefits. Services not related to the patient's terminal illness are made under normal Medicare payment guidelines.
For more information concerning the reimbursement of an attending physician please see our article **Attending Physician for Patients who Elect Hospice Coverage:**

For more information concerning modifiers GV and GW, please go to the following resources:
**Billing with the GW Modifier:** https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/billing-with-gw-modifier
**Billing with the GV Modifier:** https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/billing-with-gv-modifier

**NEW RESOURCE: INTRAARTICULAR KNEE INJECTIONS OF HYALURONAN BILLING GUIDELINES**


The article supports purified natural hyaluronates, which have been approved by the FDA for the treatment of symptomatic osteoarthritis of the knee in patients who have failed to respond adequately over a three-month period to a past history of treatment with analgesics and conservative nonpharmacologic therapy and a radiological exam to support the diagnosis of osteoarthritis. The future coverage article will be effective December 1, 2018, on the Medicare Coverage Database. A lapse in coverage will not occur. For more information, see the new resource on our website: https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/intraarticular-knee-injections-hyaluronan-billing-guidelines
Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2019

MLN Matters Number: MM10941 Related Change Request (CR) Number: 10941
Related CR Release Date: September 28, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4139CP 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

This MLN Matters® Article is based on Change Request (CR) 10941 which informs MACs about the changes that will be included in the January 2019 quarterly release of the edit module for clinical diagnostic laboratory services. Make sure your billing staffs are aware of these changes.

BACKGROUND

CR 10941 announces the changes that will be included in the January 2019 quarterly release of the edit module for clinical diagnostic laboratory services. The National Coverage Determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee, and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12 - 190.34) were processed uniformly throughout the nation, effective April 1, 2003.

In accordance with Chapter 16, Section 120.2, Publication 100-04, the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. CR 10941 communicates requirements to MACs notifying them of changes to the laboratory edit module to update it for changes in laboratory NCD code lists for January 2019.
Please access the following link for the NCD spreadsheets included with CR10941 (https://www.cms.gov/medicare/coverage/determinationprocess/downloads/January2019.zip)

**Note:** MACs will adjust claims brought to their attention, but will not search their files to retract payment for claims already paid or retroactively pay claims.

## 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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International Classification of Diseases, Tenth Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)

MLN Matters Number: MM10859 Revised
Related CR Number: 10859
Related CR Release Date: November 8, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R2200OTN
Implementation Date: January 7, 2019, shared edits. September 28, 2018, local edits (See following note box for further implementation information.)

Note: This article was revised on November 9, 2018, to reflect a revised CR10859 issued on November 8. The CR was revised to (1) add ICD-10 dx H35.52 and remove H35.53 from NCD80.11, (2) remove ICD-10 dx D61.1 from the NCD110.21 non-covered list, and (3) correct NCD220.6.17 spreadsheet dx tab to align with requirements by removing ICD-10 dx C4A.12 and adding C4A.21. In addition, the correction revises business requirements 10859.1.1.1 (NCD80.11) and 10859.2 (NCD110.21) of the CR as well as the implementation date. The edits included in NCD80.11 and NCD110.21 will be implemented 30 days after the issuance of the revised CR. Also, MCS, which processes professional claims, to implement addition of ICD-10 H35.52, removal of ICD-10 H35.53 from NCD80.11 April 1, 2019. FISS & MCS to implement removal of ICD-10 D61.1 from NCD110.21 April 1, 2019. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10859 constitutes a maintenance update of International Classification of Diseases, Tenth 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. Please follow the link below for the NCD spreadsheets included with this CR: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR10859.zip. 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 at https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new NCD policy. Edits to ICD-10, and other coding updates specific to NCDs, will be included in subsequent quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

Coding (as well as payment) are separate and distinct areas of the Medicare Program from coverage policy/criteria. Revisions to codes within an NCD are carefully and thoroughly reviewed and vetted by the Centers for Medicare & Medicaid Services 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.

Note: 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.

CR10859 makes coding and clarifying adjustments to the following NCDs:

- NCD80.11 Vitrectomy
- NCD110.21 Erythropoiesis-Stimulating Agents (ESAs) for Cancer
- NCD190.3 Cytogenetics
- NCD190.11 Home Prothrombin Time (PT)/International Normalized Ratio (INR)
- NCD220.6.17 Positron Emission Tomography (PET) for Oncologic Conditions
- NCD270.3 Blood-Derived Products for Chronic, Non-Healing Wounds
- NCD260.1 Adult Liver Transplantation
- NCD110.18 Aprepitant for Chemo-Induced Emesis
- NCD270.1 Electrical Stimulation, Electromagnetic Therapy for Wounds

Note/Clarification: A/B 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 Claim Adjustment Reason Code (CARC) 50, 96, and/or 119. See latest CAQH CORE update. When denying claims associated with the NCDs referenced in CR10859, except where otherwise indicated, A/B 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 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 and Medicare Summary Notice (MSN) 8.81 per instructions in CR 7228/TR 2148.

### ADDITIONAL INFORMATION


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<td>September 11, 2018</td>
<td>The article was revised to reflect a revised CR10859 issued on September 11. The CR was revised to remove ICD-10 diagnosis code H25.13 from NCD80.11 spreadsheet that was retained in error. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.</td>
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Local Coverage Determinations (LCDs)

MLN Matters Number: MM10901 Related Change Request (CR) Number: 10901
Related CR Release Date: October 3, 2018 Effective Date: October 3, 2018
Related CR Transmittal Number: R829PI Implementation Date: January 8, 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) 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 healthcare 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 Internet website on the Medicare 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 e-mail, 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 healthcare 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.
5. Contractor Advisory Committee (CAC)

The CAC is to be composed of healthcare 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 one per jurisdiction with representation from each state, ensuring that each state has a full committee and the opportunity to discuss the quality of evidence used to make a determination.

The CAC’s purpose is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MACs and the healthcare 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 listservs to announce this information or may use other education methods to adequately inform the public. The listserv or other method should clearly identify the location, dates and telephone/video/online 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 contained 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, i.e., 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 Web site. 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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Magnetic Resonance Imaging (MRI)

MLN Matters Number: MM10877  Related Change Request (CR) Number: 10877
Related CR Release Date: October 19, 2018  Effective Date: April 10, 2018
Related CR Transmittal Number: R4147CP and R208NCD  Implementation Date: December 10, 2018

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR10877 informs MACs and providers that effective for claims with dates of service on and after April 10, 2018, Medicare will allow for MRI coverage for beneficiaries with an Implanted Pacemaker (PM), Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronization Therapy Pacemaker (CRT-P), or Cardiac Resynchronization Therapy Defibrillator (CRT-D). Please make sure your billing staffs are aware of these changes.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) opened a National Coverage Analysis (NCA) to reconsider coverage indications for MRI, specifically, in the Medicare National Coverage Determinations (NCD) Manual, Section 220.2(C)(1) Contraindications. This NCA focused on the contraindications for a PM, ICD, CRT-P, or CRT-D in patients undergoing MRIs both on and off Food and Drug Administration (FDA) label.

CMS determined the evidence is sufficient to conclude that MRI for Medicare beneficiaries with an Implanted Pacemaker (PM), Implantable Cardioverter Defibrillator (ICD), Cardiac Resynchronization Therapy Pacemaker (CRT-P), or Cardiac Resynchronization Therapy Defibrillator (CRT-D) is reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act (the Act) under certain circumstances. CMS is modifying the NCD to eliminate the collection of additional information under the Coverage with Evidence Development (CED) paradigm under Section 1862(a) (1)(E) of the Act.
CMS is revising the language in the NCD Manual to:

1. Remove the contraindication for Medicare coverage of MRI in a beneficiary who has an implanted PM or ICD (Section 220(C)(1))
2. Expand coverage to include CRT-P, or CRT-D devices (Section 220.2(B)(3))
3. Expand coverage for beneficiaries who have an implanted Food & Drug Administration (FDA)-approved, ICD, CRT-P, or CRT-D correspondingly under 220.2(B)(3) of the NCD Manual as a nationally covered MRI indication
4. Expand coverage for beneficiaries who have an implanted PM, ICD, CRT-P, or CRT-D device that does not have FDA labeling specific for an MRI under certain conditions under Section 220.2(B)(3)
5. Remove the CED requirement

Effective for claims with dates of service on or after April 10, 2018, MACs will allow MRI line items for beneficiaries with implanted PMs, implanted ICDs, CRT-Ps, and CRT-Ds that include an appropriate MRI code, AND, ICD-10 diagnosis (dx) code Z95.0 - presence of cardiac pacemaker, (Z95.0 also includes presence of CRT-P), OR, ICD-10 dx Z95.810 presence of automatic ICD (Z95.810 also includes presence of automatic ICD with CRT-P, and, presence of CRT-D). MRI line items for beneficiaries with implanted PMs, implanted ICDs, CRT-Ps, and CRT-Ds that do not meet these requirements will be denied with the following messages:

1. Claim Adjustment Reason Code (CARC) 146 – Diagnosis was invalid for the date(s) of service reported
2. Group Code - CO

Your MAC will pay claims as follows for these Types of Bills (TOB) (deductible and coinsurance apply):

1. Professional claims (practitioners and suppliers) - based on the Medicare Physician Fee Schedule (MPFS)
2. TOB 11X - Prospective payment system (PPS), based on the diagnosis-related group
3. TOB 13X – Outpatient Prospective Payment System (OPPS), based on the ambulatory payment classification
4. Rural Health Clinics/Federally Qualified Health Centers (71x/77x). The professional component bills for the MRI with a qualified visit only, there is no payment for this service on an RHC/FQHC claim. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of the technical service bills their MAC on the ANSI X12N 837P or hardcopy Form CMS-1500 and payment is made under the MPFS
5. TOB 85X (Critical Access Hospitals (CAHs) - For CAHs that elected the optional method of payment for outpatient services, the payment for technical services would be the same as the CAHs that did not elect the optional method - Reasonable cost. The professional component will be paid at 115 percent of the MPFS.
Effective April 10, 2018, the -Q0 and -KX modifiers on claims for MRIs for beneficiaries with an implanted pacemaker are no longer required and can be end-dated.

Any MRI for patients with an implanted pacemaker, ICD, CRT-P, or CRT-D that does not have FDA labeling specific to use in an MRI environment is only covered under the following conditions:

- MRI field strength is 1.5 Tesla using Normal Operating Mode;
- The PM, ICD, CRT-P, or CRT-D system has no fractured, epicardial, or abandoned leads;
- The facility has implemented a checklist which includes the following:
  - Patient assessment is performed to identify the presence of a PM, ICD, CRT-P, or CRT-D;
  - Before the scan, the facility communicates the benefits and harms of the MRI scan to the patient or the patient’s delegated decision-maker;
  - Prior to the MRI scan, the PM, ICD, CRT-P, or CRT-D is interrogated and programmed into the appropriate MRI scanning mode;
  - A qualified physician, nurse practitioner, or physician assistant with expertise with PMs, ICDs, CRT-Ps, or CRT-Ds must directly supervise the MRI scan as defined in 42 CFR § §410.28 and 410.32;
  - Patients are observed throughout the MRI scan via visual and voice contact and monitored with equipment to assess vital signs and cardiac rhythm;
  - An advanced cardiac life support provider must be present for the duration of the MRI scan;
  - A discharge plan that includes before being discharged from the hospital/facility, the patient is evaluated, and the PM, ICD, CRT-P, or CRT-D is re-interrogated immediately after the MRI scan to detect and correct any abnormalities that might have developed.

**Be Aware:** For claims with dates of service on or after April 10, 2018, but processed prior to implementation of CR10877, MACs will not search their files. However, your MAC will adjust claims 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](http://go.cms.gov/MAC-website-list).
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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: August 28, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R205DEMO Implementation Date: January 7, 2019

Note: This 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.

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
• 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:

More information about the Next Generation ACO Model is available at: https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/.

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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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): http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

Visit our website at the link below for more information: https://www.wpsgha.com/wps/portal/mac/site/policies/news-and-updates

December 2018 – There are no new policies for December 2018

November 2018

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<tr>
<td>J5/J8</td>
<td>Intraarticular Knee Injections of Hyaluronan Billing Guidelines</td>
<td>A56157</td>
<td>NA</td>
<td>12/01/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: CORUS® CAD ASSAY</td>
<td>L37770</td>
<td>MolDX-046</td>
<td>12/17/2018</td>
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</table>

October 2018 – There are no new policies/articles for October 2018

RETIREDPOLICIES
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:

December 2018 – There are no retired policies for December 2018

November 2018

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<tr>
<td>J5/J8</td>
<td>Intra-articular Injections of Hyaluronan</td>
<td>L34525</td>
<td>INJ-033</td>
<td>12/01/2018</td>
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<tr>
<td></td>
<td>This LCD with Billing and Coding Guidelines are being retired December 1, 2018, and replaced with A56157 Article Intra-articular Knee Injections of Hyaluronan Billing Guidelines.</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>DL37917</td>
<td>MolDX-050</td>
<td>11/01/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Comprehensive Genomic Profiling to Guide Treatment in Patients with Advanced Primary Periitoneal, Fallopian Tube and Ovarian Cancer</td>
<td>DL37203</td>
<td>MolDX-028</td>
<td>11/01/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Comprehensive Genomic Profiling to Guide Treatment in Patients with Metastatic Melanoma</td>
<td>DL37220</td>
<td>MolDX-032</td>
<td>11/01/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: NSCLC, Comprehensive Genomic Profile Testing</td>
<td>L36803</td>
<td>MolDX-017</td>
<td>11/01/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Vita Risk™ Pharmacogenetic Test for Dry Age-related Macular Degeneration (AMD)</td>
<td>DL37218</td>
<td>MolDX-031</td>
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<td>J5/J8</td>
<td>MolDX: Approved Gene Testing</td>
<td>A55248</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: VectraDA, a Multibiomarker Disease Activity Test for Rheumatoid Arthritis (RA)</td>
<td>DL37201</td>
<td>MolDX-027</td>
<td>10/01/2018</td>
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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):
December 2018

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<tr>
<td>J5/J8</td>
<td>Cosmetic and Reconstructive Surgery</td>
<td>L34698</td>
<td>GSURG-032</td>
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</table>

CMS National Coverage Policy:
Updated IOM references/titles/chapters and sections,

Added CMS PUB. 100-03 Medicare National Coverage Determinations Manual, Chapter 1, Part 4, §250.4 – Treatment of Actinic Keratosis,

Added CMS PUB. 100-02 Medicare Benefit Policy Manual, Chapter 16-General Exclusions from Coverage, §120 Cosmetic Surgery,

Added National Coverage Determination 250.5 Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome and to Coverage Indications, Limitations, and/or Medical Necessity to B. 10 Dermal Injections.

CMS National Coverage Policy added additional verbiage to Title XVIII of the Social Security Act (SSA): 1862 (a)(1)(A) Medically Reasonable & Necessary tests used in the diagnosis and management of illness or injury or to improve the function of a malformed body part.

Added: Title XVIII of the Social Security Act (SSA): 1862 (a)(1)(D) Investigational or Experimental;

Added: Title XVIII of the Social Security Act, Section 1862 (a)(10). This section excludes Cosmetic Surgery.

Added Change Request 10901, Transmittal 829, Local Coverage Determinations (LCDs) October 3, 2018.

Coverage Indications, Limitations, and/or Medical Necessity added Per the Medicare Benefit Policy Manual cosmetic surgery or expenses incurred in connection with such surgery, for the sole purpose of improving one’s appearance, is not covered.

No change in coverage.

Updated Billing and Coding Guidelines:
Removed verbiage performed for a cosmetic reason will be denied as non-covered from #1.- #7. and #9.

Removed #10. Billing for dermal injections for the treatment of Facial Lipodystrophy Syndrome (LDS) that meet the criteria in the NCD and associated information. Dermal injection guidance provided in policy.


No change in coverage.

J5/J8    | Drug Administration Coding                     | A54176           | NA           | 12/01/2018     |

Added J3490 Onpattro™ (patisiran).
Added the following verbiage for NOC Drug Billing:

Office/Clinic:

Providers submit NOC codes in the 2400/SV101-2 data element in the 5010 professional claim transaction (837P). When billing an NOC code, providers are required to provide a description in the 2400/SV101-7 data element. The 5010 TR3 Implementation Guide instructs: "Use SV101-7 to describe non-specific procedure codes." (Do not use the 2400 NTE segment to describe non-specific procedure codes with 5010.) The SV101-7 data element allows for 80 bytes (i.e., characters, including spaces) of information.

In order for WPS GHA to correctly reimburse NOC drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Item 19 of the CMS 1500 form:
- The name of the drug,
- The total dosage (plus strength of dosage, if appropriate), and
- The method of administration.

Important: 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.)

See NOC Billing/NOC Drug and Biological Codes on our website for further information: https://www.wpsgha.com/wps/portal/mac/site/claims/guides-and-resources/not-otherwise-classified-billing

ASC and Hospital Outpatient Departments:

HCPCS code C9399, Unclassified drug or biological, should be used for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.


- Claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier. Unused drugs or biologicals from single use vials or single use packages that are opened and the entire dose/quantity is not administered and the remainder is discarded. (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals).
- Providers must document the discarded drugs or biologicals in the patient's medical record.
- This modifier, billed on a separate line, will provide payment for the amount of discarded drugs or biologicals.

See CR 9603

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<td>Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring)</td>
<td>L34636</td>
<td>CV-016</td>
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<td>A56157</td>
<td>NA</td>
<td>12/01/2018</td>
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</table>

Reformatted article guidance without change in coverage.

Added the following information under Article Guidance: All procedures are furnished by and administered by a physician and/or appropriately trained providers in the appropriate setting.

Removed the following items: the definition of Osteoarthritis, the reference to clinical studies of sodium hyaluronate, and removed duplicative information regarding coverage of incident to and FDA safety and effectiveness.

Billing of Viscosupplements: added the following sentence:
Dosing frequency of injections per series and/or dosing frequency per series as listed/supported with the FDA approved dosing/package insert must be documented in the medical record. Providers are responsible for determining the code that most accurately describes the intraarticular agent furnished.

Added the following Sources of Information:
FDA package inserts including Safety and Effectiveness Data;

The Medical Letter (August 27, 2018). Two New Intra-articular Injections for Knee Osteoarthritis. Vol. 60 (1554);


Other MACs LCD/Articles.

| J5/J8    | MolDX: ConfirmMDx Epigenetic Molecular Assay | L37005 | MolDX-020 | 12/01/2018 |

The Analysis of Evidence was updated: Quality: Limited to Moderate changed to Moderate and Strength and Weight were limited and changed to Low. It now reads:

**Analysis of Evidence**
(Rationale for Determination)

**Level of Evidence**
Quality of Evidence – Moderate
Strength – Low
Weight – Low

| J5/J8    | Nerve Conduction Studies and Electromyography and Billing and Coding Guidelines | L34594 | NEURO-005 | 12/01/2018 |

Coverage Guidance: removed sentence: "It would be highly unlikely that this training and/or credentialing is possessed by providers other than Neurologists, or Physical
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<td>Somatosensory Testing</td>
<td>L32902</td>
<td>NEURO-013</td>
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</table>

Coverage Guidance: Changed “physician” to "providers" in the following sentences: A provider trained in interpreting clinical evoked potential studies analyzes the waveforms.

Documentation Requirements:
Medical record documentation maintained by the performing provider must clearly indicate the medical necessity of the service being billed.
This documentation should include a hard copy computer generated recording of the test results along with the provider’s interpretation.
The provider’s SEP report should note which nerves were tested, latencies at various testing points, and an evaluation of whether the resulting values are normal or abnormal.

Coverage Guidance for clarification added paragraph:
CMS long-standing policy that the concept of physician supervision does not apply (PSI of “09”) to these PT-designated diagnostic services, which allows payment to be made for the PC or global code to the ABPTS-PT, excepted by regulation, as long as it is legal for the ABPTS-PT to provide the service in that state, and the TC has been either personally performed by the ABPTS-PT or the PT without the ABPTS certification has met the supervision requirements for the technical component portion of the service consistent with the applicable supervision indicator.

In training and expertise sentence added the following verbiage to “certification by a nationally recognized organization, or by an accredited post-graduate training course covering anatomy, neurophysiology and forms of electrodiagnostics (including both NCS and EMG).”

In Coverage Guidance removed the sentence: “It is anticipated only allopathic or osteopathic physicians will have the necessary training to meet these requirements.”

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<tr>
<td>J5/J8</td>
<td>MolDX: Afi...</td>
<td>A55139</td>
<td>NA</td>
<td>11/01/2018</td>
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</table>

Policy Clarification:
Added numbering and “patient must have 1 and 2” to the coverage below.

The MolDX Team has completed the Afi... assessment and determined that the test meets criteria for analytical and clinical validity, and clinical utility as a reasonable and necessary Medicare benefit. Effective 01/01/12, MolDX will reimburse Afi... services for patients with the following conditions (patient must have 1 and 2):

1. Patients with one or more thyroid nodules with a history or characteristics suggesting malignancy such as:
   - Nodule growth over time
   - Family history of thyroid cancer
   - Hoarseness, difficulty swallowing or breathing
   - History of exposure to ionizing radiation
   - Hard nodule compared with rest of gland consistency
   - Presence of cervical adenopathy

2. Have an indeterminate follicular pathology on fine needle aspiration

Changed coverage date from 01/01/2012 to 10/01/2015.

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<td>MolDX: Déc...</td>
<td>L36791</td>
<td>MolDX-010</td>
<td>11/01/2018</td>
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The quality, strength, and weight of evidence have been updated.

**Analysis of Evidence**
(Rationale for Determination)
**Level of Evidence**
Quality of Evidence – Moderate
Strength – Low
Weight – Low

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<td>L36807</td>
<td>MolDX-004</td>
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<tr>
<td>J5/J8</td>
<td>Vertebroplasty (Percutaneous) and Vertebral Augmentation including cavity creation</td>
<td>L34592</td>
<td>RAD-032</td>
<td>11/01/2018</td>
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</table>

Due to the 04Q18 Code Update & AMA CPT Proprietary Laboratory Analyses (PLA) Codes Long Descriptors document, the following deleted codes have been removed from this policy:
0020U Rx test prsmv ur w/def conf
0028U Cyp2d6 gene cpy nmr cnm vrnt

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<tr>
<td>J5/J8</td>
<td>2019 ICD-10 Code Update</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>J5/J8</td>
<td>Chemotherapy Agents for Non-Oncologic Conditions</td>
<td>A55639</td>
<td>NA</td>
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</table>

ICD-10 CM Code updates: Group 6: O00.212 description change.

The article addresses chemotherapy administration codes which apply to parenteral administration of anti-neoplastic agents provided for treatment of noncancer diagnoses or to substances such as monoclonal antibody agents, and other biologic response modifiers.

The article has been updated and reformatted to support Article Guidance on Non-Oncological Conditions.

Removed from Group 1 Code Table:
A9606  Radium ra-223 dichloride therapeutic, per microcurie
J9151  Injection, Daunorubicin citrate, liposomal formulation 10 mg
J9165  Injection, Diethylstilbestrol diprophosphate 250 mg
J9270  Injection, Plicamycin 2.5mg and
Q2017  Injection, Teniposide 50 mg.

These medications were removed as they are applicable to oncologic conditions and do not support the article guidance for non-oncological conditions. This article is
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<td>INJ-023</td>
<td>10/01/2018</td>
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</table>

Added CR 10859 ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs), effective 01/01/2019 to CMS National Coverage Policy Section.

Changes/reformatting to

Group 4 Paragraph:

C. Indications other than Renal Disease
1. Anemias related to therapy with Zidovudine (AZT)
Requires one of the following:

related to LCD L37205 Chemotherapy Drugs and their Adjuncts. Please refer to the LCD for coverage for chemotherapy agents.

Removed Group 1 Paragraph and associated information.
A9606 Radium ra-223 dichloride, (Xofigo) therapeutic, per microcurie
For the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. It is administered at 4-week intervals for a total of 6 doses. Off label use is not covered. Do not use both diagnosis codes if the indications have not been met.
C61 and C79.51 or C79.52.

Group 1 Codes:
C61 Malignant neoplasm of prostate
C79.51 Secondary malignant neoplasm of bone
C79.52 Secondary malignant neoplasm of bone marrow.

Please refer to NCCN Radiation Therapy Compendium™ for guidance.

Removed Group 3 Paragraph and associated information:
J9151 Daunorubicin citrate, liposomal formulation (DaunoXome) 10 mg,
J9165 Diethylstilbestrol diphosphate 250 mg,
J9270 Plicamycin (Mithracin) 2.5 mg, and
Q2017 Teniposide (Vumon) 50 mg.

Removed Group 3 Codes:
[C00.0 - C96.0] Malignant neoplasms of lip, oral cavity and pharynx- Multifocal and plurisystemic (disseminated) Langerhans-cell histiocytosis
[C96.21 - D46.9] Aggressive systemic mastocytosis - myelodysplastic syndrome, unspecified
[D47.09 - D49.9] Other mast cell neoplasms of uncertain behavior – Neoplasm of unspecified behavior of unspecified site
[E34.0 - E34.9] Carcinoid syndrome-Endocrine disorder, unspecified.

Group Paragraphs and Group Codes corrected for numerical order.
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<tr>
<td>Group 4</td>
<td>removed D64.9 Anemia, unspecified and replaced with D64.89 Other specified anemias or D75.9 Disease of blood and blood-forming organs, unspecified. Group 6 Paragraph: THREE DIAGNOSES ARE NECESSARY FOR J0881 or J0885 Requires: *D64.81, <em>Z79.899, AND an additional diagnosis code INDICATING THE CONDITION BEING TREATED Group 6 Codes removed D64.9 Anemia, unspecified and replaced with D64.81</em> Anemia due to antineoplastic therapy.</td>
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<tr>
<td>J5/J8</td>
<td><strong>Human Granulocyte/Macrophage Colony Stimulating Factor</strong></td>
<td>L34699</td>
<td>INJ-019</td>
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Please see combined article for ICD-10 CM Code Updates. Coverage Indications updated verbiage to match FDA indications to F. Indications for tbo-filgrastim (GRANIX) (J1447)

1. To decrease the duration of severe neutropenia in adult and pediatric patients 1 month and older with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Added to Group 5 Codes T45.1X5D Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter

Change Request 10923, October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS) - Effective October 1, 2018


Coverage Indications, Limitations, and/or Medical Necessity added:


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


1. Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
2. Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML).
3. Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT).
4. Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
5. Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Group 1 Paragraph: added
Q5108 Injection, Pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg
Q5110 Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram

Group 8 Paragraph
Q5108

Group 8 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

Group 9 Paragraph
Q5110

Group 9 Codes
C92.00 Acute myeloblastic leukemia, not having achieved remission
C92.02 Acute myeloblastic leukemia, in relapse
C92.40 Acute promyelocytic leukemia, not having achieved remission
C92.42 Acute promyelocytic leukemia, in relapse
C92.50 Acute myelomonocytic leukemia, not having achieved remission
C92.52 Acute myelomonocytic leukemia, in relapse
C92.60 Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.62 Acute myeloid leukemia with 11q23-abnormality in relapse
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<td>C92.A0</td>
<td>Acute myeloid leukemia with multilineage dysplasia, not having achieved remission</td>
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<tr>
<td>C92.A2</td>
<td>Acute myeloid leukemia with multilineage dysplasia, in relapse</td>
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<td>Congenital agranulocytosis</td>
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<tr>
<td>D70.1</td>
<td>Agranulocytosis secondary to cancer chemotherapy</td>
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<tr>
<td>D70.4</td>
<td>Cyclic neutropenia</td>
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<td>D70.8</td>
<td>Other neutropenia</td>
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<td>D70.9</td>
<td>Neutropenia, unspecified</td>
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<td>Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter</td>
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<td>Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter</td>
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<tr>
<td>Z48.290</td>
<td>Encounter for aftercare following bone marrow transplant</td>
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<tr>
<td>Z51.11</td>
<td>Encounter for antineoplastic chemotherapy</td>
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<tr>
<td>Z52.011</td>
<td>Autologous donor, stem cells</td>
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<tr>
<td>Z52.091</td>
<td>Other blood donor, stem cells</td>
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<tr>
<td>Z92.21</td>
<td>Personal history of antineoplastic chemotherapy</td>
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<tr>
<td>Z94.81</td>
<td>Bone marrow transplant status</td>
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<tr>
<td>Z94.84</td>
<td>Stem cells transplant status</td>
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</table>

**J5/J8 MoLX: Avise PG Assay Billing/Coding Update**

| A55144 | NA | 10/01/2018 |

Effective 10/01/2017: The following diagnosis codes have been added to the list of ICD-10 Codes that Support Medical Necessity:

- M05.09  Felty's syndrome, multiple sites
- M05.19  Rheumatoid lung disease with rheumatoid arthritis of multiple sites
- M05.29  Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
- M05.39  Rheumatoid heart disease with rheumatoid arthritis of multiple sites
- M05.49  Rheumatoid myopathy with rheumatoid arthritis of multiple sites
- M05.69  Rheumatoid arthritis of multiple sites with involvement of other organs and systems
- M05.79  Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
- M05.89  Other rheumatoid arthritis with rheumatoid factor of multiple sites
- M06.09  Rheumatoid arthritis without rheumatoid factor, multiple sites
- M06.29  Rheumatoid bursitis, multiple sites
- M06.39  Rheumatoid nodule, multiple sites
- M06.89  Other specified rheumatoid arthritis, multiple sites

**J5/J8 MoLX: Biomarkers in Cardiovascular Risk Assessment**

| L36523 | NA | 10/01/2018 |

These diagnosis codes are being added in addition to the new ICD-010 code update:

- I63.00  Cerebral infarction due to thrombosis of unspecified precerebral artery
<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>
</table>
| I63.011-I63.13 | Cerebral infarction due to thrombosis of right vertebral artery  
Cerebral infarction due to thrombosis of left vertebral artery  
Cerebral infarction due to thrombosis of bilateral vertebral arteries |                  |              |                |
| I63.019   | Cerebral infarction due to thrombosis of unspecified vertebral artery         |                  |              |                |
| I63.02    | Cerebral infarction due to thrombosis of basilar artery                       |                  |              |                |
| I63.031-163.033 | Cerebral infarction due to thrombosis of right carotid artery  
Cerebral infarction due to thrombosis of left carotid artery  
Cerebral infarction due to thrombosis of bilateral carotid arteries |                  |              |                |
| I63.039   | Cerebral infarction due to thrombosis of unspecified carotid artery           |                  |              |                |
| I63.09    | Cerebral infarction due to thrombosis of other precerebral artery             |                  |              |                |
| I63.10    | Cerebral infarction due to embolism of unspecified precerebral artery         |                  |              |                |
| I63.111-I63.113 | Cerebral infarction due to embolism of right vertebral artery  
Cerebral infarction due to embolism of left vertebral artery  
Cerebral infarction due to embolism of bilateral vertebral arteries |                  |              |                |
| I63.119   | Cerebral infarction due to embolism of unspecified vertebral artery           |                  |              |                |
| I63.12    | Cerebral infarction due to embolism of basilar artery                         |                  |              |                |
| I63.131-I63.133 | Cerebral infarction due to embolism of right carotid artery  
Cerebral infarction due to embolism of left carotid artery  
Cerebral infarction due to embolism of bilateral carotid arteries |                  |              |                |
<p>| I63.139   | Cerebral infarction due to embolism of unspecified carotid artery             |                  |              |                |</p>
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<tr>
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<td>I63.22</td>
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<tr>
<td>I63.231-I63.233</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries</td>
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<tr>
<td>I63.239</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries</td>
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<td>I63.29</td>
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<tr>
<td>I63.30</td>
<td>Cerebral infarction due to thrombosis of unspecified cerebral artery</td>
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<tr>
<td>I63.311-I63.313</td>
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<tr>
<td>I63.319</td>
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</tbody>
</table>
| I63.321-I63.323 | Cerebral infarction due to thrombosis of right anterior cerebral artery  
Cerebral infarction due to thrombosis of left anterior cerebral artery  
Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries |
| I63.329   | Cerebral infarction due to thrombosis of unspecified anterior cerebral artery                           |
| I63.331-I63.333 | Cerebral infarction due to thrombosis of right posterior cerebral artery  
Cerebral infarction due to thrombosis of left posterior cerebral artery  
Cerebral infarction to thrombosis of bilateral posterior cerebral arteries |
| I63.339   | Cerebral infarction due to thrombosis of unspecified posterior cerebral artery                         |
| I63.341- I63.343 | Cerebral infarction due to thrombosis of right cerebellar artery  
Cerebral infarction due to thrombosis of left cerebellar artery  
Cerebral infarction to thrombosis of bilateral cerebellar arteries |
| I63.349   | Cerebral infarction due to thrombosis of unspecified cerebellar artery                                 |
| I63.39    | Cerebral infarction due to thrombosis of other cerebral artery                                         |
| I63.40    | Cerebral infarction due to embolism of unspecified cerebral artery                                     |
| I63.411- I63.413 | Cerebral infarction due to embolism of right middle cerebral artery  
Cerebral infarction due to embolism of left middle cerebral artery  
Cerebral infarction due to embolism of bilateral middle cerebral arteries |
<p>| I63.419   | Cerebral infarction due to embolism of unspecified middle cerebral artery                              |</p>
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<td>Cerebral infarction due to embolism of bilateral anterior cerebral arteries</td>
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<tr>
<td>I63.431-I63.433</td>
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<td>Cerebral infarction due to embolism of left posterior cerebral artery</td>
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<td>Cerebral infarction due to embolism of bilateral posterior cerebral arteries</td>
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<tr>
<td>I63.439</td>
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<tr>
<td>I63.441-I63.443</td>
<td>Cerebral infarction due to embolism of right cerebellar artery</td>
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<td>Cerebral infarction due to embolism of left cerebellar artery</td>
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<td>Cerebral infarction due to embolism of bilateral cerebellar arteries</td>
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<tr>
<td>I63.449</td>
<td>Cerebral infarction due to embolism of unspecified cerebellar artery</td>
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<tr>
<td>I63.49</td>
<td>Cerebral infarction due to embolism of other cerebral artery</td>
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<tr>
<td>I63.50</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery</td>
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<tr>
<td>I63.511-I63.513</td>
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<td>Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery</td>
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<td></td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries</td>
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<tr>
<td>I63.519</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery</td>
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<td>I63.521-I63.523</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery</td>
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<td>Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery</td>
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<td></td>
<td></td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries</td>
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<td></td>
<td>I63.529</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery</td>
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<td></td>
<td>I63.531-I63.533</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery</td>
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<td>Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery</td>
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<td>Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior cerebral arteries</td>
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<td>I63.539</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery</td>
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<td>I63.541-I63.543</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery</td>
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<td>Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery</td>
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<td></td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries</td>
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<td></td>
<td>I63.549</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery</td>
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<td>I63.59</td>
<td>Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery</td>
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<tr>
<td></td>
<td>I63.9</td>
<td>Cerebral infarction, unspecified</td>
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</table>

Also see the 2019 ICD-10 code update article.

**J5/J8**

**MolDX: BRCA1 and BRCA2 Genetic Testing**

<table>
<thead>
<tr>
<th></th>
<th>L36813</th>
<th>MolDX-007</th>
<th>10/01/2018</th>
</tr>
</thead>
</table>


**Criteria for Testing**

- Individual with breast, ovarian1, pancreatic, or prostate cancer from a family with a known deleterious BRCA1 or BRCA2 gene mutation.
- Individual with a personal history of ovarian1 cancer
<table>
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<tr>
<th>Contract</th>
<th>Policy Title</th>
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<th>WPS Policy #</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Individual with a breast cancer diagnosis meeting any of the following criteria:</td>
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<td>o Diagnosed ≤45 y</td>
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<td></td>
<td>o Triple negative breast cancer (estrogen receptor (ER) negative,</td>
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<td>progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative) breast cancer diagnosed ≤ 60 y</td>
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<td>o Diagnosed at 46-50 with:</td>
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<td></td>
<td>▪ An additional breast cancer primary</td>
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<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with breast cancer at any age, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with prostate cancer (Gleason score ≥7) or</td>
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<td>▪ An unknown or limited family history3</td>
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<td></td>
<td>o Breast cancer diagnosed at any age, and</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with breast cancer ≤50 y, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with ovarian cancer at any age, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with metastatic prostate cancer or pancreatic cancer at any age, or</td>
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<td></td>
<td>▪ ≥2 additional diagnoses of breast cancer at any age in patient and/or in close blood relatives, or</td>
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<td></td>
<td>▪ A first, second, or third degree male relative with breast cancer</td>
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<td></td>
<td>▪ For an individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish) no additional family history may be required</td>
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<td></td>
<td>o Male breast cancer</td>
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<tr>
<td></td>
<td>• Personal history of prostate cancer (Gleason score ≥7) at any age with:</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with ovarian cancer at any age, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with breast cancer ≤50 y, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with pancreatic cancer at any age, or</td>
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<tr>
<td></td>
<td>▪ ≥1 first, second, or third degree relative5 with metastatic prostate cancer pancreatic cancer at any age, or</td>
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<tr>
<td></td>
<td>▪ ≥2 first, second, or third degree relatives5 with breast cancer and/or pancreatic cancer and/or prostate cancer (any grade) at any age, or</td>
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<tr>
<td></td>
<td>▪ Ashkenazi Jewish ancestry</td>
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<td></td>
<td>• Personal history of pancreatic cancer at any age</td>
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<td></td>
<td>• Personal history of metastatic prostate cancer (radiographic evidence of or biopsy-proven disease)</td>
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<td></td>
<td>• BRCA1/2 pathogenic mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis</td>
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</tbody>
</table>

*1Includes fallopian tube and primary peritoneal cancers. BRCA – related ovarian cancers are associated with epithelial, non-mucinous histology.
2Two breast cancer primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or
Medicare will cover BRCA-testing for an adopted individual with breast cancer diagnosed ≤ 50 y that is suspicious of being a BRCA-related cancer. Individuals with limited family history/structure, defined as fewer than 2 female first- or second-degree relatives having lived beyond age 45 in either lineage may also be eligible for BRCA gene testing. Similar to all testing, these situations require explanation of medical necessity for BRCA testing in the patient's medical record, and documentation of genetic counseling prior to BRCA testing.

Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Comprehensive BRCA1/2 testing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if any of the other BRCA-related criteria are met. NCCN defines blood relative as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on same side of family.

### MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

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<tr>
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<th>CMS MCD Policy #</th>
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<th>Effective Date</th>
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<td>J5/J8</td>
<td>MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease</td>
<td>L36815</td>
<td>MolDX-016</td>
<td>10/01/2018</td>
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Effective 07/01/2017: The following diagnosis codes have been added to the list of ICD-10 Codes that Support Medical Necessity:

- **C91.00** Acute lymphoblastic leukemia not having achieved remission
- **C91.01** Acute lymphoblastic leukemia, in remission
- **C91.02** Acute lymphoblastic leukemia, in relapse

### MolDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay

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<td>J5/J8</td>
<td>MolDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay</td>
<td>L36789</td>
<td>MolDX-009</td>
<td>07/01/2018</td>
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CPT 81479 Unlisted molecular pathology code has been replaced with the new code 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: Molecular Diagnostic Tests (MDT)

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<td>L36807</td>
<td>MolDX-004</td>
<td>10/01/2018</td>
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The following new codes are effective 07/01/2018 and have been added to this policy:

- 0045U ONC BRST DUX CARC IS 12 GENE;
- 0046U FLT3 GENE ITD VARIANTS QUAN;
- 0047U ONC PRST8 MRNA 17 GENE ALG;
- 0048U ONC SLD ORG NEO DNA 468 GENE;
- 0049U NPM1 GENE ANALYSIS QUAN;
- 0050U TRGT GEN SEQ DNA 194 GENES;
- 0051U RX MNTR LC-MS/MS UR 31 PNL;
- 0052U LPOPRTN BLD W/5 MAJ CLASSES;
- 0053U ONC PRST8 CA FISH ALYS 4 GEN;
- 0054U RX MNTR 14+ DRUGS & SBSTS;
- 0055U CARD HRT TRNSPL 96 DNA SEQ;
- 0056U HEM AML DNA GENE REARGMT;
- 0057U ONC SLD ORG NEO MRNA 51 GENE;
- 0058U ONC MERKEL CLL CARC SRM QUAN;
- 0059U ONC MERKEL CLL CARC SRM +/-;
- 0060U TWN ZYG GEN SEQ ALYS CHRMS2;
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<td>0061U TC MEAS 5 BMRK SFDI M-S ALYS;</td>
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<td>J5/J8</td>
<td><strong>MolDX: Myriad’s BRACAnalysis CDx® Coding and Billing Guidelines</strong></td>
<td>A55224</td>
<td>NA</td>
<td>11/15/2018</td>
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<td>The following unspecified diagnosis codes have been removed from this article. The article has more specific codes in it.</td>
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<td></td>
<td>C50.019 Malignant neoplasm of nipple and areola, unspecified female breast</td>
<td></td>
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<tr>
<td></td>
<td>C50.029 Malignant neoplasm of nipple and areola, unspecified male breast</td>
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<tr>
<td></td>
<td>C50.119 Malignant neoplasm of central portion of unspecified female breast</td>
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<tr>
<td></td>
<td>C50.129 Malignant neoplasm of central portion of unspecified male breast</td>
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<tr>
<td></td>
<td>C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast</td>
<td></td>
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<td>C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast</td>
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<td>C50.319 Malignant neoplasm of lower-inner quadrant of unspecified female breast</td>
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<td>C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast</td>
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<td>C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast</td>
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<td>C50.619 Malignant neoplasm of axillary tail of unspecified female breast</td>
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<td>C50.629 Malignant neoplasm of axillary tail of unspecified male breast</td>
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<td>C50.819 Malignant neoplasm of overlapping sites of unspecified female breast</td>
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<td>C50.829 Malignant neoplasm of overlapping sites of unspecified male breast</td>
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<td>C50.919 Malignant neoplasm of unspecified site of unspecified female breast</td>
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<td>C50.929 Malignant neoplasm of unspecified site of unspecified male breast</td>
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<td>C56.9 Malignant neoplasm of unspecified ovary</td>
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<td></td>
<td>C57.00 Malignant neoplasm of unspecified fallopian tube</td>
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<td><strong>MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™)</strong></td>
<td>L37199</td>
<td>MolDX-026</td>
<td>07/01/2018</td>
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<td>CPT 81479 Unlisted molecular pathology code has been replaced with the new code 0045U Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by realtime RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score.</td>
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<td>J5/J8</td>
<td><strong>Wound Care Coding Companion for Wound Care</strong></td>
<td>A55909</td>
<td>NA</td>
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<td>Added L98.495 to Group One ICD-10 Codes. Also see combined article for ICD-10 CM Code Updates.</td>
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Electronic Data Interchange (EDI)

Claim Status Category and Claim Status Codes Update

MLN Matters Number: MM10925
Related Change Request (CR) Number: 10925
Related CR Release Date: August 24, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4115CP
Implementation Date: January 7, 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) 10925 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 allows the industry 6 months for implementation of newly added or changed codes.

All code changes approved during the September/October 2018 committee meeting shall be posted on these sites on or about November 1, 2018.

The Centers for Medicare & Medicaid Services (CMS) will issue future updates to these codes, as needed. 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 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 CR 10925.

The CMS’ Medicare contractors must comply with the requirements contained in the current standards adopted under HIPAA for electronically submitting certain health care transactions, among them the ASC X12 276/277 Health Care Claim Status Request and Response. These contractors must use valid Claim Status Category Codes and Claim Status Codes when sending ASC X12 277 Health Care Claim Status Responses. They must also use valid Claim Status Category Codes and Claim Status Codes when sending ASC X12 277 Healthcare Claim Acknowledgments. References in CR 10925 to “277 responses” and “claim status responses” encompass both the ASC X12 277 Health Care Claim Status Response and the ASC X12 277 Healthcare Claim Acknowledgment transactions.

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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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: MM10904  Related Change Request (CR) Number: 10904
Related CR Release Date: August 24, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4117CP  Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR 10904 instructs the MACs and Medicare’s Shared System Maintainers to update their systems based on the CORE 360 Uniform Use of CARC, RARC, and CAGC Rule publication. These system updates are based on the CORE Code Combination List to be published on or about October 1, 2018. Make sure that your billing staff is aware of these changes.

BACKGROUND

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

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.
CR10904 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 October 1, 2018. This update is based on the CARC and RARC updates as posted at the Washington Publishing Company (WPC) website on or about July 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. See: [http://www.wpc-edi.com/](http://www.wpc-edi.com/), for 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.

Per the Affordable Care Act mandate, 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 business scenarios. Medicare can use any code combination if the business scenario is not one of the four CORE defined business scenarios. With the four 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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General Information

Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) (2018 Q4)

MLN Matters Number: MM11004  Related Change Request (CR) Number: 11004
Related CR Release Date: November 2, 2018  Effective Date: December 4, 2018
Related CR Transmittal Number: R120GI, R249BP, and R4163CP  Implementation Date: December 4, 2018

PROVIDER TYPE AFFECTED

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

WHAT YOU NEED TO KNOW

CR 11004 updates the Medicare manuals to clarify existing content about SNF policy. These changes correct various omissions and minor technical errors. No policy, processing, or system changes are anticipated.

BACKGROUND

The Medicare General Information, Eligibility, and Entitlement Manual (Pub. 100-01) is revised as follows:

Chapter 4, Section 40.1: This section is revised by adding appropriate cross-references.

Chapter 5, Section 10.2: This section is revised by adding an appropriate cross-reference.

The Medicare Benefit Policy Manual (Pub. 100-02) is revised as follows:

Chapter 8, Section 10.1: This section is revised to correct a cross-reference.

Chapter 8, Section 20.1: This section is revised to clarify that “general inpatient care” under the hospice benefit can count toward meeting the SNF benefit’s qualifying hospital stay requirement only when actually furnished in the hospital setting.

Chapter 8, Section 30.6: This section is revised to correct a typographical error.

Chapter 8, Section 70.4: This section is revised to clarify that HHS’s Office of the Inspector
General (OIG) is the component that addresses questions on interpreting and enforcing the statutory anti-kickback provisions, and by adding an appropriate cross-reference.

**The Medicare Claims Processing Manual (Pub. 100-04) is revised as follows:**

**Chapter 1, Section 30.1.3:** This section is revised by adding appropriate cross-references.

**Chapter 6, Section 10:** This section is revised to clarify that the exclusion of certain customized devices from consolidated billing applies solely to designated prosthetic devices and not to orthotics (which, as a class, remain subject to consolidated billing), and by adding appropriate cross-references.

**Chapter 6, Section 10.1:** This section is revised in order to abbreviate the term “consolidated billing” (CB) consistently throughout the section, and by adding an appropriate cross-reference.

**Chapter 6, Section 10.4.1:** This section is revised to clarify the language on sample agreements between SNFs and their suppliers, and by adding an appropriate cross-reference.

**Chapter 6, Section 20.2.2:** This section is revised to clarify the explanation of why hospice services are not subject to consolidated billing.

**Chapter 6, Section 20.4:** This section is revised to clarify the explanation of why certain Part-D-only preventive vaccines are not subject to consolidated billing.

**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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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 Achievement identifying the length of time of education events. You may use these certificates (without an index number) to receive Continuing Education Units (CEUs) from most accrediting organizations.

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.

Here are some of the events currently available in the Learning Center, for registration and those coming in the near future:

**Teleconferences:**

**New to Medicare Series**
This is a series of teleconferences specifically created for provider staff who have no experience billing Medicare claims. This series is designed to give the billing novice a basic understanding of the Medicare program.

All calls — 9:00 AM - 10:00 AM CT (10:00 AM - 11:00 AM ET)
01/08/2019 — New to Medicare – LCDs and NCDs
02/05/2019 — New to Medicare – Finding What You Need
03/05/2019 — New to Medicare – Getting Started with Provider Enrollment
04/02/2019 — New to Medicare – Determining Patient Eligibility

**Provider Enrollment Series**
Beginning with an Ask-the-Contractor teleconference, this series of teleconferences explains the various processes involved with enrolling as a Medicare provider. Throughout the year, each month will address provider enrollment for specific provider types.

10:00 AM - 11:30 AM CT (11:00 AM - 12:30 PM ET)
01/16/2019 — Provider Enrollment Ask-the-Contractor Teleconference (ACT)
All other calls: 10:00 AM CT - 11:00 AM CT (11:00 AM ET - 12:00 PM ET)
01/16/2019 — Provider Enrollment – Revalidation
02/20/2019 — Provider Enrollment – Physicians
03/20/2019 — Provider Enrollment – Hospitals
2019 Updates to Medicare
WPS GHA Provider Outreach and Education will present a teleconference covering updates to Medicare regulation for 2019. Important updates from final rules and transmittals will be highlighted.

9:00 AM - 11:30 AM CT (8:00 AM - 10:30 AM ET)
01/09/2019 — What's New for 2019

Webinars

9:00 AM – 10:00 AM CT (10:00 AM – 11:00 AM ET)
02/12/2019 — New to Medicare – Exploring Resources

J5A In Person Events

Facilities Completing Provider Enrollment
02/05/2019 — Bellevue, NE — 8:30 AM – 11:30 AM CT

Outpatient Therapy Billing and Payment
02/05/2019 — Bellevue, NE — 1:00 PM – 4:00 PM CT

Outpatient Therapy (PT and OT) – Effective Documentation
02/05/2019 — Bellevue, NE — 8:30 AM – 11:30 AM CT

Redeterminations, Reconsideration or Reopening?
02/06/2019 — Bellevue, NE — 1:00 PM – 4:00 PM CT

Targeted Probe and Educate: Findings and Future Reviews
02/06/2019 — Bellevue, NE — 8:30 AM – 11:30 AM CT

J8A In Person Events
Coming soon!

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. 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, and the All Fee-For-Service Providers Web page at: 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.

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.

2019 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments

MLN Matters Number: MM10968 Related Change Request (CR) Number: 10968
Related CR Release Date: September 28, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4142CP Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10968 provides files for the automated payments of Health Professional Shortage Area (HPSA) bonuses for dates of service January 1, 2019, through December 31, 2019. Make sure your billing staffs are aware of these changes.

BACKGROUND

Section 413(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 mandated an annual update to the automated HPSA bonus payment file. The Centers for Medicare & Medicaid Services (CMS) automated HPSA ZIP code file are populated using the latest designations as close as possible to November 1st of each year. The HPSA ZIP code file shall be made available to the MACs in early December of each year. MACs shall implement the HPSA ZIP code file and for claims with dates of service January 1st to December 31st of the following year and make automatic HPSA bonus payments to physicians providing eligible services in a ZIP code contained on the file.

You should review the Physician Bonuses webpage at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HPSAPSAPhysicianBonuses/index.html each year to determine whether you need to add modifier AQ to your claim in order to receive the bonus payment, or to see if the ZIP code in which you rendered services will automatically receive the HPSA bonus payment.
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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Annual Clotting Factor Furnishing Fee Update 2019

MLN Matters Number: MM10918
Related Change Request (CR) Number: 10918
Related CR Release Date: September 7, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4128CP
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

CR 10918 announces the clotting factor furnishing fee for 2019 is $0.220 per unit. Make sure that your billing staffs are aware of the update to the annual clotting factor furnishing fee for 2019.

BACKGROUND

The Medicare Modernization Act Section 303(e)(1) added Section 1842(o)(5)(C) of the Social Security Act which requires that a furnishing fee will be paid for items and services associated with clotting factor.

The Centers for Medicare & Medicaid Services includes the clotting factor furnishing fee in the published national payment limits for clotting factor billing codes. When the national payment limit for a clotting factor is not included on the Average Sales Price (ASP) Medicare Part B Drug Pricing File or the Not Otherwise Classified (NOC) Pricing File, the MACs make payment for the clotting factor as well as make payment for the furnishing fee. For dates of service from January 1, 2019, through December 31, 2019, the clotting factor furnishing fee of $0.220 per unit is added to the payment limit for the clotting factor.

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>
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<tr>
<td>September 7, 2018</td>
<td>Initial article released.</td>
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Fiscal Year (FY) 2019 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) PPS Changes

MLN Matters Number: MM10869  Related Change Request (CR) Number: 10869
Related CR Release Date: October 4, 2018  Effective Date: October 1, 2018
Related CR Transmittal Number: R4144CP  Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

This MLN Matters® Article is intended for hospitals that submit claims to Medicare Administrative Contractors (MACs) for inpatient hospital services provided to Medicare beneficiaries by acute care and Long-Term Care Hospitals (LTCHs).

PROVIDER ACTION NEEDED

Change Request (CR) 10869 implements Fiscal Year (FY) 2019 policy changes for the Inpatient Prospective Payment System (IPPS) and LTCH PPS. Failure to adhere to these new policies could affect payment of Medicare claims. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The Social Security Amendments of 1983 (P.L. 98-21) provided for establishment of a PPS for Medicare payment of inpatient hospital services. In addition, the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), as amended by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), required Medicare to implement a budget neutral, per discharge PPS for LTCHs based on Diagnosis-Related Groups (DRGs) for cost reporting periods beginning on or after October 1, 2002. The Centers for Medicare & Medicaid Services (CMS makes updates to these prospective payment systems annually. CR10869 outlines those changes for FY 2019.

IPPS FY 2019 Update

The following list of policy changes for FY 2019 were displayed in the Federal Register on August 2, 2018, with a publication date of August 17, 2018, and in the corresponding correction document published on October 3, 2018 in the Federal Register. The Federal Register and CR10869 covers all items in more depth and are effective for hospital discharges occurring on
or after October 1, 2018, through September 30, 2019, unless otherwise noted. New IPPS and LTCH PPS Pricer software packages were released prior to October 1, 2018, that include updated rates that are effective for claims with discharges occurring on or after October 1, 2018, through September 30, 2019. The MACs installed the new revised Pricer programs timely to ensure accurate payments for IPPS and LTCH PPS claims.

Files for download listed throughout CR10869 are available on the CMS website. MACs used the following links for files for download and hospitals may find this information helpful:


Alternatively, the files on the webpages listed above are also available on the CMS website at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html). Click on the link on the left side of the screen titled, “FY 2019 IPPS Final Rule Home Page” or the link titled “Acute Inpatient--Files for Download” (and select ‘Files for FY 2019 Final Rule and Correction Notice’).

**IPPS FY 2019 Update**

**A. FY 2019 IPPS Rates and Factors**

For the Operating Rates/Standardized Amounts and the Federal Capital Rate, refer to Tables 1A-C and Table 1D, respectively, of the FY 2019 IPPS/LTCH PPS Final Rule, available on the FY 2019 Final Rule Tables webpage. For other IPPS factors, including applicable percentage increase, budget neutrality factors, High Cost Outlier (HCO) threshold, and Cost-of-Living Adjustment (COLA) factors, refer to MAC Implementation Files 1 available on the FY 2019 MAC Implementation Files webpage.

**B. Medicare Severity -Diagnosis Related Group (MS-DRG) Grouper and Medicare Code Editor (MCE) Changes**

The Grouper Contractor, 3M Health Information Systems (3M-HIS), developed the new International Classification of Diseases Tenth Edition (ICD-10) MS-DRG Grouper, Version 36.0, software package effective for discharges on or after October 1, 2018. The GROUPER assigns each case into a MS-DRG on the basis of the reported diagnosis and procedure codes and demographic information (that is age, sex, and discharge status). The ICD-10 MCE Version 36.0, which is also developed by 3M-HIS, uses edits for the ICD-10 codes reported to validate correct coding on claims for discharges on or after October 1, 2018.
For discharges occurring on or after October 1, 2018, the Fiscal Intermediary Shared System (FISS) calls the appropriate GROUPER based on discharge date.

For discharges occurring on or after October 1, 2018, the MCE selects the proper internal code edit tables based on discharge date. Note that the MCE version continues to match the Grouper version. CMS increased the number of MS-DRGs from 754 to 761 for FY 2019. CMS is implementing 18 new MS-DRGs for FY 2019 and deleting 11 MS-DRGs.

**FY 2019 New MS-DRGs**

- MS-DRG 783 Cesarean Section with Sterilization with MCC
- MS-DRG 784 Cesarean Section with Sterilization with CC
- MS-DRG 785 Cesarean Section with Sterilization without CC/MCC
- MS-DRG 786 Cesarean Section without Sterilization with MCC
- MS-DRG 787 Cesarean Section without Sterilization with CC
- MS-DRG 788 Cesarean Section without Sterilization without CC/MCC
- MS-DRG 796 Vaginal Delivery with Sterilization/D&C with MCC
- MS-DRG 797 Vaginal Delivery with Sterilization/D&C with CC
- MS-DRG 798 Vaginal Delivery with Sterilization/D&C without CC/MCC
- MS-DRG 805 Vaginal Delivery without Sterilization/D&C with MCC
- MS-DRG 806 Vaginal Delivery without Sterilization/D&C with CC
- MS-DRG 807 Vaginal Delivery without Sterilization/D&C without CC/MCC
- MS-DRG 817 Other Antepartum Diagnoses with O.R. Procedure with MCC
- MS-DRG 818 Other Antepartum Diagnoses with O.R. Procedure with CC
- MS-DRG 819 Other Antepartum Diagnoses with O.R. Procedure without CC/MCC
- MS-DRG 831 Other Antepartum Diagnoses without O.R. Procedure with MCC
- MS-DRG 832 Other Antepartum Diagnoses without O.R. Procedure with CC
- MS-DRG 833 Other Antepartum Diagnoses without O.R. Procedure without CC/MCC

**FY 2019 Deleted MS-DRGs**

- MS-DRG 685 Admit for Renal Dialysis
- MS-DRG 765 Cesarean Section with CC/MCC
- MS-DRG 766 Cesarean Section without CC/MCC
- MS-DRG 767 Vaginal Delivery with Sterilization and/or D&C
- MS-DRG 774 Vaginal Delivery with Complicating Diagnosis
- MS-DRG 775 Vaginal Delivery without Complicating Diagnosis
- MS-DRG 777 Ectopic Pregnancy
- MS-DRG 778 Threatened Abortion
- MS-DRG 780 False Labor
- MS-DRG 781 Other Antepartum Diagnoses with Medical Complications
- MS-DRG 782 Other Antepartum Diagnoses without Medical Complications
CMS revised the titles to the following MS-DRGs for FY 2019:

**MS-DRG Revised Title Descriptions for FY2019**

- MS-DRG 11 Tracheostomy For Face, Mouth & Neck Diagnoses Or Laryngectomy With MCC
- MS-DRG 12 Tracheostomy For Face, Mouth & Neck Diagnoses Or Laryngectomy With CC
- MS-DRG 13 Tracheostomy For Face, Mouth & Neck Diagnoses Or Laryngectomy Without CC/MCC
- MS-DRG 16 Autologous Bone Marrow Transplant With CC/MCC Or T-Cell Immunotherapy
- MS-DRG 864 Fever And Inflammatory Conditions
- MS-DRG 207 Respiratory System Diagnosis With Ventilator Support>96 Hours Or Peripheral Extracorporeal Membrane Oxygenation (ECMO)
- MS-DRG 291 Heart Failure & Shock With MCC Or Peripheral Extracorporeal Membrane Oxygenation (ECMO)
- MS-DRG 296 Cardiac arrest, unexplained w MCC Or Peripheral Extracorporeal Membrane Oxygenation (ECMO)
- MS-DRG 870 Septicemia Or Severe Sepsis With MV >96 Hours Or Peripheral Extracorporeal Membrane Oxygenation (ECMO)

See the ICD-10 MS-DRG V36.0 Definitions Manual Table of Contents and the Definitions of Medicare Code Edits V36 manual at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html) for the complete list of FY 2019 ICD-10 MS-DRGs and Medicare Code Edits.

**C. Post-acute Transfer and Special Payment Policy**

The changes to MS-DRGs for FY 2019 have been evaluated against the general post-acute care transfer policy criteria using the FY 2017 MedPAR data according to the regulations under Sec. 412.4(c). As a result of this review no new MS-DRGs will be added to the list of MS-DRGs subject to the post-acute care transfer policy. However, MS-DRGs 023 (Craniotomy with Major Device Implant or Acute CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) were added to the special payment policy list.

See Table 5 of the FY 2019 IPPS/LTCH PPS Final Rule for a listing of all Post-acute and Special Post-acute MS-DRGs available on the FY 2019 Final Rule Tables.

CMS notes that implementation of the inclusion of discharges to hospice care as a post-acute care transfer subject to the payment adjustments beginning in FY 2019, as required by Section 53109 of the Bipartisan Budget Act of 2018, was addressed in Change Request 10602 (Transmittal 2094; June 20, 2018).
D. New Technology Add-On

The following items will continue to be eligible for new-technology add-on payments in FY 2019:

1. Name of Approved New Technology: Defitelio®
   - Maximum Add-on Payment: $80,500 (Note, this amount has been updated for FY 2019)
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW03392 or XW04392

2. Name of Approved New Technology: ZINPLAVA™
   - Maximum Add-on Payment: $1,900
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW033A3 or XW043A3

3. Name of Approved New Technology: Stelara®
   - Maximum Add-on Payment: $2,400
   - Identify and make new technology add-on payments with ICD-10-PCS procedure code: XW033F3

The following items are eligible for new-technology add-on payments in FY 2019:

1. Name of Approved New Technology: VYXEOS™
   - Maximum Add-on Payment: $36,425
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW033B3 or XW043B3

2. Name of Approved New Technology: Remedē® System
   - Maximum Add-on Payment: $17,250
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: 0JH60DZ and 05H33MZ in combination with procedure code: 05H03MZ or 05H43MZ

3. Name of Approved New Technology: GIAPREZA™
   - Maximum Add-on Payment: $1,500
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW033H4 or XW043H4

4. Name of Approved New Technology: AndexXa™
   - Maximum Add-on Payment: $14,062.50
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW03372 or XW04372
5. Name of Approved New Technology: Sentinel® Cerebral Protection System™
   - Maximum Add-on Payment: $1,400
   - Identify and make new technology add-on payments with ICD-10-PCS procedure code: X2A5312

6. Name of Approved New Technology: Aquabeam®
   - Maximum Add-on Payment: $1,250
   - Identify and make new technology add-on payments with ICD-10-PCS procedure code: XV508A4

7. Name of Approved New Technology: VABOMERE™
   - Maximum Add-on Payment: $5,544
   - Identify and make new technology add-on payments with an NDC of 70842012001 or 65293000901 (VABOMERE™ Meropenem-Vaborbactam Vial)

8. Name of Approved New Technology: ZEMDRI™ (Plazomicin)
   - Maximum Add-on Payment: $2,722.50
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW033G4 or XW043G4

9. Name of Approved New Technology: Kymriah®/Yescarta®
   - Maximum Add-on Payment: $186,500
   - Identify and make new technology add-on payments with ICD-10-PCS procedure codes: XW033C3 or XW043C3

E. Cost of Living Adjustment (COLA) Update for IPPS PPS

There are no changes to the COLA factors for FY 2019. For reference, a table showing the applicable COLAs that are effective for discharges occurring on or after October 1, 2018, is available in the FY 2019 IPPS/LTCH PPS final rule and in MAC Implementation File 1 available on the FY 2019 MAC Implementation Files webpage.

F. Wage Index Changes and Issues

1. New CBSA
   In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. As discussed in the FY 2019 final rule, effective for FY 2019 new urban 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.
2. Section 505 Hospitals (Out-Commuting Adjustment)

Section 505 of the Medicare Modernization Act of 2003 (MMA), also known as the “outmigration adjustment,” is an adjustment that is based primarily on commuting patterns and is available to hospitals that are not reclassified by the Medicare Geographic Classification Review Board (MGCRB), reclassified as a rural hospital under § 412.103, or redesignated under Section 1886(d)(8)(B) of the Act.

G. Treatment of Certain Providers Redesignated Under Section 1886(d)(8)(B) of the Act and Certain Urban Hospitals Reclassified as Rural Hospitals Under Section 412.103

42 CFR 412.64(b)(3)(ii) implements Section 1886(d)(8)(B) of the Act, which redesignates certain rural counties adjacent to one or more urban areas as urban for the purposes of payment under the IPPS. (These counties are commonly referred to as “Lugar counties”.) Accordingly, hospitals located in Lugar counties are deemed to be located in an urban area and their IPPS payments are determined based upon the urban area to which they are redesignated. A hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and is considered rural for all IPPS purposes. The list of hospitals that have waived Lugar status for FY 2019 is available on the FY 2019 MAC Implementation File webpage.

An urban hospital that reclassifies as a rural hospital under § 412.103 is considered rural for all IPPS purposes. Note, hospitals reclassified as rural under § 412.103 are not eligible for the capital Disproportionate Share Hospitals (DSH) adjustment since these hospitals are considered rural under the capital PPS (see § 412.320(a)(1)).

H. Multicampus Hospitals

1. Wage Index

Beginning with the FY 2008 wage index, CMS instituted a policy that allocates the wages and hours to the CBSA in which a hospital campus is located when a multi-campus hospital has campuses located in different CBSAs. Medicare payment to a hospital is based on the geographic location of the hospital facility at which the discharge occurred. Therefore, if a hospital has a campus or campuses in different CBSAs, the MAC adds a suffix to the CCN of the hospital in the Provider Specific File (PSF), to identify and denote a sub-campus in a different CBSA, so that the appropriate wage index associated with each campus’s geographic location can be assigned and used for payment for Medicare discharges from each respective campus. Also, note that, under certain circumstances, it is permissible for individual campuses to have reclassifications to another CBSA, in which case, the appropriate reclassified CBSA and wage index is noted in the PSF. In general, subordinate campuses are subject to the same rules regarding withdrawals and cancellations of reclassifications as main providers.

2. Qualification for Certain Special Statuses

In the FY 2019 Final rule, CMS codified its current policies regarding how multi-campus hospitals may qualify for special status as a Sole-Community Hospital (SCH), Rural Referral Center (RRC), Medicare-Dependent Hospital (MDH), and rural reclassification under § 412.103.
Specifically, the main campus of a hospital cannot obtain a SCH, RRC, or MDH status or rural reclassification independently or separately from its remote location(s), and vice versa. Rather, the hospital (the main campus and its remote location(s)) are granted the special treatment or rural reclassification as one entity if the criteria are met. To meet the criteria, combined data from the main campus and its remote location(s) are used where the regulations at § 412.92 for SCH, § 412.96 for RRC, § 412.103 for rural reclassification, and § 412.108 for MDH require data, such as bed count, number of discharges, or case-mix index, for example. Where the regulations require data that cannot be combined, specifically qualifying criteria related to location, mileage, travel time, and distance requirements, the hospital needs to demonstrate that the main campus and its remote location(s) each independently satisfy those requirements in order for the entire hospital, including its remote location(s), to be reclassified as rural or obtain a special status.

I. Updating the PSF for Wage Index, Reclassifications and Redesignations

MACs will update the PSF by following the steps, in order, in Attachment 1 of CR10869 to determine the appropriate wage index and other payments.

J. Hospital Specific (HSP) Rate Factors for Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospital (MDH) Program

For FY 2019, MACs must update the Hospital-Specific (HSP) amount in the PSF for all SCHs and MDHs. The HSP amount must be updated from FY 2012 dollars to FY 2018 dollars by applying an update factor of 1.04058 to the current HSP amount in the PSF before entering this final amount in the PSF with an effective date of 10/1/2018. The factor of 1.04058 represents the product of all of the annual market basket updates (that is, applicable percentage increases), the DRG budget neutrality factors for FYs 2012 through 2018, and the cumulative documentation and coding adjustment factor for FYs 2011 through 2014 of 0.9480. PRICER will apply the update and DRG budget neutrality factor to the HSP amount for FY 2019.

K. Low-Volume Hospitals – Criteria and Payment Adjustments for FY2019

Section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Specifically, Section 50204 amended the qualifying criteria for low-volume hospitals to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 50204 also amended the statute to provides that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for hospitals with 500 or fewer discharges to 0 percent additional payment for hospitals with more than 3,800 total discharges in the fiscal year. A hospital’s total discharges, which includes Medicare and non-Medicare discharges, is based on the hospital’s most recently submitted cost report. The regulations implementing the hospital payment adjustment policy are at section 412.101. For FY 2019, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2018, in order for the applicable low-volume
payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2018 (through September 30, 2019). Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment for FY 2018 may continue to receive a low-volume hospital payment adjustment for FY 2019 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2019. As in previous years, such a hospital had to send written verification that was received by its MAC no later than September 1, 2018, stating that it meets the mileage criterion applicable for FY 2019. If a hospital’s request for low-volume hospital status for FY 2019 was received after September 1, 2018, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital’s FY 2019 discharges, effective prospectively within 30 days of the date of the MAC’s low-volume hospital status determination.

For FY 2019, for each qualifying hospital, MACs must determine the low-volume hospital payment adjustment using the hospital’s total discharges in its most recently submitted cost report as of the time of the MAC’s low-volume hospital status determination as follows:

- For hospitals with 500 or fewer total discharges, the adjustment is an additional 25 percent for each Medicare discharge.
- For hospitals with 501 and fewer than 3,800 total discharges, the adjustment for each Medicare discharge is an additional percent calculated using the formula: \((95 / 330) - \left(\frac{\text{number of total discharges}}{13,200}\right)\)

As noted above, “number of total discharges” includes Medicare and non-Medicare discharges and based on the hospital’s most recently submitted cost report at the time of the hospital’s low-volume hospital payment adjustment request.

**L. Hospital Quality Initiative**

The hospitals that will receive the quality initiative bonus are listed at the following Web site: [www.qualitynet.org](http://www.qualitynet.org). Should a provider later be determined to have met the criteria after publication of this list, they will be added to the Web site. A list of hospitals that will receive the statutory reduction to the annual payment update for FY 2019 under the Hospital IQR Program is available in MAC Implementation File 3 available on the FY 2019 MAC Implementation Files webpage.

**M. Hospital Acquired Condition Reduction Program (HAC)**

The Hospital-Acquired Conditions (HAC) Reduction Program requires the Secretary of Health and Human Services (HHS) to adjust payments to hospitals that rank in the worst-performing 25 percent of all subsection (d) hospitals with respect to HAC quality measures. Hospitals with a Total HAC Score greater than the 75th percentile of all Total HAC Scores (that is, the worst-performing quartile) will be subject to a 1 percent payment reduction. This payment adjustment applies to all Medicare discharges for that fiscal year.

CMS did not make the list of providers subject to the HAC Reduction Program for FY 2019 public in the final rule because hospitals had until August 2018 to notify CMS of any errors in the calculation of their Total HAC Score under the Scoring Calculations Review and Corrections
period. Updated hospital level data for the HAC Reduction Program will be made publicly available on the Hospital Compare website following the review and corrections process in January 2019.

**N. Hospital Value Based Purchasing (VBP)**

For FY 2019 CMS will implement the base operating MS-DRG payment amount reduction and the value-based incentive payment adjustments, as a single value-based incentive payment adjustment factor applied to claims for discharges occurring in FY 2019. CMS expects to post the final value-based incentive payment adjustment factors for FY 2019 in the near future in Table 16B of the FY 2019 IPPS/LTCH PPS final rule (which will be available through the Internet on the FY 2019 IPPS/LTCH PPS Final Rule Tables webpage).

**O. Hospital Readmissions Reduction Program (HRRP)**

CMS expects to post the HRRP payment adjustment factors for FY 2019 in Table 15 of the FY 2019 IPPS/LTCH PPS final rule (which are available on the FY 2019 IPPS Final Rule Tables webpage). Hospitals that are not subject to a reduction under the HRRP in FY 2019 (such as Maryland hospitals), have a readmission adjustment factor of 1.0000. For FY 2019, hospitals should only have a readmission adjustment factor between 1.0000 and 0.9700.

**P. Medicare Disproportionate Share Hospitals (DSH) Program**

Section 3133 of the Affordable Care Act modified the Medicare DSH program beginning in FY 2014. Under current law, hospitals received 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH. The remainder, equal to 75 percent of what otherwise would have been paid as Medicare DSH, will become an uncompensated care payment after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH hospital will receive a portion of the aggregate amount available for uncompensated care payments based on its share of total uncompensated care reported by Medicare DSH hospitals.

The Medicare DSH payment is reduced to 25 percent of the amount they previously would have received under the current statutory formula in PRICER. The calculation of the Medicare DSH payment adjustment will remain unchanged and the 75 percent reduction to the DSH payment is applied in PRICER.

The total uncompensated care payment amount to be paid to Medicare DSH hospitals was finalized in the FY 2019 IPPS Final Rule, and the uncompensated care payment will continue to be paid on the claim as an estimated per discharge amount to the hospitals that have been projected to receive Medicare DSH for FY 2019. The Uncompensated Care Per Discharge Amount and Projected DSH Eligibility are located in the Medicare DSH Supplemental Data File for FY 2019, which are available on the FY 2019 Final Rule Data Files webpage.

For FY 2019, new hospitals with a CCN established after October 1, 2015 that are eligible for Medicare DSH will have their Factor 3 calculated at cost report settlement using uncompensated care costs reported on Line 30 of Worksheet S-10 as the numerator and a denominator of $30,210,112,106. Factor 3 is then applied to the total uncompensated care
payment amount finalized in the FY 2019 IPPS Final Rule to determine the total amount to be paid to the hospital. If a new hospital has a CCR on line 1 of Worksheet S-10 in excess of 0.93, MACs will contact Section3133DSH@cms.hhs.gov for further instructions on how to calculate the uncompensated care costs for the numerator. MACs can refer to the Medicare DSH Supplemental Data File on the CMS website to confirm whether a hospital should be treated as new. CMS notes it is possible that there are additional new hospitals during FY 2019 and therefore those would not be listed on the Medicare DSH Supplemental Date File. In the case of a new hospital in Puerto Rico, the hospital's Factor 3 would need to be calculated by the MAC based on cost report’s Medicaid days, which may need to be annualized, plus 14% for SSI proxy, and then divided by denominator of 37,539,919.

Q. Recalled Devices

A hospital's IPPS payment is reduced, for specified MS-DRGs when the implantation of a device is replaced without cost or with a credit equal to 50 percent or more of the cost of the replacement device. New MS-DRGs are added to the list subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit when they are formed from procedures previously assigned to MS-DRGs that were already on the list. There are no new MS-DRGs for FY 2019 subject to the policy for replaced devices offered without cost or with a credit.

LTCH PPS FY 2019 Update

A. FY 2019 LTCH PPS Rates and Factors

The FY 2019 LTCH PPS Standard Federal Rates are located in Table 1E available on the FY 2019 Final Rule Tables webpage. Other FY 2019 LTCH PPS Factors are available in MAC Implementation File 2 on the FY 2019 MAC Implementation File webpage.

The LTCH PPS Pricer is updated with the Version 36.0 MS-LTC-DRG table, weights and factors, effective for discharges occurring on or after October 1, 2018, and on or before September 30, 2019.

B. Application of the Site Neutral Payment Rate

Section 1886(m)(6) of the Act establishes patient-level criteria for payments under the LTCH PPS for cost reporting periods beginning on or after October 1, 2015. LTCH discharges that do not meet the patient-level criteria are paid the site neutral payment rate. The application of the site neutral payment rate is codified in the regulations at § 412.522.

The statute originally established a transitional blended payment rate for site neutral payment rate LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, which was extended by subsequent legislation to cost reporting periods beginning during FY 2018 and FY 2019. The blended payment rate is comprised of 50 percent of the site neutral payment rate for the discharge and 50 percent of the LTCH PPS standard Federal payment rate that would have applied to the discharge. This transitional blended payment rate for site neutral
rate LTCH discharges is included in the Pricer logic.

Under Section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123), the IPPS comparable amount under the site neutral payment rate is reduced by 4.6 percent for FYs 2018 through 2026. This adjustment is included in the Pricer logic.

The temporary exception to the site neutral payment rate for certain severe wound discharges from certain LTCHs expires for cost reporting periods that begin on or after October 1, 2018.

C. The 25-Percent Threshold Policy

CMS eliminated the 25-percent threshold policy in the FY 2019 IPPS/LTCH PPS final rule, effective October 1, 2018. Accordingly, the regulations describing the 25-percent threshold policy at Section 412.538 have been removed and reserved.

D. LTCH Quality Reporting (LTCHQR) Program

Under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program, for FY 2019, the annual update to a standard Federal rate will continue to be reduced by 2.0 percentage points if a LTCH does not submit quality-reporting data in accordance with the LTCHQR Program for that year.

E. Provider Specific File (PSF)

The PSF required fields for all provider types, which require a PSF are available in Pub. 100-04, Medicare Claims Processing Manual, Chapter 3, §20.2.3.1 and Addendum A.

In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. As discussed in the FY 2019 final rule, effective for FY 2019 new urban 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

Table 8C contains the FY 2019 Statewide average LTCH total Cost-to-Charge Ratios (CCRs) for urban and rural LTCHs. Table 8C is available on the FY 2019 Final Rule Tables webpage. Per the regulations in 42 CFR Sections 412.525(a)(4)(iv)(C) and 412.529(f)(4)(iii), for FY 2019, Statewide average CCRs are used in the following instances:

1. New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, a new hospital is defined as an entity that has not accepted assignment of an existing hospital’s provider agreement in accordance with 42 CFR Section 489.18).
2. LTCHs with a total CCR is in excess of 1.280 (referred to as the total CCR ceiling).
3. Any hospital for which data to calculate a CCR is not available.
NOTE: Hospitals and/or MACs can request an alternative CCR to the statewide average CCR per the instructions in Section 150.24 of Chapter 3 of Pub. 100-04, Medicare Claims Processing Manual.

F. Cost of Living Adjustment (COLA) under the LTCH PPS

There are no updates to the COLAs for FY 2019. The COLAs effective for discharges occurring on or after October 1, 2018 are available in the FY 2019 IPPS/LTCH PPS final rule and are also located in MAC Implementation File 2 available on the FY 2019 MAC Implementation Files webpage. (Note that the same COLA factors are used under the IPPS and the LTCH PPS for FY 2019.)

G. Discharge Payment Percentage

Beginning with LTCHs’ FY 2016 cost reporting periods, the statute requires LTCHs to be notified of their “Discharge Payment Percentage” (DPP), which is the ratio (expressed as a percentage) of the LTCHs’ FFS discharges which received LTCH PPS standard Federal rate payment to the LTCHs’ total number of LTCH PPS discharges. MACs shall continue to provide notification to the LTCH of its DPP upon final settlement of the cost report.

Hospitals Excluded from the IPPS

The update to extended neoplastic disease care hospital’s target amount is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is equal to the percentage increase projected by the hospital market basket index. In the FY 2019 IPS/LTCH PPS final rule, CMS established an update to an extended neoplastic disease care hospital’s target amount for FY 2018 of 2.9 percent.

ADDITIONAL INFORMATION

The official instruction, CR10869, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4144CP.pdf. 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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Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2019

MLN Matters Number: MM10992 Related Change Request (CR) Number: CR10992
Related CR Release Date: October 19, 2018 Effective Date: January 1, 2019
Related CR Transmittal Number: R4148CP Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Home Health Agencies (HHAs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

CR10992 updates the 60-day national episode rates, the national per-visit amounts, Low Utilization Payment Adjustment (LUPA) add-on amounts, the non-routine medical supply payment amounts, and the cost-per-unit payment amounts used for calculating outlier payments under the HH PPS for CY 2019. Make sure that your billing staffs are aware of these changes.

BACKGROUND

Section 1895(b)(3)(B) of the Social Security Act (the Act) requires that the Medicare Home Health Prospective Payment System (HH PPS) rates provided to HHAs for furnishing home health services, must be updated annually. The CY 2019 HH PPS rate update includes an update to the case-mix weights as provided by Section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act. The CY 2019 HH PPS rates for services provided to beneficiaries who reside in rural areas will be increased as required by Section 421(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as amended by Section 50208 of the Bipartisan Budget Act of 2018.

Market Basket Update

Section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended Section 1895(b)(3)(B) of the Act, increasing the market basket percentage for home health payments for CY 2019 to 2.2 percent. Further, Section 1895(b)(3)(B) of the Act requires that the home health payment update be decreased by 2 percentage points for those Home Health Agencies (HHAs) that do not submit quality data as required by the Secretary of Health
and Human Services. For HHAs that do not submit the required quality data for CY 2019, the home health payment update would be 0.2 percent (2.2 percent minus 2 percentage points). The CY 2019 HH PPS final rule also changed the labor-related share used to wage-adjust payments under the HH PPS to 76.1 percent and the corresponding non-labor-related share to 23.9 percent.

**National, Standardized 60-Day Episode Payment**

As described in the CY 2019 HH PPS final rule, in order to calculate the CY 2019 national, standardized 60-day episode payment rate, the Centers for Medicare & Medicaid Services (CMS) applies a wage index budget neutrality factor of 0.9985 and a case-mix budget neutrality factor of 1.0169 to the previous calendar year's national, standardized 60-day episode rate ($3,039.64). Additionally, the national, standardized 60-day episode payment rate is updated by the CY 2019 HH payment update percentage of 2.2 percent for HHAs that submit the required quality data and by 2.2 percent minus 2 percentage points, or 0.2 percent, for HHAs that do not submit quality data. These two episode payment rates are shown in Tables 1 and 2, below. Please note that these payments are further adjusted by the individual episode's case-mix weight and by the wage index.

**Table 1 - CY 2019 National, Standardized 60-Day Episode Payment Amount**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$3,039.64</td>
<td>X 0.9985</td>
<td>X 1.0169</td>
<td>X 1.022</td>
<td>$3,154.27</td>
</tr>
</tbody>
</table>

**Table 2 - CY 2019 National, Standardized 60-Day Episode Payment Amount for HHAs That DO NOT Submit the Quality Data**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$3,039.64</td>
<td>X 0.9985</td>
<td>X 1.0169</td>
<td>X 1.002</td>
<td>$3,092.55</td>
</tr>
</tbody>
</table>

**National Per-Visit Rates**

To calculate the CY 2019 national per-visit payment rates, CMS starts with the CY 2018 national per-visit rates and applies a wage index budget neutrality factor of 0.9996 to ensure budget neutrality for LUPA per-visit payments after applying the CY 2019 wage index. The per-visit rates are then updated by the CY 2019 HH payment update of 2.2 percent for HHAs that submit the required quality data and by 0.2 percent for HHAs that do not submit quality data.
The per-visit rates are shown in Tables 3 and 4, below.

**Table 3 - CY 2019 National Per-Visit Payment Amounts for HHAs That DO Submit the Required Quality Data**

<table>
<thead>
<tr>
<th>HH Discipline</th>
<th>CY 2018 Per-Visit Payment</th>
<th>Wage Index Budget Neutrality Factor</th>
<th>CY 2019 HH Payment Update</th>
<th>CY 2019 Per-Visit Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Health Aide</td>
<td>$64.94</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$66.34</td>
</tr>
<tr>
<td>Medical Social Services</td>
<td>$229.86</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$234.82</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>$157.83</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$161.24</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>$156.76</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$160.14</td>
</tr>
<tr>
<td>Skilled Nursing</td>
<td>$143.40</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$146.50</td>
</tr>
<tr>
<td>Speech- Language Pathology</td>
<td>$170.38</td>
<td>X 0.9996</td>
<td>X 1.022</td>
<td>$174.06</td>
</tr>
</tbody>
</table>

**Table 4 - CY 2019 National Per-Visit Payment Amounts for HHAs That DO NOT Submit the Required Quality Data**

<table>
<thead>
<tr>
<th>HH Discipline</th>
<th>CY 2018 Per-Visit Rates</th>
<th>Wage Index Budget Neutrality Factor</th>
<th>CY 2019 HH Payment Update Minus 2 Percentage Points</th>
<th>CY 2019 Per-Visit Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Health Aide</td>
<td>$64.94</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$65.04</td>
</tr>
<tr>
<td>Medical Social Services</td>
<td>$229.86</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$230.23</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>$157.83</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$158.08</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>$156.76</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$157.01</td>
</tr>
<tr>
<td>Skilled Nursing</td>
<td>$143.40</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$143.63</td>
</tr>
<tr>
<td>Speech- Language Pathology</td>
<td>$170.38</td>
<td>X 0.9996</td>
<td>X 1.002</td>
<td>$170.65</td>
</tr>
</tbody>
</table>

**Non-Routine Supply Payments**

CMS computes payments for Non-Routine Supplies (NRS) by multiplying the relative weight for a particular NRS severity level by an NRS conversion factor. To determine the CY 2019 NRS conversion factors, CMS updates the CY 2018 NRS conversion factor by the CY 2019 HH payment update of 2.2 percent for HHAs that submit the required quality data and by 0.2 percent for HHAs that do not submit quality data. CMS does not apply any standardization factors as the NRS payment amount calculated from the conversion factor is neither wage nor case-mix adjusted when the final payment amount is computed. The NRS conversion factor for CY 2019 payments for HHAs that do submit the required quality data is shown in Table 5a and the payment amounts for the various NRS severity levels are shown in Table 5b. The NRS conversion factor for CY 2019 payments for HHAs that do not submit quality data is shown in Table 6a and the payment amounts for the various NRS severity levels are shown in Table 6b.
### Table 5A
CY 2019 NRS Conversion Factor for HHAs That DO Submit the Required Quality Data

<table>
<thead>
<tr>
<th>CY 2018 NRS Conversion Factor</th>
<th>CY 2019 HH Payment Update</th>
<th>CY 2019 NRS Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>$53.03</td>
<td>X 1.022</td>
<td>$54.20</td>
</tr>
</tbody>
</table>

### Table 5B:
CY 2019 NRS Payment Amounts for HHAs That DO Submit the Required Quality Data

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Points (Scoring)</th>
<th>Relative Weight</th>
<th>CY 2019 NRS Conversion Factor</th>
<th>CY 2019 NRS Payment Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0.2698</td>
<td>$54.20</td>
<td>$14.62</td>
</tr>
<tr>
<td>2</td>
<td>1 to 14</td>
<td>0.9742</td>
<td>$54.20</td>
<td>$52.80</td>
</tr>
<tr>
<td>3</td>
<td>15 to 27</td>
<td>2.6712</td>
<td>$54.20</td>
<td>$144.78</td>
</tr>
<tr>
<td>4</td>
<td>28 to 48</td>
<td>3.9686</td>
<td>$54.20</td>
<td>$215.10</td>
</tr>
<tr>
<td>5</td>
<td>49 to 98</td>
<td>6.1198</td>
<td>$54.20</td>
<td>$331.69</td>
</tr>
<tr>
<td>6</td>
<td>99+</td>
<td>10.5254</td>
<td>$54.20</td>
<td>$570.48</td>
</tr>
</tbody>
</table>

### Table 6A:
CY 2019 NRS Conversion Factor for HHAs That DO NOT Submit the Required Quality Data

<table>
<thead>
<tr>
<th>CY 2018 NRS Conversion Factor</th>
<th>CY 2019 HH Payment Update Percentage Minus 2 Percentage Points</th>
<th>CY 2019 NRS Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>$53.03</td>
<td>X 1.002</td>
<td>$53.14</td>
</tr>
</tbody>
</table>

### Table 6B:
CY 2019 NRS Payment Amounts for HHAs That DO NOT Submit the Required Quality Data

<table>
<thead>
<tr>
<th>Severity Level</th>
<th>Points (Scoring)</th>
<th>Relative Weight</th>
<th>CY 2019 NRS Conversion Factor</th>
<th>CY 2019 NRS Payment Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0.2698</td>
<td>$54.20</td>
<td>$14.34</td>
</tr>
<tr>
<td>2</td>
<td>1 to 14</td>
<td>0.9742</td>
<td>$54.20</td>
<td>$51.77</td>
</tr>
<tr>
<td>3</td>
<td>15 to 27</td>
<td>2.6712</td>
<td>$54.20</td>
<td>$141.95</td>
</tr>
<tr>
<td>4</td>
<td>28 to 48</td>
<td>3.9686</td>
<td>$54.20</td>
<td>$210.89</td>
</tr>
<tr>
<td>5</td>
<td>49 to 98</td>
<td>6.1198</td>
<td>$54.20</td>
<td>$325.21</td>
</tr>
<tr>
<td>6</td>
<td>99+</td>
<td>10.5254</td>
<td>$54.20</td>
<td>$559.32</td>
</tr>
</tbody>
</table>
Rural Add-On Provision

Section 421(b)(1) of the MMA, as amended by Section 50208 of the BBA of 2018, provides that rural counties would be placed into one of three categories for purposes of receiving HH rural add-on payments:

1. Rural counties and equivalent areas in the highest quartile of all counties or equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under part A of Medicare or enrolled for benefits under part B of Medicare only, but not enrolled in a Medicare Advantage plan under part C of Medicare, as provided in Section 421(b)(1)(A) of the MMA (the “High utilization” category)

2. Rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the category provided in Section 421(b)(1)(A) of the MMA, as provided in Section 421(b)(1)(B) of the MMA (the “Low population density” category)

3. Rural counties and equivalent areas not in the categories provided in either Sections 421(b)(1)(A) or 421(b)(1)(B) of the MMA, as provided in Section 421(b)(1)(C) of the MMA (the “All other” category)

CY 2019 HH PPS payments will be increased by:
- 1.5 percent when services are provided to beneficiaries who reside in rural counties and equivalent areas in the “High utilization” category
- 4.0 percent when services are provided to beneficiaries who reside in rural counties and equivalent areas in the “Low population density” category
- 3.0 percent when services are provided to beneficiaries who reside in rural counties and equivalent areas in the “All other” category.

Beginning in CY 2019, HHAs will be required to enter the Federal Information Processing Standards (FIPS) state and county code where the beneficiary resides on each claim. HHAs will continue to enter Core Based Statistical Area (CBSA) codes on the claims.

Outlier Payments

The Fixed Dollar Loss (FDL) ratio and the loss-sharing ratio used to calculate outlier payments must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by Section 1895(b)(5)(A) of the Act). Historically, CMS has used a value of 0.80 for the loss-sharing ratio which, it is believed, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made based under the HH PPS, CMS is revising the FDL ratio for CY 2019 from 0.55 to 0.51 to better approximate the 2.5 percent statutory maximum. It is not revising the loss-sharing ratio of 0.80.

In the CY 2017 HH PPS final rule (81 FR 76702), CMS finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes,
accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, CMS now converts the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. The cost-per-unit payment rates used for the calculation of outlier payments are in the following Tables:

Table 7a: Cost-Per-Unit Payment Rates for the Calculation of Outlier Payments for HHAs that **DO** Submit the Required Quality Data

<table>
<thead>
<tr>
<th>HH Discipline</th>
<th>Average Minutes per Visit</th>
<th>CY 2019 Per-Visit Payment</th>
<th>Cost-per-unit (1 unit = 15 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Health Aide</td>
<td>63.0</td>
<td>$66.34</td>
<td>$15.80</td>
</tr>
<tr>
<td>Medical Social Services</td>
<td>56.5</td>
<td>$234.82</td>
<td>$62.34</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>47.1</td>
<td>$161.24</td>
<td>$51.35</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>46.6</td>
<td>$160.14</td>
<td>$51.55</td>
</tr>
<tr>
<td>Skilled Nursing</td>
<td>44.8</td>
<td>$146.50</td>
<td>$49.05</td>
</tr>
<tr>
<td>Speech- Language Pathology</td>
<td>48.1</td>
<td>$174.06</td>
<td>$54.28</td>
</tr>
</tbody>
</table>

Table 7b: Cost-Per-Unit Payment Rates for the Calculation of Outlier Payments for HHAs that **DO NOT** Submit the Required Quality Data

<table>
<thead>
<tr>
<th>HH Discipline</th>
<th>Average Minutes per Visit</th>
<th>CY 2019 Per-Visit Payment</th>
<th>Cost-per-unit (1 unit = 15 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Health Aide</td>
<td>63.0</td>
<td>$65.04</td>
<td>$15.49</td>
</tr>
<tr>
<td>Medical Social Services</td>
<td>56.5</td>
<td>$230.23</td>
<td>$61.12</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>47.1</td>
<td>$158.08</td>
<td>$50.34</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>46.6</td>
<td>$157.01</td>
<td>$50.54</td>
</tr>
<tr>
<td>Skilled Nursing</td>
<td>44.8</td>
<td>$143.63</td>
<td>$48.09</td>
</tr>
<tr>
<td>Speech- Language Pathology</td>
<td>48.1</td>
<td>$170.65</td>
<td>$53.22</td>
</tr>
</tbody>
</table>
ADDITIONAL INFORMATION

The official instruction, CR10992, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4148CP.pdf. Part of the CR includes an updated version of the Medicare Claims Processing Manual, Chapter 10 (Home Health Agency Billing), Section 70.4 (Decision Logic Used by the Pricer on Claims).

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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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>November 16, 2018</td>
<td>Initial article released.</td>
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</table>

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Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2019

MLN Matters Number: MM11021  Related Change Request (CR) Number: 11021

Related CR Release Date: November 14, 2018  Effective Date: January 1, 2019

Related CR Transmittal Number: R250BP  Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for End Stage Renal Disease (ESRD) facilities that submit claims to Medicare Administrative Contractors (MACs) for renal dialysis services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR11021 implements the Calendar Year (CY) 2019 rate updates for the ESRD Prospective Payment System (PPS) and updates the payment for renal dialysis services furnished to beneficiaries with Acute Kidney Injury (AKI) in ESRD facilities. The CR also includes some changes to Chapter 11, Section 60 of the Medicare Benefit Policy Manual, with the revised manual section attached to CR11021. Please make sure that your billing staffs are aware of these changes.

BACKGROUND

Effective January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the ESRD PPS based on the requirements of Section 1881(b)(14) of the Social Security Act (the Act) as added by Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA). Section 1881(b)(14)(F) of the Act, as added by Section 153(b) of MIPPA and amended by Section 3401(h) of the Affordable Care Act established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in Section 1886(b)(3)(B)(xi)(II) of the Act. The ESRD bundled (ESRDB) market basket increase factor minus the productivity adjustment will update the ESRD PPS base rate.

As required by section 1834(r) of the Act, CMS pays ESRD facilities for furnishing renal dialysis

The ESRD PPS includes consolidated billing requirements for limited Part B services included in the ESRD facility’s bundled payment. CMS periodically updates the lists of items and services that are subject to Part B consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

CY 2019 ESRD PPS Updates are as follows:

**ESRD PPS base rate:**

2. A wage index budget-neutrality adjustment factor of 0.999506. ($235.39 × 0.999506 = $235.27)

**Wage index:**

1. The wage index adjustment will be updated to reflect the latest available wage data.
2. The wage index floor will increase to 0.50.

**Labor-related share:**

The labor-related share should be updated to 52.3 percent.

**Outlier Policy:**

CMS made the following updates to the adjusted average outlier service Medicare Allowable Payment (MAP) amount per treatment:

1. For adult patients, the adjusted average outlier service MAP amount per treatment is $38.51.
2. For pediatric patients, the adjusted average outlier service MAP amount per treatment is $35.18.

CMS made the following updates to the Fixed Dollar Loss (FDL) amount that is added to the predicted MAP to determine the outlier threshold:

1. The fixed dollar loss amount is $65.11 for adult patients.
2. The fixed dollar loss amount is $57.14 for pediatric patients.

CMS made the following changes to the list of outlier services:

1. Renal dialysis drugs that are oral equivalents to injectable drugs are based on the most recent prices retrieved from the Medicare Prescription Drug Plan Finder, are updated to
reflect the most recent mean unit cost. In addition, CMS will add or remove any renal dialysis items and services that are eligible for outlier payment. See Attachment A of CR11021 for a list of these drugs.

2. The mean dispensing fee of the National Drug Codes (NDCs) qualifying for outlier consideration is revised to $0.75 per NDC per month for claims with dates of service on or after January 1, 2019.

**Consolidated Billing Requirements:**

For CY 2019, there are no changes to the ESRD PPS consolidated billing requirements. The current version of the consolidated billing requirements are available at [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).

**New non-ESRD Healthcare Common Procedure Coding System (HCPCS) code**

There is a new HCPCS Q5106 for Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units. This code will not be permitted on the Type of Bill 072x for an ESRD PPS claim. It is permitted for AKI claims as discussed in CR10839. (See the related MLN Matters article at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10839.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10839.pdf).

**CY 2019 AKI Dialysis Payment Rate for Renal Dialysis Services:**

1. Beginning January 1, 2019, CMS will pay ESRD facilities $235.27 per treatment.
2. The labor-related share is 52.3 percent.
3. The AKI dialysis payment rate will be adjusted for wages using the same wage index that is used under the ESRD PPS.
4. The AKI dialysis payment rate is not reduced for the ESRD Quality Incentive Program (QIP).
5. The Transitional Drug Add-on Adjustment (TDAPA) does not apply to AKI claims.

The key changes made to the Medicare Benefit Policy Manual, Chapter 11, Section 60 are as follows:

- To qualify for the comorbidity adjustment there must be adherence to diagnosis coding requirements. Diagnosis codes are updated annually and are posted at [http://www.cms.gov/Medicare/Coding/ICD10/index.html](http://www.cms.gov/Medicare/Coding/ICD10/index.html) and are effective each October 1st.
- Beginning January 1, 2019, if there is a Change of Ownership (CHOW) that results in a change in provider number due to a facility-type change (for example, hospital-based dialysis facility to independent dialysis facility) and the new owner accepts the Medicare agreement, the ESRD facility can qualify for the Low Volume Payment Adjustment (LVPA) if they otherwise meet the LVPA eligibility criteria. This policy does not extend to CHOWs where a new PTAN is issued for any other reason.
- Effective January 1, 2019, ESRD facilities that change their fiscal year end for cost reporting purposes, outside of a CHOW, qualify for the LVPA if they otherwise meet the
LVPA eligibility criteria. When this occurs, the MACs will combine the two nonstandard cost reporting periods of less than 12 months to equal a full 12-consecutive month period or combine the two non-standard cost reporting periods, that in combination may exceed 12-consecutive months, and prorate the data to equal a full 12-consecutive month period. This does not impact or change requirements for reporting, as established by the MACs, or those set forth in regulations at Section 413.24(f)(3).

- November 1st of each year is the mandatory deadline for the submission of attestations for ESRD facilities that believe they are eligible to receive the low-volume payment adjustment. Beginning January 1, 2019, ESRD facilities may request an extraordinary circumstance exception to the November 1 deadline. In order to request an extraordinary circumstance exception, the facility is required to submit a narrative explaining the rationale for the exception to their MAC. The MAC will evaluate the narrative to determine if an exception is justified. The determination will be final, with no appeal.

**ADDITIONAL INFORMATION**

The official instruction, CR11021, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R250BP.pdf. 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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Influenza Vaccine Payment Allowances - Annual Update for 2018-2019 Season

MLN Matters Number: MM10914
Related Change Request (CR) Number: 10914
Related CR Release Date: August 31, 2018
Effective Date: August 1, 2018
Related CR Transmittal Number: R4124CP
Implementation Date: No later than October 1, 2018

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for influenza vaccines provided to Medicare Beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10914 informs MACs about payment allowances for influenza virus vaccines, which are updated on August 1 of each year. The Centers for Medicare & Medicaid Services (CMS) will post the payment allowances for influenza vaccines that are approved after the release of CR 10914 at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html. Make sure your billing staffs are aware that the payment allowances are being updated.

BACKGROUND

The Medicare Part B payment allowance limits for influenza and pneumococcal vaccines are 95 percent of the Average Wholesale Price (AWP), as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department, Rural Health Clinic (RHC), or Federally Qualified Health Center (FQHC). Where the vaccine is furnished in the hospital outpatient department, RHC, or FQHC, payment for the vaccine is based on reasonable cost.

Annual Part B deductible and coinsurance amounts do not apply. All physicians, non-physician practitioners, and suppliers who administer the influenza virus vaccination and the pneumococcal vaccination must take assignment on the claim for the vaccine.

The Medicare Part B payment allowances for dates of service of August 1, 2018, through July 31, 2019, are still pending as of the date of CR10914 for CPT codes 90630, 90653, 90654, 90655, 90656, 90657, 90661, 90662, 90672, 90673, 90674, 90682, 90685, 90686, 90687,
90688, 90756, and HCPCS codes Q2035, Q2036, Q2037, and Q2038. Once payment allowances are available, they will be posted at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html.

Payment allowances for codes for which products have not yet been approved will be provided when the products have been approved and pricing information becomes available to CMS.

The payment allowances for pneumococcal vaccines are based on 95 percent of the AWP and are updated on a quarterly basis via the Quarterly Average Sales Price (ASP) Drug Pricing Files.

**Note:** MACs will reprocess any previously processed and paid claims for the current flu season that were paid using influenza vaccine payment allowances other than the allowances published in the influenza vaccine pricing website for the 2018/2019 season, that began on August 1, 2018. This reprocessing should occur by November 1, 2018.

**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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January 2019 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM11016  Related Change Request (CR) Number: 11016
Related CR Release Date: October 26, 2018  Effective Date: January 1, 2019
Related CR Transmittal Number: R4154CP  Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 11016 provides the quarterly update for Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to the prior quarterly pricing files. CR11016 instructs MACs to download and implement the January 2019 and, if released, the revised October 2018, July 2018, April 2018, and January 2018 files. Medicare shall use the January 2019 ASP and Not Otherwise Classified (NOC) drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after January 1, 2019 with dates of service January 1, 2019, through March 31, 2019. Make sure your billing staffs are aware of these updates.

BACKGROUND

The ASP methodology is based on quarterly data submitted to the Centers for Medicare & Medicaid Services (CMS) by manufacturers. CMS will supply 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 OPPS are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in Chapter 4, Section 50 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance-Manuals/Downloads/clm104c04.pdf.
For any drug or biological not listed in the ASP or NOC drug pricing files, your 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 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 which is available at https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf.

Note: MACs will not search and adjust claims that have already been processed unless you bring such claims to their attention.

ADDITIONAL INFORMATION


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MLN Matters Number: MM10611 Revised  Related CR Release Date: November 2, 2018
Related Change Request (CR) Number: 10611  Effective Date: June 12, 2018
Related CR Transmittal Number: R2194OTN  Implementation Date: June 12, 2018

Note: This article was revised on November 6, 2018, to reflect revisions to CR10611, issued on October 24 and November 2. The article was revised to extend the MAC portals to be open until January 2, 2019, instead of July 2, 2018. As a result of the revision to the article, providers that wish to electronically submit their MCR must do so using MCReF on or after January 2, 2019, instead of the original date of July 2, 2018. As a result of the November 2 CR revision, an incorrect Web address for new user registration is corrected. In addition, the CR release date, transmittal number, and the Web address for CR10611 are also revised. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for cost report staff submitting annual Medicare Cost Reports (MCRs) to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10611 informs MACs and providers of the new MCR e-filing (MCReF) system available for electronic transmission of cost reports. Medicare Part A providers file an annual MCR with the Centers for Medicare & Medicaid Services (CMS). The reports are filed with a MAC assigned to each provider. The MCR is used to determine the providers’ Medicare reimbursable costs. MACs may suspend payments to providers that fail to file their MCR on the due date. Make sure your cost report staffs are aware of the new MCReF System.

BACKGROUND

In accordance with Chapter 1, Section 104 of the Provider Reimbursement Manual, Part II (PRM-II), providers that continue to participate in the Medicare Program are required to submit a cost report within 5 months of their cost reporting fiscal year end. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period. Exceptions to this due date for “no Medicare utilization” cost reports are
addressed in PRM-II, Section 110.A. MACs are required to suspend payments to providers that fail to file their MCR by the due date.

**Current Medicare Cost Report (MCR) Filing and Receipt Process:**

Generally, each provider must perform the following steps to properly submit an MCR to their MAC:

- Generate an MCR consisting of a machine-readable file (ECR) and a human-readable file (PDF or equivalent, also referred to as the Print Image), using CMS-approved MCR vendor software.
- Submit the Worksheet S (Certification Page) signed by an officer or administrator of the provider. A “wet” signature is required for cost reports ending before December 31, 2017; an electronic signature is allowed for cost reports ending on or after December 31, 2017.
- Provide supporting cost report documentation including, but not limited to, the working trial balance, financial statements, Medicare Bad Debt Listing, Interns and Residents Information System data, and so on.
- Submit the MCR package to their MAC via mail (or hand delivery), which account for 91 percent of all MCR submissions, or a hybrid of mail and electronic submissions which account for 9 percent of total submissions. The signed worksheet S must be mailed to the MAC.

**Streamlined the MCR Filing Process:**

To streamline the MCR filing process, the 2018 Inpatient Prospective Payment System (IPPS) Final Rule allows for an electronic signature on the MCR Worksheet S (Certification Page) for cost reports ending on or after December 31, 2017. Additionally, beginning May 1, 2018, CMS will make the MCREF system available to Part A providers for electronic transmission (e-Filing) of an MCR package directly to a MAC. A CMS Enterprise Identity Management (EIDM) account is required to use MCREF, which is the same account providers use to order copies of their Provider Statistical and Reimbursement Reports (PS&R).

Upon login, providers will be able to select the Fiscal Year End for which they are filing, upload all corresponding MCR materials as attachments, and submit the documents directly to their MAC. The system will perform a basic review of the attached materials to determine if the MCR is “receivable” (See Attachment A of CR10611. The Web address of CR10611 is in the Additional Information section of this article.). If issues are identified, the provider will immediately receive an error/warning message. If no issues are identified, the provider will receive a confirmation number, as well as an electronic postmark date, which can be used in correspondence regarding the submission. Once the cost report is deemed “receivable,” the MAC will perform the acceptability review within 30 days. The MAC will issue a rejection letter if the cost report is rejected.

**Medicare Cost Report e-Filing (MCREF) System Access:**

MCREF will be hosted at the following URL: [https://mcref.cms.gov](https://mcref.cms.gov). System access to MCREF will be controlled by the EIDM system, as previously noted. Part A Provider Security Officials (SOs) and their backups (BSOs), already registered in EIDM for access to CMS PS&R, will inherit access to MCREF by default through their existing account.
Providers that are not registered in EIDM, but wish to gain access to MCreF, must register in EIDM and assign an SO for their organization. New user registration is available at [https://portal.cms.gov/wps/portal/unauthportal/selfservice/newuserregistration](https://portal.cms.gov/wps/portal/unauthportal/selfservice/newuserregistration).

**Note:** It is important for providers to keep their EIDM credentials in good standing to avoid problems using MCreF to e-file cost reports and obtaining PS&R. This includes password updates per CMS policy and the timely replacement of SOs due to staffing changes. Issues with maintaining EIDM credentials will not constitute a valid reason for filing a cost report past its due date.

Starting **January 2, 2019**, providers that wish to e-file their MCR must use MCreF. MAC portals will no longer be an acceptable means of submission. Providers that wish to mail or hand deliver MCRs to MACs, may continue to do so.

**Benefits of Streamlined MCR Processes:**

- Increases CMS access to MCR data as submitted by providers to assist with responding to inquiries and remove additional administrative burdens on MACs and CMS.
- Eliminates MAC processes for populating the CMS Healthcare Cost Reporting Information System (HCRIS) – including the submission of 100,000 cost reports to HCRIS and subsequent resubmission.
- Eliminates the need for MACs to enter MCR Postmarked Date, Received Date, and HCRIS Sent Date.
- Enables direct receipt/promotion of IRIS data to its required end-state in STAR (eliminates manually upload IRIS data).
- Large provider chain organizations will electronically submit MCRs to one system instead of transmitting their MCRs to their assigned MAC jurisdiction’s portals or physical mailing addresses.
- An MCR submitted through MCreF will be directed automatically to the correct MAC eliminating the risk of submitting the MCR to an incorrect MAC.
- Providers will receive immediate feedback on whether the MCR is received.
- Providers will save time compiling the paperwork (files) needed to create electronic media and mail the MCR package;
- Providers will have until 11:59 p.m. eastern time on the due date to submit the MCR through MCreF.
- MCreF has a simple, straightforward user interface with just one screen.
- Reduces provider confusion due to conflicting MAC “receivability” rules.

**ADDITIONAL INFORMATION**


Chapter 1 of the Provider Reimbursement Manual 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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Update to Rural Health Clinic (RHC) All-Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2019

MLN Matters Number: MM10989
Related Change Request (CR) Number: 10989
Related CR Release Date: October 12, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4145CP
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Rural Health Clinics (RHCs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

CR 10989 updates the RHC payment limit per visit for Calendar Year (CY) 2019. Please make sure your billing staffs are aware of this update.

BACKGROUND

Medicare Part B payment to RHCs is 80 percent of the All-Inclusive Rate (AIR), subject to a payment limit for medically necessary medical, and qualified preventive face-to-face visits with a practitioner and a Medicare beneficiary for RHC services. As authorized by §1833(f) of the Social Security Act, the payment limits for a subsequent year shall be increased in accordance with the rate of increase in the Medicare Economic Index (MEI). Based on historical data through second quarter 2018, the CY 2019 MEI is 1.5 percent. The RHC payment limit per visit for CY 2019 is $84.70 effective January 1, 2019, through December 31, 2019. The CY 2019 RHC payment limit reflects a 1.5 percent increase above the CY 2018 payment limit of $83.45.

To avoid unnecessary administrative burden, MACs shall not retroactively adjust individual RHC bills paid at a previous payment limit. However, MACs retain the discretion to make adjustments to the interim payment rate or a lump sum adjustment to total payments already made to take into account any excess or deficiency in payments to date.

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>November 16, 2018</td>
<td>Initial article released.</td>
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