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

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Items of Importance

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

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

WPS GHA Medicare eNews announces the posting of the following:
- Time-sensitive national and local Medicare news
- Medicare program changes
- Policy updates, including new, retired, and revised policies
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- Communiqué newsletters
- Specialty- and service-specific educational articles
- Much, much more!

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

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

Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): 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) Committee on Operating Rules for Information Exchange (CORE)

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9767 informs MACs of the regular update in the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) defined code combinations per Operating Rule 360 - Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule. Make sure that your billing staffs are aware of these changes.

Background

The Department of Health and Human Services (HHS) adopted the Phase III CAQH CORE EFT & ERA Operating Rule Set that was implemented on January 1, 2014, under the Patient Protection and Affordable Care Act. The Health Insurance Portability and Accountability Act (HIPAA) amended the Act by adding Part C—Administrative

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Simplification—to Title XI of the Social Security Act, requiring the Secretary of HHS (the Secretary) 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.

Through the Affordable Care Act, Congress sought to promote implementation of electronic transactions and achieve cost reduction and efficiency improvements by creating more uniformity in the implementation of standard transactions. This was done by mandating the adoption of a set of operating rules for each of the HIPAA transactions. The Affordable Care Act defines operating rules and specifies the role of operating rules in relation to the standards.

CR9767 deals with the regular update in CAQH CORE defined code combinations per Operating Rule 360 - Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule.

CAQH CORE will publish the next version of the Code Combination List on or about February 1, 2017. This update is based on the Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC) updates as posted at the WPC website on or about November 1, 2016. This will also include updates based on Market Based Review (MBR) 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.


Note: Per 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/Group Code for a minimum set of 4 Business Scenarios. Medicare can use any code combination if the business scenario is not one of the 4 CORE defined business scenarios. With the 4 CORE defined business scenarios, Medicare must use the code combinations from the lists published by CAQH CORE.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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Implementing Provider File Updates and PECOS to FISS Interface Via Extract
File Updates to Accommodate Section 603 Bipartisan Budget Act of 2015

Provider Types Affected

This MLN Matters® Article is intended for hospitals with off-campus outpatient departments submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9613 reminds you that all off-campus outpatient departments of a hospital provider are required to be correctly identified. Make sure that your billing staffs are aware of these requirements.

Background

Hospital providers are required to include all practice locations on the CMS 855A enrollment form. The Centers for Medicare & Medicaid Services (CMS) has performed a revalidation process (March 25, 2011 – March 23, 2015) where in the last 4 years all hospital providers have completed an 855A enrollment form to either 1) initially enroll in Medicare, 2) add a new practice location, or 3) revalidate its enrollment information. If a hospital claim is submitted with a service facility location that was not included on the CMS 855A enrollment form, it will be returned to the provider until the CMS 855A enrollment form and claims processing system is updated.

Section 1833(t) of the Social Security Act (the Act), as amended by Section 603 of the Bipartisan Budget Act of 2015, requires that certain off-campus departments of a hospital...
provider be paid under the “applicable payment system” rather than under the Hospital Outpatient Prospective Payment System. CMS established payment policies to pay nonexcepted off-campus departments of a hospital provider under the Medicare Physician Fee Schedule effective for services furnished on or after January 1, 2017. It is important for hospitals to ensure that an accurate address for each hospital department practice location is included on the CMS 855A enrollment form.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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MLN Matters® Number: MM9708 Related Change Request (CR) #: CR 9708
Related CR Release Date: November 18, 2017 Effective Date: February 21, 2017
Related CR Transmittal #: R275FM Implementation Date: February 21, 2017

Internet-Only Manual, Pub. 100-06, Chapter 3, Section 90 (Provider Liability) Revision

**Provider Types Affected**

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

**What You Need to Know**

Change Request (CR) 9708 provides additional criteria for determining when a contractor shall assume a physician, provider, or supplier should have known about a policy or rule. CR9708 updates Chapter 3, Section 90 of the “Medical Financial Management Manual.” Make sure your billing staff is aware of these updates.

**Background**

Contractors shall assume the provider, physician, or supplier should have known about a policy or rule, if:

- The policy or rule is in the provider, physician, or supplier manual or in Federal regulations;
- The Centers for Medicare & Medicaid Services (CMS) or a CMS contractor provided general notice to the medical community concerning the policy or rule;
- CMS, a CMS contractor, or the Office of Inspector General (OIG) gave written notice of the policy or rule to the particular provider/physician/supplier;

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- The provider, physician, or supplier was previously investigated or audited as a result of not following the policy or rule;
- The provider, physician, or supplier previously agreed to a Corporate Integrity Agreement as a result of not following the policy or rule;
- The provider, physician, or supplier was previously informed that its claims had been reviewed/denied as a result of the claims not meeting certain Medicare requirements which are related to the policy or rule; or
- The provider, physician, or supplier previously received documented training/outreach from CMS or one of its contractors related to the same policy or rule.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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Issuing Compliance Letters to Specific Providers and Suppliers Regarding Inappropriate Billing of Qualified Medicare Beneficiaries (QMBs) for Medicare Cost-Sharing

Note: This article was revised on November 18, 2016, to reflect the revised CR9817 issued that same day. In the article, the effective date, CR release date, transmittal number, and the Web address for CR9817 are revised. The sample letters at the end of the article have slight wording changes to show that the Medicaid program also helps low-income beneficiaries pay their Medicare premiums. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for providers submitting claims to Medicare Administrative Contractors (MACs) and Durable Medical Equipment MACs (DME MACs) for services provided to certain Medicare beneficiaries.

Provider Action Needed

Federal law bars Medicare providers from charging individuals enrolled in the Qualified Medicare Beneficiary Program (QMB) for Medicare Part A and B deductibles, coinsurances, or copays. QMB is a Medicaid program that assists low-income beneficiaries with Medicare premiums and cost-sharing. Change Request (CR) 9817 instructs MACs to issue a compliance letter instructing named providers and suppliers to refund any erroneous charges and recall any past or existing billing with regard to improper QMB billing. Please make sure your billing staffs are aware of this aspect of your Medicare provider agreement.

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Background

In 2013, approximately seven million Medicare beneficiaries were enrolled in QMB, a Medicaid program that assists low-income beneficiaries with Medicare premiums and cost sharing.

State Medicaid programs are liable to pay Medicare providers who serve QMB individuals for the Medicare cost sharing. However, federal law permits states to limit provider payment for Medicare cost sharing to the lesser of the Medicare cost sharing amount, or the difference between the Medicare payment and the Medicaid rate for the service provided. Regardless, Medicare providers must accept the Medicare payment and Medicaid payment (if any, and including any permissible Medicaid cost sharing from the beneficiary) as payment in full for services rendered to a QMB individual.

Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions, as described in Sections 1902(n)(3); 1905(p); 1866(a)(1)(A); and 1848(g)(3) of the Social Security Act (the Act).

In July 2015, the Centers for Medicare & Medicaid Services issued a study finding that:

- Erroneous billing of QMB individuals persists
- Confusion about billing rules exists amongst providers and beneficiaries

Note: The study, titled “Access to Care Issues Among Qualified Medicare Beneficiaries (QMB),” is available at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.

In September 2016, all Medicare beneficiaries received “Medicare & You 2017,” which contains new language to advise QMB individuals about their billing protections. Also, a toll-free number (1-800-MEDICARE) is available to QMB individuals if they cannot resolve billing problems with their providers. In addition, effective September 17, 2016, Beneficiary Contact Center (BCC) Customer Service Representatives (CSRs) can identify a caller’s QMB status and advise them about their billing rights.

BCC CSRs will begin escalating beneficiary inquiries involving QMB billing problems that the beneficiary has been unable to resolve with the provider to the appropriate MAC. MACs will issue a compliance letter for all inquiries referred. This compliance letter will instruct named providers and suppliers to refund any erroneous charges and recall any past or existing QMB billing (including referrals to collection agencies).

MACs will also send a copy of the compliance letter to the named beneficiary, with a cover letter advising the beneficiary to show the mailing to the named provider and verify that the provider corrected the billing problem. Examples of these letters are included following the "Document History" section of this article.
Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Document History

- November 18, 2016 - The effective date, CR release date, transmittal number, and the Web address for CR9817 are revised in the article due to a revised CR9817. The sample letters at the end of the article have slight wording changes to show that the Medicaid program also helps low-income beneficiaries pay their Medicare premiums.
- November 4, 2016 - Initial Issuance

Example of Cover Letter for affected QMB Individuals sent by MAC

[month] [day], [year]
[address]
[City] ST [Zip]
Reference ID: (NPI, etc.)

Dear [Beneficiary Name]:

You contacted Medicare about a bill you got from [Provider/Supplier Name]. Then we sent [Provider/Supplier Name] the letter on the next page.

You are in the Qualified Medicare Beneficiary (QMB) program. It helps pay your Medicare premiums and costs. **Medicare providers cannot bill you for Medicare deductibles, coinsurance, or copays for covered items and services.**

The letter tells the provider to stop billing you and to refund you any amounts you already paid. **Here's what you can do:**

1. Show this letter to your provider to make sure they fixed your bill.
2. Tell all of your providers and suppliers you are in the QMB program.
3. Show your Medicare and your Medicaid or QMB cards each time you get items or services.

If you have questions about this letter, call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. Call 1-877-486-2048 if you use TTY.

Sincerely,

[Name]
[Title]
[MAC name]

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Example of Compliance Letter Sent to Provider by the MAC

[month] [day], [year]
[address]
[City] ST [Zip]

Reference ID: (NPI, etc.)

Dear [Provider/Supplier Name]:

The Centers for Medicare & Medicaid Services (CMS) received information that [Provider/Supplier Name] is improperly billing [Medicare beneficiary name/HICN number] for Medicare cost-sharing.

This beneficiary is enrolled in the Qualified Medicare Beneficiary (QMB) program, a state Medicaid program that helps low-income beneficiaries pay their Medicare premiums and cost-sharing. Federal law says Medicare providers can’t charge individuals enrolled in the QMB program for Medicare Part A and B deductibles, coinsurances, or copays for items and services Medicare covers.

- Promptly review your records for efforts to collect Medicare cost-sharing from [Medicare beneficiary name/HICN number], refund any amounts already paid, and recall any past or existing billing (including referrals to collection agencies) for Medicare-covered items and services
- Ensure that your administrative staff and billing software exempt individuals enrolled in the QMB program from all Medicare cost-sharing billing and related collection efforts

Medicare providers must accept Medicare payment and Medicaid payment (if any) as payment in full for services given to individuals enrolled in the QMB program. Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. (See Sections 1902(n)(3); 1905(p); 1866(a)(1)(A); 1848(g)(3) of the Social Security Act.)

Finally, please refer to this Medicare Learning Network (MLN) Matters® article for more information on the prohibited billing of QMBs: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1128.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1128.pdf). If you have questions, please contact [MAC information].

Sincerely,

[Name]
[Title]
[MAC name]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9935 Revised
Related Change Request (CR) #: CR 9935
Related CR Release Date: January 27, 2017
Effective Date: February 21, 2017
Related CR Transmittal #: R3698CP
Implementation Date: February 21, 2017

Medicare Outpatient Observation Notice (MOON) Instructions

Note: This article was revised on February 2, 2017 to reflect a revised CR9935 issued on January 27. In the article, the CR release date, transmittal number, and the Web address for accessing the CR were revised. All other information remains the same.

Provider Types Affected
This MLN Matters® Article is intended for hospitals, including Critical Access Hospitals (CAHs) submitting claims to Medicare Administrative Contractors (MACs) for outpatient observation services provided to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9935 updates Chapter 30 of the “Medicare Claims Processing Manual” to include the Medicare Outpatient Observation Notice (MOON), CMS-10611, and related instructions. Providers should use the MOON to inform Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or a Critical Access Hospital (CAH). The instructions included in Chapter 30 provide guidance for proper issuance of the MOON. The updated Chapter 30 is attached to CR9935.

Background
The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), passed on August 6, 2015. This law amended Section 1866(a)(1) of the Social Security Act by adding new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such

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notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs.

**Scope**

Hospitals and CAHs must provide the MOON to beneficiaries in Original Medicare (Fee-For-Service) who receive observation services as outpatients for more than 24 hours. **(Note: MA plans are to follow MOON instructions outlined in CR9935/Section 400 of Chapter 30 of the Medicare Claims Processing Manual.**

All beneficiaries receiving services in hospitals and CAHs must receive a MOON no later than 36 hours after observation services as an outpatient begin. For purposes of these instructions, the term “beneficiary,” means either beneficiary or representative, when a representative is acting for a beneficiary.

This also includes beneficiaries in the following circumstances:

- Beneficiaries who do not have Part B coverage
- Beneficiaries who are subsequently admitted as an inpatient prior to the required delivery of the MOON
- Beneficiaries for whom Medicare is either the primary or secondary payer

The statute expressly provides that the MOON be delivered to beneficiaries receiving observation services as an outpatient for more than 24 hours. In other words, the MOON should not be delivered to all beneficiaries receiving outpatient services. The MOON is intended to inform beneficiaries who receive observation services for more than 24 hours that they are outpatients receiving observation services and not inpatients, and the reasons for such status, and must be delivered no later than 36 hours after observation services begin.

However, hospitals and CAHs may deliver the MOON to an individual receiving observation services as an outpatient before such individual has received more than 24 hours of observation services. Allowing delivery of the MOON before an individual has received 24 hours of observation services affords hospitals and CAHs the flexibility to deliver the MOON consistent with any applicable State law that requires notice to outpatients receiving observation services within 24 hours after observation services begin. The flexibility to deliver the MOON any time up to, but no later than, 36 hours after observation services begin also allows hospitals and CAHs to spread out the delivery of the notice and other hospital paperwork in an effort to avoid overwhelming and confusing beneficiaries.

**Hospitals Affected by These Instructions**

These instructions apply to hospitals as well as CAHs per Section 1861(e) and Section 1861(mm) of the Social Security Act.

**Medicare Outpatient Observation Notice**

The MOON is subject to the Paperwork Reduction Act (PRA) process and approved by the Office of Management and Budget (OMB). OMB-approved notices may only be modified
as per their accompanying form instructions, as well as per guidance in this section of the manual. Unapproved modifications cannot be made to the OMB-approved, standardized MOON. The notice and accompanying form instructions are available at [http://www.cms.gov/Medicare/Medicare-General-Information/BNI](http://www.cms.gov/Medicare/Medicare-General-Information/BNI).

Alterations to the Notice

In general, the MOON must remain two pages, except as needed for the additional information field discussed below or to include State-specific information below. Hospitals and CAHs subject to State law observation notice requirements may attach an additional page to the MOON to supplement the “Additional Information” section in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. The pages of the notice can be two sides of one page or one side of separate pages, but **must not** be condensed to one page.

Hospitals may include their business logo and contact information on the top of the MOON. Text may not be shifted from page 1 to page 2 to accommodate large logos, address headers, or any other information.

Completing the MOON

Hospitals must use the OMB-approved MOON (CMS-10611). Hospitals must type or write the following information in the corresponding blanks of the MOON:

- Patient name
- Patient number
- Reason patient is an outpatient

Hospital Delivery of the MOON

Hospitals and CAHs must provide both the standardized written MOON, as well as oral notification. Oral notification must consist of an explanation of the standardized written MOON. The format of such oral notification is at the discretion of the hospital or CAH, and may include, but is not limited to, a video format. However, a staff person must always be available to answer questions related to the MOON, both in its written and oral delivery formats.

The hospital or CAH must ensure that the beneficiary or representative signs and dates the MOON to demonstrate that the beneficiary or representative received the notice and understands its contents. Use of assistive devices may be used to obtain a signature.

Electronic issuance of the MOON is permitted. If a hospital or CAH elects to issue a MOON viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the MOON with the required beneficiary specific information inserted, at the time of notice delivery.

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Refusal to Sign the MOON

If the beneficiary refuses to sign the MOON, and there is no representative to sign on behalf of the beneficiary, the notice must be signed by the staff member of the hospital/CAH who presented the written notification. The staff member’s signature must include the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented. The staff member annotates the “Additional Information” section of the MOON to include the staff member’s signature and certification of delivery. The date and time of refusal is considered to be the date of notice receipt.

MOON Delivery to Representatives


The MOON may also be delivered to an authorized representative. Generally, an authorized representative is an individual who, under State or other applicable law, may make health care decisions on a beneficiary’s behalf (for example, the beneficiary’s legal guardian, or someone appointed in accordance with a properly executed durable medical power of attorney).

Notification to a beneficiary who has been deemed legally incompetent is typically made to an authorized representative of the beneficiary. However, if a beneficiary is temporarily incapacitated, a person (typically, a family member or close friend) whom the hospital or CAH has determined could reasonably represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the MOON. Such a representative should act in the beneficiary’s best interests and in a manner that is protective of the beneficiary and the beneficiary’s rights. Therefore, a representative should have no relevant conflict of interest with the beneficiary.

In instances where the notice is delivered to a representative who has not been named in a legally binding document, the hospital or CAH should annotate the MOON with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact.

Note: There is an exception to the in-person notice delivery requirement. If the MOON must be delivered to a representative who is not physically present to receive delivery of the notice, the hospital/CAH is not required to make an off-site delivery to the representative. The hospital/CAH must complete the MOON as required and telephone the representative.

• The information provided telephonically should include all contents of the MOON.

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• Note the date and time the hospital or CAH communicates (or makes a good faith attempt to communicate) this information telephonically to the representative is considered the receipt date of the MOON.

• Annotate the “Additional Information” section to reflect that all of the information indicated above was communicated to the representative.

• Annotate the “Additional Information” section with the name of the staff person initiating the contact, the name of the representative contacted by phone, the date and time of the telephone contact, and the telephone number called.

A copy of the annotated MOON should be mailed to the representative the day telephone contact is made.

A hard copy of the MOON must be sent to the representative by certified mail, return receipt requested, or any other delivery method that can provide signed verification of delivery (for example: FedEx or UPS). The burden is on the hospital or CAH to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

If the hospital or CAH and the representative both agree, the hospital or CAH may send the notice by fax or e-mail; however, the hospital or CAH’s fax and e-mail systems must meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

**Ensuring Beneficiary Comprehension**

The OMB-approved standardized MOON is available in English and Spanish. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, hospitals and CAHs must employ their usual procedures to ensure notice comprehension. Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies.

Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with Limited English Proficiency (LEP) consistent with Section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act of 1973.

**Completing the Additional Information Field of the MOON**

This section may be populated with any additional information a hospital wishes to convey to a beneficiary. Such information may include, but is not limited to:

• Contact information for specific hospital departments or staff members
• Additional content required under applicable State law related to notice of observation services

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• Part A cost-sharing responsibilities if a beneficiary is admitted as an inpatient before 36 hours following initiation of observation services
• The date and time of the inpatient admission if a patient is admitted as an inpatient prior to delivery of the MOON
• Medicare Accountable Care Organization information
• Hospital waivers of the beneficiary’s responsibility for the cost of self-administered drugs
• Any other information pertaining to the unique circumstances regarding the particular beneficiary

If a hospital or CAH wishes to add information that cannot be fully included in the “Additional Information” section, an additional page may be attached to the MOON.

Notice Retention for the MOON

The hospital or CAH must retain the original signed MOON in the beneficiary’s medical record. The beneficiary should receive a paper copy of the MOON that includes all of the required information. Electronic notice retention is permitted.

Intersection with State Observation Notices

Hospitals and CAHs in States that have State-specific observation notice requirements may add State-required information to the “Additional Information” field, attach an additional page, or attach the notice required under State law to the MOON.

Additional Information

The official instruction, CR9935, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3698CP.pdf. As mentioned earlier, the notice and accompanying instructions are available at http://www.cms.gov/Medicare/Medicare-General-Information/BNI.

If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Document History

• January 24, 2017 - Initial issuance
• February 2, 2017 - The article was revised to reflect a revised CR9935 issued on January 27, 2017. In the article, the CR release date, transmittal number, and the Web address for accessing the CR were revised. All other information remains the same.

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Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9911 modifies the Medicare claims processing systems to help providers more readily identify the Qualified Medicare Beneficiary (QMB) status of each patient and to support providers’ ability to follow QMB billing requirements. Beneficiaries enrolled in the QMB program are not liable to pay Medicare cost-sharing for all Medicare A/B claims. CR 9911 adds an indicator of QMB status to Medicare’s claims processing systems. This system enhancement will trigger notifications to providers (through the Provider Remittance Advice) and to beneficiaries (through the Medicare Summary Notice) to reflect that the beneficiary is enrolled in the QMB program and has no Medicare cost-sharing liability. Make sure that your billing staffs are aware of these changes.

Background

QMB is a Medicaid program that assists low-income beneficiaries with Medicare premiums and cost-sharing. In 2015, 7.2 million persons (more than one out of every ten Medicare beneficiaries) were enrolled in the QMB program.

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Under federal law, Medicare providers may not bill individuals enrolled in the QMB program for Medicare deductibles, coinsurance, or copayments, under any circumstances. (See Sections 1902(n)(3)(B); 1902(n)(3)(C); 1905(p)(3); 1866(a)(1)(A); 1848(g)(3)(A) of the Social Security Act.) State Medicaid programs may pay providers for Medicare deductibles, coinsurance, and copayments. However, as permitted by Federal law, states can limit provider reimbursement for Medicare cost-sharing under certain circumstances. Nonetheless, Medicare providers must accept the Medicare payment and Medicaid payment (if any, and including any permissible Medicaid cost sharing from the beneficiary) as payment in full for services rendered to an individual enrolled in the QMB program.

CR 9911 aims to support Medicare providers’ ability to meet these requirements by modifying the Medicare claims processing system to clearly identify the QMB status of all Medicare patients. Currently, neither the Medicare eligibility systems (the HIPAA Eligibility Transaction System (HETS)), nor the claims processing systems (the FFS Shared Systems), notify providers about their patient’s QMB status and lack of Medicare cost-sharing liability. Similarly, Medicare Summary Notices (MSNs) do not inform those enrolled in the QMB program that they do not owe Medicare cost-sharing for covered medical items and services.

CR 9911 includes modifications to the FFS claims processing systems and the “Medicare Claims Processing Manual” to generate notifications to Medicare providers and beneficiaries regarding beneficiary QMB status and lack of liability for cost-sharing.

With the implementation of CR 9911, Medicare’s Common Working File (CWF) will obtain QMB indicators so the claims processing systems will have access to this information.

- CWF will provide the claims processing systems the QMB indicators if the dates of service coincide with a QMB coverage period (one of the occurrences) for the following claim types: Part B professional claims; Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) claims; and outpatient institutional Types of Bill (TOB) 012x, 013x, 014x, 022x, 023x, 034x, 071x, 072x, 074x, 075x, 076x, 077x, and 085x; home health claims (TOB 032x) only if the revenue code for the line item is 0274, 029x, or 060x; and Skilled Nursing Facility (SNF) claims (based on occurrence code 50 date for revenue code 0022 lines on TOBs 018x and 021x).

- CWF will provide the claims processing systems the QMB indicator if the "through date" falls within a QMB coverage period (one of the occurrences) for inpatient hospital claims (TOB 011x) and religious non-medical health care institution claims (TOB 041x).

The QMB indicators will initiate new messages on the Remittance Advice that reflect the beneficiary’s QMB status and lack of liability for Medicare cost-sharing with three new
Remittance Advice Remark Codes (RARC) that are specific to those enrolled in QMB. As appropriate, one or more of the following new codes will be returned:

- N781 – No deductible may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible or co-payments.
- N782 – No coinsurance may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible or co-payments.
- N783 – No co-payment may be collected as patient is a Medicaid/Qualified Medicare Beneficiary. Review your records for any wrongfully collected coinsurance, deductible or co-payments.

In addition, the MACs will include a Claim Adjustment Reason Code of 209 (“Per regulatory or other agreement. The provider cannot collect this amount from the patient. However, this amount may be billed to subsequent payer. Refund to patient if collected. (Use only with Group code OA (Other Adjustment)).

Finally, CR 9911 will modify the MSN to inform beneficiaries if they are enrolled in QMB and cannot be billed for Medicare cost-sharing for covered items and services.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).
The Process of Prior Authorization

Provider Types Affected

This MLN Matters® Article is intended for providers ordering certain DMEPOS items and suppliers submitting claims to Medicare Administrative Contractors (MACs) for items furnished to Medicare beneficiaries.

What You Need to Know

Change Request (CR) 9940 updates the Centers for Medicare & Medicaid Services (CMS) “Program Integrity Manual” to permit the MACs to conduct prior authorization processes, as so directed by CMS through individualized operational instructions. As of January 2017, Prior Authorization of Certain Durable Medical Equipment, Prosthetic, Orthotic, and Supply Items, frequently subject to unnecessary utilization, is the only permanent (non-demonstration) prior authorization program approved for implementation. Make sure your billing staff is aware of these changes.

Background

Prior authorization is a process through which a request for provisional affirmation of coverage is submitted to a medical review contractor for review before the item or service is furnished to the beneficiary and before the claim is submitted for processing. It is a process that permits the submitter/requester (for example, provider, supplier, beneficiary) to send in medical documentation, in advance of the item or service being rendered, and subsequently billed, in order to verify its eligibility for Medicare claim payment.

For any item or service to be covered by Medicare it must:

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• Be eligible for a defined Medicare benefit category
• Be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member
• Meet all other applicable Medicare coverage, coding and payment requirements

Contractors shall, at the direction of CMS or other authorizing entity, conduct prior authorizations and alert the requester/submitter of any potential issues with the information submitted.

A prior authorization request decision can be either a provisional affirmative or a non-affirmative decision.

• A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the item or service likely meets Medicare’s coverage, coding, and payment requirements.
• A non-affirmative decision is a finding that the submitted information/documentation does not meet Medicare’s coverage, coding, and payment requirements, and if a claim associated with the prior authorization is submitted for payment, it would not be paid. MACs shall provide notification of the reason for the non-affirmation, if a request is non-affirmative, to the submitter/requester. If a prior authorization request receives a non-affirmative decision, the prior authorization request can be resubmitted an unlimited number of times.
• Prior authorization may also be a condition of payment. This means that claims submitted without an indication that the submitter/requester received a prior authorization decision (that is, Unique Tracking Number (UTN)) will be denied payment.

Each prior authorization program will have an associated Operational Guide that will be available on the CMS website. In addition, MACs will educate stakeholders each time a new prior authorization program is launched. That education will include the requisite information and timeframes for prior authorization submissions and the vehicle to be used to submit such information to the MAC.

Prior Authorization Program for DME MACs

A prior authorization program for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items that are frequently subject to unnecessary utilization is described in 42 CFR 414.234. Among other things, this section establishes a Master List of certain DMEPOS items meeting inclusion criteria and potentially subject to prior authorization. CMS will select Healthcare Common Procedure Coding System (HCPCS) codes from the Prior Authorization Master List to be placed on the Required Prior Authorization List, and such codes will be subject to prior authorization as a condition of payment. In selecting HCPCS codes, CMS may consider factors such as geographic...
location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis.

- The Prior Authorization Master List is the list of DMEPOS items that have been identified using the inclusion criteria described in 42 CFR 414.234.

- The List of Required DMEPOS Prior Authorization Items contains those items selected from the Prior Authorization Master List to be implemented in the Prior Authorization Program. The List of Required DMEPOS Prior Authorization Items will be updated as additional codes are selected for prior authorization.

- CMS may suspend prior authorization requirements generally or for a particular item or items at any time and without undertaking rulemaking. CMS provides notification of the suspension of the prior authorization requirements via Federal Register notice and posting on the CMS prior authorization website.


### Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).
Update to Medicare Deductible, Coinsurance and Premium Rates for 2017

Provider Types Affected

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

Provider Action Needed

Change Request (CR) provides instruction for MACs to update the claims processing system with the new Calendar Year (CY) 2017 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.

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Most individuals age 65 and older, and many disabled individuals under age 65, are insured for Health Insurance (HI) 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.

### 2017 Part A - Hospital Insurance (HI)
- **Deductible:** $1,316.00
- **Coinsurance**
  - $329.00 a day for 61st-90th day
  - $658.00 a day for 91st-150th day (lifetime reserve days)
  - $164.50 a day for 21st-100th day (Skilled Nursing Facility coinsurance)
- **Base Premium (BP):** $413.00 a month
- **BP with 10 percent surcharge:** $454.30 a month
- **BP with 45 percent reduction:** $227.00 a month (for those who have 30-39 quarters of coverage)
- **BP with 45 percent reduction and 10 percent surcharge:** $249.70 a month

### 2017 Part B - Supplementary Medical Insurance (SMI)
- **Standard Premium:** $134.00 a month
- **Deductible:** $183.00 a year
- **Pro Rata Data Amount**
  - $125.73 1st month
  - $57.27 2nd month
- **Coinsurance:** 20 percent

### Additional Information


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If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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NEW WPS GHA BRANDING IMPACTS TO 835 TRANSACTIONS - J5 PART A

WPS GHA is more than just a facelift, this effort refocuses our service on our government partners so that Medicare providers and beneficiaries get the best possible service. Under our new brand, WPS Government Health Administrators, we continue to rely on our experience to drive our efforts while our efficiency helps us control costs. As part of the branding effort, you will see changes in the 835 transactions for Medicare A, effective February 17, 2017. This may impact 835 trading partners who rely on information in the 1000A/NM102 for file processing.

835 Examples:

N1*PR*WPS GHA - MAC J5 PART A~
N3*PO BOX 8799~
N4*MADISON*WI*537088799~
REF*2U*05901~

N1*PR*WPS GHA - MAC J5 PART A~
N3*PO BOX 8799~
N4*MADISON*WI*537088799~
REF*2U*05001~

WPS GHA reports the MAC contract code for the 835 in the 1000A/REF02.

WPS GHA Companion Guides (http://www.wpsic.com/edi/files/med_a_837i_companion.pdf)

If you need additional information you may visit our EDI site (http://www.wpsic.com/edi) or contact the WPS EDI hotline at (866) 518-3285, option 1.
NEW WPS GHA BRANDING IMPACTS TO 835 TRANSACTIONS - J8 PART A

WPS GHA is more than just a facelift, this effort refocuses our service on our government partners so that Medicare providers and beneficiaries get the best possible service. Under our new brand, WPS Government Health Administrators, we continue to rely on our experience to drive our efforts while our efficiency helps us control costs. As part of the branding effort, you will see changes in the 835 transactions for Medicare A, effective February 17, 2017. This change may impact 835 trading partners who rely on information in the 1000A/NM102 for file processing.

835 Examples:

N1*PR*WPS GHA - MAC J8 PART A~
N3*PO BOX 8799~
N4*MADISON*WI*537088799~
REF*2U*08101~

N1*PR*WPS GHA - MAC J8 PART A~
N3*PO BOX 8799~
N4*MADISON*WI*537088799~
REF*2U*08201~

WPS GHA reports the MAC contract code for the 835 in the 1000A/REF02.

WPS GHA Companion Guides (http://www.wpsic.com/edi/files/med_a_837i_companion.pdf)

If you need additional information you may visit our EDI site (http://www.wpsic.com/edi) or contact the WPS EDI hotline at (866) 234-7331, option 1.
Claim Submission

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9771 Revised
Related Change Request (CR) #: CR 9771
Related CR Release Date: October 7, 2016
Effective Date: January 1, 2017
Related CR Transmittal #: R3618CP
Implementation Date: January 3, 2017

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

**Note:** This article was revised on January 12, 2017, to correct in the table on page 2. The table incorrectly listed HCPCS code 97177. The correct HCPCS code is HCPCS 97167 (OT EVAL HIGH COMPLEX 60 MIN). All other information is unchanged.

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9771 provides the 2017 annual update to the list of HCPCS codes used by Medicare systems to enforce consolidated billing of home health services. Make sure that your billing staffs are aware of these changes.

Background

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

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

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

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

Section 1842(b)(6) of the Social Security Act requires that payment for home health services provided under a home health plan of care is made to the home health agency.

The HCPCS codes in the table below are being added to the HH consolidated billing therapy code list, effective for services on or after January 1, 2017. These codes replace HCPCS codes: 97001, 97002, 97003, 97004.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>97161</td>
<td>PT EVAL LOW COMPLEX 20 MIN</td>
</tr>
<tr>
<td>97162</td>
<td>PT EVAL MOD COMPLEX 30 MIN</td>
</tr>
<tr>
<td>97163</td>
<td>PT EVAL HIGH COMPLEX 45 MIN</td>
</tr>
<tr>
<td>97164</td>
<td>PT RE-EVAL EST PLAN CARE</td>
</tr>
<tr>
<td>97165</td>
<td>OT EVAL LOW COMPLEX 30 MIN</td>
</tr>
<tr>
<td>97166</td>
<td>OT EVAL MOD COMPLEX 45 MIN</td>
</tr>
<tr>
<td>97167</td>
<td>OT EVAL HIGH COMPLEX 60 MIN</td>
</tr>
<tr>
<td>97168</td>
<td>OT RE-EVAL EST PLAN CARE</td>
</tr>
</tbody>
</table>

G0279 and G0280 are deleted from the HH consolidated billing therapy code list. These codes were replaced with 0019T and should have been removed from the list in earlier updates. Effective January 1, 2015, these codes were redefined for another purpose. MACs will adjust claims denied due to HH consolidated billing with HCPCS codes G0279 and G0280 and line item dates of service on or after January 1, 2015, if brought to their attention.

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Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>1/12/2017</td>
<td>This article was revised to correct in the table on page 2. The table incorrectly listed HCPCS code 97177. The correct HCPCS code is HCPCS 97167 (OT EVAL HIGH COMPLEX 60 MIN).</td>
</tr>
<tr>
<td>11/17/2016</td>
<td>Initial article released</td>
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Changes to the End-Stage Renal Disease (ESRD) Facility Claim (Type of Bill 72X) to Accommodate Dialysis Furnished to Beneficiaries with Acute Kidney Injury (AKI)

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 renal dialysis services provided to Medicare beneficiaries.

What You Need to Know

Change Request (CR) 9598 implements changes to the ESRD Facility claim (Type of Bill 72x) to accommodate dialysis furnished to beneficiaries with Acute Kidney Injury (AKI). This MLN Matters Special Edition Article summarizes these changes. Make sure that your billing staffs are aware of these changes.

Background

On June 29, 2015, The Trade Preferences Extension Act of 2015 was enacted in which Section 808 amended Section 1861(s)(2)(F) of the Social Security Act (42 U.S.C. 1395x(s)(2)(F)) by extending renal dialysis services paid under Section 1881(b)(14) to beneficiaries with AKI effective January 1, 2017.

Beginning January 1, 2017, ESRD facilities will be able to furnish dialysis to AKI patients. The AKI provision was signed into law on June 29, 2015. (See Sec. 808 Public Law 114-27.)

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The provision provides Medicare payment beginning on dates of service January 1, 2017, and after to ESRD facilities, that is, hospital-based and freestanding, for renal dialysis services furnished to beneficiaries with AKI (both adult and pediatric). Medicare will pay ESRD facilities for the dialysis treatment using the ESRD Prospective Payment System (PPS) base rate adjusted by the applicable geographic adjustment factor, that is, wage index. In addition to the dialysis treatment, the ESRD PPS base rate pays ESRD facilities for the items and services considered to be renal dialysis services as defined in 42 CFR 413.171 and there will be no separate payment for those services.

Renal dialysis services as defined in 42 CFR 413.171, would be considered to be renal dialysis services for patients with AKI. No separate payment would be made for renal dialysis drugs, biologicals, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI.

Items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR 413.171, are separately payable. Specifically, drugs, biologicals, laboratory services, supplies, and other services that ESRD facilities are certified to furnish and that would otherwise get furnished to a beneficiary with AKI in a hospital outpatient setting will be paid separately using the applicable Part B fee schedule. This includes vaccines. ESRD facilities may provide vaccines to beneficiaries with AKI and seek reimbursement under the applicable CMS vaccination policies discussed in Chapter 18 of the “Medicare Claims Processing Manual.”

For payment under Medicare, ESRD facilities shall report all items and services furnished to beneficiaries with AKI by submitting the 72x type of bill with condition code 84 - Dialysis for Acute Kidney Injury (AKI) on a monthly basis. Since ESRD facilities bill Medicare for renal dialysis services by submitting the 72x type of bill for ESRD beneficiaries, condition code 84 will differentiate an ESRD PPS claim from an AKI claim. AKI claims will require one of the following diagnosis codes:

1. N17.0 - Acute kidney failure with tubular necrosis
2. N17.1 - Acute kidney failure acute cortical necrosis
3. N17.2 - Acute kidney failure with medullary necrosis
4. N17.8 - Other acute kidney failure
5. N17.9 - Acute kidney failure, unspecified
6. T79.5XXA - Traumatic anuria, initial encounter
7. T79.5XXD - Traumatic anuria, subsequent encounter
8. T79.5XXS - Traumatic anuria, sequela
9. N99.0 - Post-procedural (acute)(chronic) renal failure

In addition, ESRD facilities are required to include revenue code 082x, 083x, 084x, or 085x for the modality of dialysis furnished with the Current Procedural Terminology (CPT) code G0491 (Long descriptor – Dialysis procedure at a Medicare certified ESRD facility for

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Acute Kidney Injury without ESRD; Short descriptor – dialysis Acu Kidney no ESRD). Beneficiaries with AKI are able to receive either peritoneal dialysis or hemodialysis in an ESRD facility. Based on the level of care required for these beneficiaries, at this time, CMS is not extending the home dialysis benefit to beneficiaries with AKI.

AKI claims will not have limits on how many dialysis treatments can be billed for the monthly billing cycle, however, there will only be payment for one treatment per day across settings, except in the instance of uncompleted treatments. If a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, the facility is paid based on the full base rate. An example includes medical emergencies such as rushing a dialysis patient to an emergency room mid-treatment. This is a rare occurrence and must be fully documented to your MAC’s satisfaction.

**Applicability of Other ESRD and CMS Adjustments**

**ESRD Network Fee**

The ESRD Network Fee reduction is not applicable to claims for beneficiaries with AKI. The operationalization of this policy occurs via CR 9814 effective April 1, 2017 and claims submitted between January 1, 2017 and March 31, 2017 will be adjusted once the CR is implemented.

**ESRD Quality Incentive Program (QIP)**

The ESRD QIP is not applicable for beneficiaries with AKI at this time.

**Sequestration Adjustments**

The 2 percent sequestration adjustment is applicable to claims for beneficiaries with AKI. This is global CMS adjustments and applies to AKI claims.

**ESRD Conditions for Coverage (CfCs)**

The ESRD CfCs at 42 CFR part 494 are health and safety standards that all Medicare-participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients, including ESRD and AKI patients, receive safe and appropriate care.

**Low Volume Payment Adjustment (LVPA)**

AKI dialysis treatments count toward the LVPA threshold when determining total number of treatments provided when a facility prepares the low volume attestation to determine eligibility for the LVPA.

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Additional Information


42 CFR 413.171 is available at http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=3233ff9c843c3f74275cab5dcbcf088c&mc=true&n=pt42.2.413&r=PART&tv=HTML#se42.2.413_1171.

42 CFR 494 is available at http://www.ecfr.gov/cgi-bin/text-index?SID=0cf1f211399c42665d1bfb2ed9b6783a&mc=true&tpl=/ecfrbrowse/Title42/42cfrr494_main_02.tpl.


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.


The Calendar Year 2017 Final rule is available at https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-26152.pdf

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9934 Related Change Request (CR) #: CR 9934
Related CR Release Date: January 13, 2017 Effective Date: October 1, 2016
Related CR Transmittal #: R3691CP Implementation Date: April 3, 2017

Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2017

Provider Types 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

Change Request (CR) 9934 informs MACs about the changes that will be included in the April 2017 quarterly release of the edit module for clinical diagnostic laboratory services. Make sure that your billing staffs are aware of these changes.

Background

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 laboratory claims subject to one of the 23 NCDs (“Medicare National Coverage Determinations Manual,” Sections 190.12 - 190.34, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part3.pdf) were processed uniformly throughout the nation effective April 1, 2003.

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In accordance with Chapter 16, Section 120.2 of the “Medicare Claims Processing Manual,” 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. This manual chapter is available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf). 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 ICD-10-CM codes. CR9934 lists numerous changes to the codes applicable to the various laboratory NCDs code lists for April 2017. Those changes are too numerous to repeat in this article, but the changes are detailed in the spreadsheet attachments to CR9934.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2017

Note: This article was revised on November 17, 2016, to reflect the revised CR issued on November 16. In the article, the implementation date is now December 5, 2016. Also, 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 provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9806 announces changes that will be included in the January 2017 quarterly release of the edit module for clinical diagnosis laboratory services. Make sure your billing staffs are aware of these changes to ensure proper billing to Medicare.

Background

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. Medicare developed nationally uniform software that was 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 United States effective April 1, 2003.
CR9806 communicates requirements to Medicare system maintainers and the MACs regarding changes to the NCD code lists used for laboratory claims edit software for January 2017. 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 ICD-10-CM codes. Please see Section II (Business Requirements Table) of CR9806 for the lengthy list of codes added or deleted. Note that where codes are deleted, the effective date of deletion is September 30, 2016 and the effective date for codes added is October 1, 2016.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html.

Document History

- November 16, 2016 - Article revised to show a revised implementation date of December 5, 2016
- September 23, 2016 - initial issuance
MLN Matters® Number: MM9769  Related Change Request (CR) #: CR 9769
Related CR Release Date: November 18, 2016  Effective Date: April 1, 2017
Related CR Transmittal #: R3661CP  Implementation Date: April 3, 2017

Claim Status Category and Claim Status Codes Update

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9769 informs MACs about system changes to update, 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 that your billing staffs are aware of these changes.

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 and ASC X12 277 Health Care Claim Acknowledgment transactions. 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.
MLN Matters® Number: MM9769  Related Change Request Number: 9769


Included in the code lists are specific details, including the date when a code was added, changed, or deleted. All code changes approved during the January 2017 committee meeting shall be posted on these sites on or about February 1, 2017. Your MAC will complete entry of all applicable code text changes and new codes, and terminated use of deactivated codes, by the implementation date of CR 9769.

These code changes are to be used in editing of all ASC X12 276 transactions processed on or after the date of implementation and to be reflected in the ASC X12 277 transactions issued on and after the date of implementation of CR 9769.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

HCPCS Code Update for Preventive Services

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9888, announces that, effective for dates of service on and after January 1, 2017, CPT code 76706 replaces HCPCS code G0389. MACs will apply all editing that was applied to HCPCS code G0389 to CPT code 76706, including the waiver of deductible and coinsurance. Make sure that your billing staffs are aware of these changes.

Background

Section 5112 of the Deficit Reduction Act of 2005 allows for only one ultrasound screening test for an abdominal aortic aneurysm by Medicare. CPT code 76706 replaces HCPCS code G0389 as of January 1, 2017, for billing this service. CR9888 also updates the “Medicare Claims Processing Manual,” Chapter 9, to show the current CPT codes for smoking cessation. The revised Chapter 9 is attached to CR9888.

Additional Information


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If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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January 2017 Integrated Outpatient Code Editor (I/OCE) Specifications
Version 18.0

Provider Types Affected

This MLN Matters® Article is intended for providers who submit institutional claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice (HH+H) MACs, for services provided to Medicare beneficiaries.

What You Need to Know

Change Request (CR) 9892 provides instructions and specifications for the Integrated Outpatient Code Editor (I/OCE) used for Outpatient Prospective Payment System (OPPS) and non-OPPS claims. This is 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 (PPS) or to a hospice patient for the treatment of a non-terminal illness. Make sure that your billing staffs are aware of these changes. The I/OCE specifications will be posted at http://www.cms.gov/OutpatientCodeEdit/. These specifications contain the appendices mentioned in the table below.

Key I/OCE Changes for January 2017

The following table summarizes the modifications of the IOCE for the January 2017 v18.0 release. Note that 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.
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<th>Edits Affected</th>
<th>Modification</th>
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<td>1/1/2017</td>
<td></td>
<td>Implement new program logic for the Community Mental Health Center (CMHC) outlier limitation (see OPPS processing logic and Appendix E). Apply new Payment Method Flag 6 to all OPPS payable lines if condition code 66 is present for claims with bill type 76x.</td>
</tr>
<tr>
<td>1/1/2017</td>
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<td>Implement new program logic to include Negative Pressure Wound Therapy (NPWT) procedure codes 97607 and 97608 to the list of codes reportable for Home Health claims with bill type 34x that are payable under OPPS (see OPPS special processing logic and Appendix F-(a)).</td>
</tr>
<tr>
<td>8/1/2016</td>
<td>67</td>
<td>Implement mid-quarter Food and Drug Administration (FDA) approval edit for 90674.</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>100</td>
<td>Implement new edit: Claim for Hematopoietic Stem Cell Transplantation (HSCT) allogeneic transplantation lacks required revenue code line for donor acquisition services (claim is Returned to Provider (RTP)). Edit criteria: A claim reporting HSCT allogeneic transplantation (procedure code 38240) is reported and there is no additional line on the claim reporting revenue code 815 for donor acquisition services (see Table 4).</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>41</td>
<td>Add new revenue code 815 (Allogeneic stem cell acquisition services) to the valid revenue code list.</td>
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<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement updated program logic to process conditional Ambulatory Payment Classification (APC)/packaging, critical care ancillary packaging and advance care planning across the claim rather than by day (see OPPS processing logic).</td>
</tr>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement updated program logic for processing terminated device-intensive procedure offset determinations by HCPCS code, not by APC. Note: This also includes table changes for the quarterly data file reports.</td>
</tr>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement new program logic for payment adjustment of film x-ray HCPCS codes. Film x-ray HCPCS codes with modifier FX reported are assigned new payment adjustment flag 21 (see OPPS processing logic, Table 7 and Appendix G).</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>22</td>
<td>Add new modifiers FX (X-ray taken using film), PN (Non-excepted off-campus svc), 95 (Synchronous Telemedicine Service) and V1, V2, V3 (Demonstration modifiers 1, 2, 3) to the valid modifier list.</td>
</tr>
</tbody>
</table>

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<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement new Status Indicator (SI) value E1, to replace former SI E for non-covered services (see Table 7). Note: Edits 9, 28 and 50 applied formerly for HCPCS with SI = E are now applied to HCPCS with SI = E1.</td>
</tr>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement new SI value E2 (Items and services for which pricing information and claims data are not available) (see Table 7).</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>13</td>
<td>Reactivate edit 13: Separate payment for services is not provided by Medicare (LIR). Edit criteria: there is a line item HCPCS present with SI = E2 (see OPPS processing logic, Table 4, Table 7).</td>
</tr>
<tr>
<td>1/1/2014</td>
<td></td>
<td>Correction of program logic for Extended Assessment and Management (EAM) composite APC 8009 to not consider conditional APC processing of sometimes therapy codes with SI = Q1 resulting in final SI = A as criteria for preventing assignment of the EAM composite APC. Also, units of service are not reduced to one under conditional APC processing for sometimes therapy codes resulting in final SI = A (see OPPS processing logic and Appendix K).</td>
</tr>
<tr>
<td>9/28/2016</td>
<td>68</td>
<td>Implement mid-quarter NCD coverage for G0499.</td>
</tr>
<tr>
<td>1/1/2016</td>
<td>99</td>
<td>Update the edit logic to include exceptions for certain blood clotting factor HCPCS codes that may be self-administered and do not require that an OPPS payable procedure is present. Also, program logic only is updated to apply edit 99 only to those OPPS bill types where APC information is returned (see Appendix F(a) for reference).</td>
</tr>
<tr>
<td>1/1/2016</td>
<td></td>
<td>Update the inpatient procedure processing when the patient expires to also include claims with discharge status codes indicating transfer to another hospital facility (see OPPS processing logic and Appendix L).</td>
</tr>
<tr>
<td>1/1/2016</td>
<td>70</td>
<td>Update the edit logic and description to include transfer discharge status: Edit description: CA modifier requires patient discharge status indicating expired or transferred</td>
</tr>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Implement new program logic for identifying non-excepted items or services under Section 603 requirements that are provided in off-campus provider-based hospital outpatient departments that are reported with modifier PN may be subject to alternative payment method or reduction (see OPPS processing logic and new Appendix Q).</td>
</tr>
</tbody>
</table>

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<tr>
<td>1/1/2017</td>
<td>101</td>
<td>Implement new edit 101: Item or service with modifier PN not allowed under PFS (RTP). Edit criteria: Modifier PN is reported for an item or service that is considered to be non-excepted for an off-campus provider-based hospital outpatient department under Section 603.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2016 Update the advance care planning logic to include add-on code 99498; change the SI to A if reported with 99497 and the annual wellness visit, otherwise package with SI = N.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Update the program logic and flowcharts for partial hospitalization and daily mental health to refer to a single level per diem APC (level I/II APCs no longer applicable) (see OPPS processing logic and Appendix C (‘a’ and ‘b’)). Appendices are attached to CR9892.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 87 Update the skin substitute product lists (Appendix O, List E: Lists A and B)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 22 Modifier L1, associated with the reporting of conditionally packaged laboratory procedures is deactivated (see OPPS processing logic).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Update program logic for LDR brachytherapy composite APC primary code 55875 is assigned under comprehensive APCs if conditions are not met for composite APC 8001 assignment (see Appendix K).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Add the following new payment method flags (see Table 7 and Appendix E):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 6 (CMHC Outlier limitation reached)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 7 (Section 603 service with no reduction in OPPS Pricer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 8 (Section 603 service with PFS reduction applied in OPPS Pricer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Update the description for Payment Indicator value of 2: “Services not paid by OPPS Pricer; paid under fee schedule or other payment system (SIs A, G, K)” (see Table 7).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Add new payment adjustment flag 21 (CAA Section 502b reduction on film x-ray) (see Table 7 and Appendix G).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Add new SI values E1 and E2 (Items and services for which pricing information and claims data are not available) (see Table 7).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Update Appendix F (a) to include new edits 100 and 101.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1/1/2017 Add new Appendix Q: processing steps and criteria for non-excepted items and services under Section 603.</td>
</tr>
</tbody>
</table>

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### MLN Matters® Number: MM9892  
**Related Change Request Number: 9892**

<table>
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<tr>
<th>Effective Date</th>
<th>Edits Affected</th>
<th>Modification</th>
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<tbody>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Update Appendix L to include new SI values E1 and E2 in the list of SI’s that are edited as usual under comprehensive APC processing.</td>
</tr>
<tr>
<td>1/1/2017</td>
<td></td>
<td>Update table 4 to add new columns noting versions and dates effective for edits.</td>
</tr>
</tbody>
</table>
| 1/1/2017       |                | Update the following lists for the release (see quarterly data files):  
- Bilateral flag lists  
- Procedure and gender conflict lists (edit 8)  
- Comprehensive APC list  
- Complexity-adjusted Comprehensive APC code pairs  
- Device and Device-Procedure lists (edit 92)  
- Terminated Device offset (offset by HCPCS)  
- Pass-through device offset amounts  
- Film x-ray HCPCS (new logic)  
- Negative pressure wound therapy (new logic)  
- Section 603 override HCPCS (new logic)  
- Blood clotting factor HCPCS (edit 99 exclusion)  
- Skin substitutes (edit 87)  
- Pass-through Radiopharmaceuticals  
- Pass-through Radiopharmaceutical APC offset amounts  
- Pass-through Contrast APC offset amounts  
- Pass-through Skin substitutes  
- Pass-through Skin substitute APC offset amounts  
- Deductible-Coinsurance N/A list (Appendix O, List C)  
- Service not paid Medicare list (new SI = E2)  
- Not recognized Medicare list (edit 28)  
- Non-covered service list (edit 9)  
- Statutory exclusion list (edit 50)  
- Not recognized OPPS list (edit 62)  
- FQHC vaccines  
- FQHC code pairs  
| 1/1/2017       | 20, 40         | Make all HCPCS/APC/SI changes as specified by CMS (quarterly data files). |
| 1/1/2017       | 20, 40         | Implement version 23.0 of the NCCI (as modified for applicable outpatient institutional providers). |

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MLN Matters® Number: MM9681 Revised  Related Change Request (CR) #: CR 9681
Related CR Release Date: January 6, 2017  Effective Date: April 1, 2017
Related CR Transmittal #: R1770OTN  Implementation Date: April 3, 2017

**Modifications to the National Coordination of Benefits Agreement Crossover Process**

*Note: This article was revised on January 9, 2017, to reflect the revised CR9681 issued on January 9. In the article, references to Type of Bill 82x are deleted from the last paragraph of the Background Section. In addition, the CR release date, transmittal number, and the Web address of CR9681 are revised. All other information remains the same.*

**Provider Types Affected**

This MLN Matters® Article is intended for providers, including hospices, submitting institutional claims to Medicare Administrative Contractors (MACs) requiring Coordination of Benefits (COB) for services provided to Medicare beneficiaries.

**Provider Action Needed**

Change Request (CR) 9681 modifies Medicare's Part A claims processing system to, among other things:

- Always ensure that a Remittance Advice Remark Code (RARC) accompanies claim denials tied to Claims Adjustment Reason Code (CARC) 16, as required.

- Prevent duplicate entry of hospital day counts expressed as value codes (for example, value code 80, 81, 82).

- Prevent reporting of Present on Admission (POA) indicators on outpatient Coordination of Benefits (COB) facility claims.

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Make sure your billing staff is aware of these changes.

**Background**

The Council for Affordable Quality Healthcare Committee for Operating Rules for Information Exchange (CAQH CORE) dictates which CARC and RARC combinations must be used by all covered entities in the healthcare industry. Medicare routinely reports CARCs and RARCs on Health Insurance Portability and Accountability Act (HIPAA) Accredited Standards Institute (ASC) 835 Electronic Remittance Advice (ERA) transactions in accordance with HIPAA requirements. Medicare also includes CARCs and RARCs within HIPAA ASC 837-N claims transactions, including 837 Coordination of Benefits (COB) claims transactions. However, within 837 claims transactions, RARCs are referred to as “Claim Payment Reason Codes” and appear within the 2320 Medicare Inpatient Adjudication Information (MIA) and Medicare Outpatient Adjudication Information (MOA) segments.

As a result of systems issues, MACs are not always including a valid and relevant RARC in the 2320 MIA field when they deny Medicare claims. Medicare crossover claims are often being rejected by supplemental payers as a consequence. Though not the only example, this scenario seems to occur frequently when a claim service line is editing to deny with CARC code 16—“Claim lacks information or has submission/billing error(s) which is needed for adjudication......” CR9681 will ensure that at least one informational RARC is provided to comply with HIPAA and CAHQ/CORE requirements.

The Part A system is producing instances of duplicated hospital day counts on outbound 837 institutional COB/crossover claims. CR9681 remedies this situation. **Important:** Hospital billing staffs should avoid entering hospital day counts via Direct Data Entry (DDE) screens.

Lastly, at present there is no editing with the Part A system to prevent the entry of a POA indicator on incoming outpatient facility claims. CR9681 remedies this issue by returning to the provider (RTP) any outpatient claim (type of bill other than 11x, 18x, 21x, and 41x) that contains a POA indicator. **Important:** Billing vendors for hospitals should make it a practice to only include POA indicators on 11x, 18x, 21x, and 41x type of bill (TOB) claims submitted to Medicare.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-).
MLN Matters® Number: MM9681 Related Change Request Number: 9681

Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/

Document History

- January 9, 2017 - This article was revised on January 9, 2017, to reflect the revised CR9681 issued on January 9. In the article, references to Type of Bill 82x are deleted from the last paragraph of the Background Section. In addition, the CR release date, transmittal number, and the Web address of CR9681 are revised.
- October 31, 2017 - Initial Issuance

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

MLN Matters® Number: MM 9716 Revised
Related Change Request (CR) #: CR 9716
Related CR Release Date: November 25, 2016
Effective Date: April 1, 2017
Related CR Transmittal #: R3637CP and R276FM
Implementation Date: April 3, 2017

New Physician Specialty Code for Hospitalist

Note: This article was updated on November 28, 2016, to reflect a revised CR9716, issued on November 25. 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) 9716 announces that the Centers for Medicare & Medicaid Services (CMS) has established a new physician specialty code for Hospitalist. The new code for Hospitalist is C6. Make sure your billing staffs are aware of this physician specialty code.

Background

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

Medicare will also recognize the new code of C6 as a valid specialty for the following edits:

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MLN Matters® Number: MM9716  Related Change Request Number: 9716

- Ordering/certifying Part B clinical laboratory and imaging, durable medical equipment (DME), and Part A home health agency (HHA) claims
- Critical Access Hospital (CAH) Method II Attending and Rendering claims
- Attending, operating, or other physician or non-physician practitioner listed on CAH claims

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Document History

- November 28, 2016 – This article was updated to reflect a revised CR9716, issued on November 25. 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.
- October 28, 2016 – Initial issuance.

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New Place of Service (POS) Code for Telehealth and Distant Site Payment Policy

Provider Types Affected

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

Provider Action Needed

CR 9726 updates the Place of Service (POS) code set by creating a new code (POS 02) for Telehealth services, effective January 1, 2017. You should ensure that your billing staffs are aware of this new POS code.

Background

As an entity covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Medicare must comply with standards, and their implementation guides, adopted by regulation under this statute. The currently adopted professional implementation guide for the ASC X12N 837 standard requires that each electronic claim transaction include a Place of Service (POS) code from the POS code set that the Centers for Medicare & Medicaid Services (CMS) maintains. The POS code set provides setting information necessary to appropriately pay Medicare and Medicaid claims.
As a payer, Medicare must be able to recognize, as valid, any valid code from the POS code set that appears on the HIPAA standard claim transaction. Further, unless prohibited by national policy to the contrary, Medicare not only recognizes such codes, but also adjudicates claims that contain these codes.

At times, Medicaid has had a greater need for code specificity than has Medicare; and many of the new codes, over the past few years, have been developed to meet Medicaid’s needs. While Medicare does not always need this greater specificity in order to appropriately pay claims, it nevertheless adjudicates claims with the new codes to ease coordination of benefits and to give Medicaid and other payers the setting information they require.

Effective January 1, 2017, CMS is creating a new POS code 02 for use by the physician or practitioner furnishing telehealth services from a distant site. CR 9726 updates the current POS code set by adding this new code (POS 02: Telehealth), with a descriptor of “The location where health services and health related services are provided or received, through telecommunication technology.”

Medicare will pay for these services using the Medicare Physician Fee Schedule (MPFS), including the use of the MPFS facility rate for Method II Critical Access Hospitals billing on type of bill 85x. This Telehealth POS code would not apply to originating site facilities billing a facility fee.

**Remember that under HIPAA, the effective date for nonmedical data code sets, of which the POS code set is one, is the code set in effect the date the transaction is initiated. It is not date of service.**

Modifiers GT (via interactive audio and video telecommunications systems) and GQ (via an asynchronous telecommunications system) are still required when billing for Medicare Telehealth services. If you bill for Telehealth services with POS code 02, but without the GT or GQ modifier, your MAC will deny the service with the following messages:

- Group Code CO
- Claim Adjustment Reason Code (CARC) 4 (The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present)
- Remittance Advice Remarks Code (RARC) MA130 (Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information)

Conversely, if you bill for Telehealth services with modifiers GT or GQ, but without POS code 02, your MAC will deny the service with the following messages:

- Group Code CO
• CARC 5 (The procedure code/bill type is inconsistent with the place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present)
• RARC M77 (Missing/incomplete/invalid/inappropriate place of service)

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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New Revenue Code 0815 for Allogeneic Stem Cell Acquisition Services

Provider Types Affected

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

What You Need to Know

Medicare systems will accept revenue code 0815 (Allogeneic Stem Cell Acquisition/Donor Services), recently created by the National Uniform Billing Committee (NUBC), effective January 1, 2017, when submitted on hospital claims (Types of Bill (TOB) 011x, 012x, 013x, or 085x). Make sure that your billing staffs are aware of this change.

Background

Hematopoietic stem cell transplantation (HSCT) is a process that includes mobilization, harvesting, and transplant of stem cells and the administration of high dose chemotherapy and/or radiotherapy prior to the actual transplant. During the process stem cells are harvested from either the patient (autologous) or a donor (allogeneic) and subsequently administered by intravenous infusion to the patient.

Payment for these acquisition services is included in the Outpatient Prospective Payment System Ambulatory Payment Classification (OPPS APC) payment for the allogeneic stem cell transplant when the transplant occurs in the hospital outpatient setting, and in the Medicare Severity-Diagnosis Related Group (MS-DRG) payment for the allogeneic stem cell transplant when the transplant occurs in the inpatient setting. MACs do not make separate payments for...
these acquisition services, because hospitals may bill and receive payment only for services provided to the Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant. Unlike the acquisition costs of solid organs for transplant (for example, hearts and kidneys), which are paid on a reasonable cost basis, acquisition costs for allogeneic stem cells are included in the prospective payment.

Acquisition charges for stem cell transplants apply only to allogeneic transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Acquisition charges do not apply to autologous transplants (transplanted stem cells are obtained from the recipient himself or herself), because autologous transplants involve services provided to the beneficiary only (and not to a donor), for which the hospital may bill and receive payment. (See the “Medicare Claims Processing Manual,” Chapter 3, Section 90.3 and Chapter 4, Section 231, for information regarding billing for autologous stem cell transplants.)

Currently, when the allogeneic stem cell transplant occurs in the outpatient setting, the hospital identifies stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately in FL 42 of Form CMS-1450 (or electronic equivalent) by using revenue code 0819 (Other Organ Acquisition). Revenue code 0819 charges should include all services required to acquire stem cells from a donor, as defined above, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.

Stakeholders have expressed concern that the acquisition costs are not being accurately reflected in the transplant procedure as Revenue Code 0819 maps to cost center code 086XX (Other organ acquisition where XX is “00” through “19”) and is reported on line 112 (or applicable subscripts of line 112) of the Form CMS-2552-10 cost report.

The Centers for Medicare & Medicaid Services (CMS) requested and NUBC approved a new Revenue Code 0815 to be used when the hospital identifies stem cell acquisition charges for allogeneic bone marrow/stem cell transplants separately.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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Prolonged Services Without Direct Face-to-Face Patient Contact Separately Payable Under the Physician Fee Schedule (Manual Update)

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9905 provides that the Centers for Medicare & Medicaid Services (CMS) revises Chapter 12, Section 30.6.15.2 of the “Medicare Claims Processing Manual” to indicate that beginning Calendar Year (CY) 2017, Current Procedural Terminology (CPT) codes 99358 and 99359 (prolonged services without face-to-face contact) are separately payable under the Medicare Physician Fee Schedule. Make sure your billing staffs are aware of these CPT code changes.

Background

Prior to CY 2017, CPT codes 99358 and 99359 (prolonged services without face-to-face contact) were not separately payable, and were included for payment under the related face-to-face Evaluation and Management (E/M) service code. Practitioners were not permitted to bill the patient for services described by these codes, since they are Medicare covered services and payment was included in the payment for other billable services.

The CPT prefatory language and reporting rules apply for the Medicare billing of these codes, for example, CPT codes 99358 and 99359:

- Cannot be reported during the same service period as complex Chronic Care...
Management (CCM) services or transitional care management services

- Are not reported for time spent in non-face-to-face care described by more specific codes having no upper time limit in the CPT code set

CMS has posted a file at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html) that notes the times assumed to be typical, for purposes of Physician Fee Schedule (PFS) rate-setting. While these typical times are not required to bill the displayed codes, CMS would expect that only time spent in excess of these times would be reported under CPT codes 99358 and 99359. Further, CMS notes: 1) that these codes can only be used to report extended qualifying time of the billing physician or other practitioner (not clinical staff); and 2) Prolonged services cannot be reported in association with a companion E/M code that also qualifies as the initiating visit for CCM services. Practitioners should instead report the add-on code for CCM initiation, if applicable.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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MLN Matters® Number: MM9568 Revised Related Change Request (CR) #: CR 9568
Related CR Release Date: December 16, 2016 Effective Date: January 1, 2017
Related CR Transmittal #: R1763OTN Implementation Date: January 3, 2017

Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits

Note: This article was revised on December 16, 2016, due to a revised CR9568 issued on that date. As a result, the transmittal number, CR release date, and link to the CR are revised in this article. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for Hospitals and Skilled Nursing Facilities (SNFs) working with Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (SSP) and submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

CR 9568 allows the processing of SNF claims without having to meet the 3-day hospital stay requirement for certain designated SNFs that have a relationship with an ACO participating in the SSP. Make sure that your SNF is clear on whether or not it is eligible to participate in this initiative and that your billing staffs are aware of these changes.

Background

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing and/or rehabilitation care. Pursuant to Section 1861(i) of the Social Security Act (the Act), beneficiaries must have a prior inpatient hospital stay of no fewer than 3 consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. This has become known as the SNF 3-day rule.

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The Centers for Medicare & Medicaid Services (CMS) understands that, in certain circumstances, it could be medically appropriate for some patients to receive skilled nursing care and/or rehabilitation services provided in a SNF without prior hospitalization or with an inpatient hospital length of stay of less than 3 days.

Section 3022 of the Affordable Care Act amended Title XVIII of the Act by adding a new Section 1899 to establish the Medicare SSP. Under Section 1899(f), the Secretary of Health and Human Services is permitted to waive “such requirements of . . . title XVIII of this Act as may be necessary to carry out the provisions of this section.” As a result, CMS proposed and finalized through rulemaking (80 FR 32692 at http://www.gpo.gov/fdsys/pkg/FR-2015-06-09/pdf/2015-14005.pdf) a waiver of the prior 3-day inpatient hospitalization requirement in order to provide Medicare SNF coverage when certain beneficiaries assigned to SSP ACOs in Track 3 are admitted to designated SNF affiliates either directly from an inpatient hospital stay or after fewer than 3 inpatient hospital days, starting in January 2017. The waiver will be available for SSP ACOs in Track 3 that demonstrate the capacity and infrastructure to identify and manage patients who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospital stay of fewer than 3 days, for services otherwise covered under the Medicare SNF benefit.

To identify the beneficiaries eligible to receive the SNF 3-Day Waiver, CMS provides ACOs with a prospective beneficiary assignment list for the performance year. ACOs will receive the prospective assignment list close to the start of each performance year.

To identify the SNFs eligible to use the SNF 3-Day Waiver, ACOs designate SNFs (as SNF affiliates) eligible to participate in the SNF 3-Day Waiver with the ACO.

CMS will reimburse designated SNFs (specifically, SNF affiliates participating in Track 3 SSP ACOs), for the Medicare SNF benefit without the required 3-day in-patient hospitalization for beneficiaries that are prospectively assigned to the Track 3 ACO.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html on the CMS website under - How Does It Work.

You can learn more about the SSP by visiting our website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html. To learn more about the SNF 3-Day Waiver, visit the SSP webpage and click on Statutes/Regulations/Guidance.

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## Document History

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<th>Description</th>
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<td>December 16, 2016</td>
<td>The article was revised on December 16, 2016, due to a revised CR9568 issued on that date. As a result, the transmittal number, CR release date, and link to the CR are revised in this article.</td>
</tr>
<tr>
<td>July 5, 2016</td>
<td>The article was revised due to an updated Change Request (CR). That CR revised Shared System Maintainer (SSM) responsibility. The transmittal number, CR release date and link to the transmittal also changed.</td>
</tr>
<tr>
<td>May 11, 2016</td>
<td>Initial article release</td>
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Update for Additional International Classification of Diseases (ICD)-10 Codes for the System Changes to Implement Section 231 of the Consolidated Appropriations Act, 2016, Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals (LTCHs)

Provider Types Affected

This MLN Matters® Article is intended for hospitals, including certain Long Term Care Hospitals (LTCHs) submitting claims to Medicare Administrative Contractors (MACs)) for services provided to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 9872 which informs MACs about an update to include additional ICD-10 codes for the implementation of the temporary exception for certain wound care discharges from the site neutral payment rate for certain LTCH Hospitals within Hospitals (HwHs). Make sure that your billing staffs are aware of these changes.

Background

Under the LTCH Prospective Payment System (PPS), for LTCH discharges in cost reporting periods beginning on or after October 1, 2015, Medicare established two separate payment categories for LTCH patients upon discharge. LTCH cases meeting specific clinical criteria are paid the LTCH PPS standard Federal rate payment and those cases not meeting specific clinical criteria are paid the site neutral rate payment (the lesser of an “Inpatient Prospective Payment System (IPPS)-comparable” payment amount or 100 percent of the estimated cost of the case).
In general, in order to be paid at the LTCH PPS standard Federal rate payment amount, an LTCH discharge must either:

1. Have been admitted directly from an IPPS hospital during which at least 3 days were spent in an Intensive Care Unit (ICU) or Coronary Care Unit (CCU), but the discharge must not have a principal diagnosis in the LTCH of a psychiatric or rehabilitation diagnosis or

2. Have been admitted directly from an IPPS hospital and the LTCH discharge is assigned to an MS-LTC-DRG based on the receipt of ventilator services of at least 96 hours, but must not have a principal diagnosis in the LTCH of a psychiatric or rehabilitation diagnosis.

Section 231 of the Consolidated Appropriations Act of 2016 established an additional temporary exception from the site neutral payment rate for patients discharged from certain LTCHs with a severe wound, effective for discharges occurring before January 1, 2017. In a final rule published in the Federal Register on August 22, 2016 (81 FR 57068 through 57075), the Centers for Medicare & Medicaid Services (CMS) updated the list of ICD-10 codes that qualify as severe wounds under the categories:

- Stage 3 wound
- Stage 4 wound
- Unstageable wound
- Non-healing surgical wound
- Fistula
- Osteomyelitis

The complete list of ICD-10 codes for this provision is available for download at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/download.htm. CR9872 adds ICD-10 codes L97.112-L97.114, L97.122-L97.124, L97.912-L97.914, L97.921-L97.924, T81.30XA, T81.30XD, T81.31XA, T81.31XD, T81.32XA, T81.32XD, T81.4XX, T81.4XXA, T81.4XXD, T81.89XA, T81.89XD to this list.

As noted in CR9599, only grandfathered LTCH HwHs are eligible to qualify for this temporary exception. MACs shall verify such status upon request from a hospital.

MACs will reprocess claims with a through date (for interim claims) or a discharge date (for final claims) on or after April 21, 2016, through December 31, 2016, containing one of the above ICD-10 codes and which are eligible for this temporary exception. Such claims will be reprocessed within 60 days of the implementation date of CR9872.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

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MLN Matters® Article: Update to Editing of Therapy Services to Reflect Coding Changes

**Provider Types Affected**

This MLN Matters® Article is intended for providers submitting claims to Medicare Administrative Contractors (MACs) for physical and occupational therapy services provided to Medicare beneficiaries.

**Provider Action Needed**

Change Request (CR) 9698 instructs the MACs to apply certain coding edits to the new Current Procedural Terminology (CPT) codes that are used to report physical and occupational therapy evaluations and re-evaluations, effective January 1, 2017. Make sure your billing staffs are aware of these coding changes.

**Background**

Original Medicare claims processing systems contain edits to ensure claims for the evaluative procedures furnished by rehabilitative therapy clinicians – including physical therapists, occupational therapists and speech-language pathologists – are coded correctly. These edits ensure that when the codes for evaluative services are submitted, the therapy modifier (GP, GO or GN) that reports the type of therapy plan of care is consistent with the discipline described by the evaluation or re-evaluation code. The edits also ensure that Functional Reporting occurs, that is, that functional G-codes, along with severity modifiers, always accompany codes for therapy evaluative services.

For calendar year (CY) 2017, eight new CPT codes (97161-97168) were created to replace existing codes (97001-97004) to report physical therapy (PT) and occupational therapy (OT) evaluations and re-evaluations. The new CPT code descriptors include specific components that are required for reporting as well as the typical face-to-face times. In another recent issuance, CR...
9782, the Centers for Medicare & Medicaid Services (CMS) described the new PT and OT code sets, each comprised of three new codes for evaluation – stratified by low, moderate, and high complexity – and one code for re-evaluation. CR 9782 designated all eight new codes as “always therapy” (always require a therapy modifier) and added them to the 2017 therapy code list located at http://www.cms.gov/Medicare/Billing/TherapyServices/index.html. For a complete listing of the new codes, their CPT long descriptors, and related policies, see the article related to CR 9782 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9782.pdf.

CR 9698 applies the coding requirements for certain evaluative procedures that are currently outlined in the “Medicare Claims Processing Manual,” Chapter 5 to the new codes for PT and OT evaluations and re-evaluations. These coding requirements include the payment policies for evaluative procedures that (a) require the application of discipline-specific therapy modifiers and (b) necessitate Functional Reporting using G-codes and severity modifiers. The new codes are also added to the list of evaluation codes that CMS will except from the caps after the therapy caps are reached when an evaluation is necessary, for example, to determine if the current status of the beneficiary requires therapy services.

This notification implements the following payment policies related to claims for therapy services for the new codes for physical therapy (PT) and occupational therapy (OT) evaluative procedures – claims without the required information will be returned as unprocessable:

**Therapy modifiers.** The new PT and OT codes are added to the current list of evaluative procedures that require a specific therapy modifier to identify the plan of care under which the services are delivered to be on the claim for therapy services. Therapy modifiers GP, GO or GN are required to report the type of therapy plan of care – PT, OT, or speech language pathology (SLP), respectively. This payment policy requires that each new PT evaluative procedure code – 97161, 97162, 97163 or 97164 – to be accompanied by the GP modifier; and, (b) each new code for an OT evaluative procedure – 97165, 97166, 97167 or 97168 – be reported with the GO modifier.

**Functional Reporting.** In addition to other Functional Reporting requirements, current payment policy requires Functional Reporting, using G-codes and severity modifiers, when an evaluative procedure is furnished and billed. CR9698 adds the eight new codes for PT and OT evaluations and reevaluations – 97161, 97162, 97163, 97164, 97165, 97166, 97167, and 97168 – to the procedure code list of evaluative procedures that necessitate Functional Reporting. A severity modifier (CH – CN) is required to accompany each functional G-code (G8978-G8999, G9158-9176, and G9186) on the same line of service.

For each evaluative procedure code, Functional Reporting requires either two or three functional G-codes and related severity modifiers be on the same claim. Two G-codes are typically reported on specified claims throughout the therapy episode. However, when an evaluative service is furnished that represents a one-time therapy visit, the therapy clinician reports all three G-codes in the functional limitation set – G-codes for Current Status, Goal Status and Discharge Status.
For the documentation requirements related to Functional Reporting, please refer to the “Medicare Benefits Policy Manual,” Chapter 15, Section 220.4.

CMS coding requirements for Functional Reporting applied through CR9698 ensure that at least two G-codes in a functional set and their corresponding severity modifiers are present on the same claim with any one of the codes on this evaluative procedure code list. The required reporting of G-codes includes: (a) G-codes for Current Status and Goal Status; or, (b) G-codes for Discharge Status and Goal Status. Remember that your MAC will Return to the Provider (RTP):

1. Claims you submit for the new therapy evaluative procedures, HCPCS codes 97161-97168, without including one of the following pairs of G-codes/severity modifiers required for Functional Reporting: (a) A current status G-code/severity modifier paired with a goal status G-code/severity modifier; or, (b) A goal status G-code/severity modifier paired with a discharge status G-code/severity modifier.
2. Institutional outpatient claims reporting HCPCS codes 97161, 97162, 97163, and 97164 that you submit without including modifier GP.
3. Institutional outpatient claims reporting HCPCS codes 97165, 97166, 97167, and 97168, that you submit without including modifier GO.

Additional Information

The official instruction, CR9698, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3670CP.pdf. The updated “Medicare Claims Processing Manual,” Chapter 5 (Part B Outpatient Rehabilitation and CORF/OPT Services), Sections 10.3.2 (Exceptions Process), 10.6 (Functional Reporting), and 20.2 (Reporting of Service Units with HCPCS) is attached to CR9698.

If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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Update to the Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates

Note: This article was revised on January 5, 2017, to reflect the revised CR9831 issued on January 4. The CR revision corrected a typographical error in the FY2015 payment rate for grandfathered tribal FQHCs. In addition, 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 Federally Qualified Health Centers (FQHCs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9831 updates the FQHC PPS base payment rate and the Geographic Adjustment Factors (GAFs) for the FQHC Pricer for Calendar Year (CY) 2017. Please ensure your billing staffs are aware of these changes.

Background

Payment for FQHCs under the Prospective Payment System (PPS)
The Affordable Care Act (Section 10501(i)(3)(A); Pub. L. 111–148 and Pub. L. 111–152) added Section 1834(o) of the Social Security Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the PPS for FQHC Final Rule published in the May 2, 2014, Federal Register (79 FR 25436), the Centers for Medicare & Medicaid Services (CMS) implemented a methodology and payment rates for FQHCs under the PPS beginning on October 1, 2014.

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Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) that were Provider-Based Clinics on or Before April 7, 2000

Effective for dates of service on or after January 1, 2016, Indian Health Service (IHS) and tribal facilities and organizations that met the conditions of Section 413.65(m) on or before April 7, 2000, and have a change in their status on or after April 7, 2000 from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the Conditions of Participation (CoPs), may seek to become certified as grandfathered tribal FQHCs. These grandfathered tribal FQHCs would be required to meet all FQHC certification and payment requirements. The grandfathered PPS rate equals the Medicare outpatient per visit payment rate paid to them as a provider-based department, as set annually by the IHS.

FQHC PPS Rate

Under the FQHC PPS, Medicare pays FQHCs based on the lesser of their actual charges or the PPS rate for all FQHC services furnished to a beneficiary on the same day when a medically-necessary, face-to-face FQHC visit is furnished to a Medicare beneficiary. The Social Security Act (Section 1834(o)(2)(B)(ii)) requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). The Social Security Act (Section 1834(o)(2)(B)(ii)) also requires that in subsequent years, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI. In the Calendar Year (CY) 2017 Physician Fee Schedule (PFS) Final Rule, CMS finalized a proposal to update the FQHC PPS base payment rate using a 2013-based FQHC market basket.

- Based on historical data through second quarter 2016, the final FQHC market basket for CY 2017 is 1.8 percent.
- From January 1, 2017, through December 31, 2017, the FQHC PPS base payment rate is $163.49.
- The 2017 base payment rate reflects a 1.8 percent increase above the 2016 base payment rate of $160.60.

In accordance with the Social Security Act (Section 1834(o)(1)(A)), the FQHC PPS base rate is adjusted for each FQHC by the FQHC GAF, based on the Geographic Practice Cost Indices (GPCIs) used to adjust payment under the PFS. The FQHC GAF is adapted from the work and practice expense GPCIs, and are updated when the work and practice expense GPCIs are updated for the PFS. For CY 2017, the FQHC GAFs have been updated in order to be consistent with the statutory requirements.

Grandfathered Tribal FQHC PPS Rate

Grandfathered tribal FQHCs are paid the lesser of their charges or a grandfathered tribal FQHC PPS rate for all FQHC services furnished to a beneficiary during a medically-necessary, face-to-face FQHC visit. From January 1, 2016, through December 31, 2016, the
grandfathered tribal FQHC PPS rate is $324. FQHC claims (TOB 77X) for grandfathered tribal FQHCs submitted with dates of service on or after January 1, 2016, through December 31, 2016 paid at the CY 2015 rate of $307 must be adjusted and paid at the CY 2016 rate of $324. Grandfathered tribal FQHC claims with dates of service on or after January 1, 2017, through December 31, 2017, should be paid at the CY 2016 rate of $324 until CMS provides an updated payment rate for CY 2017. The grandfathered tribal FQHC PPS rate will not be adjusted by the FQHC PPS GAFs or be eligible for the special payment adjustments under the FQHC PPS for new patients, patients receiving an IPPE or an AWV. The rate is also ineligible for exceptions to the single per diem payment that is available to FQHCs paid under the FQHC PPS. In addition, the FQHC market basket adjustment that is applied annually to the FQHC PPS base rate, will not apply to the grandfathered tribal FQHC PPS rate.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Document History

- January 5, 2017 - Article revised to reflect a revised CR9831. The CR was revised to correct a typographical error in the FY2015 payment rate for grandfathered tribal FQHCs.
- November 15, 2016 - Initial Issuance

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Coding Revisions to National Coverage Determination (NCDs)

Note: This article was revised on November 17, 2016 to reflect the revised CR9571 issued on the same day. CR9571 was revised to change the NCD180.1 effective date in spreadsheet history to 1/1/16, in NCD160.18, remove reactivation of MCS 012L from spreadsheet history and business requirement, and in NCD220.6.20 to remove reference to 'primary diagnosis' regarding diagnosis code Z00.6 in spreadsheet, and reference FISS new RC for value code D4 in spreadsheet history. In the article, the CR release date, transmittal number and the Web address for CR9571 are revised. All other information remains the same.

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9751 is the 9th maintenance update of International Classification of Diseases, Tenth Revision (ICD-10) conversions and other coding updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically CR7818, CR8109, CR8197, CR8691, CR9087, CR9252, CR9540, and CR9631; while others are the result of revisions required to other NCD-related CRs released separately. MLN Matters® Articles MM7818, MM8109, MM8197, MM8691, MM9087, MM9252, MM9540, and MM9631 contain information pertaining to these CR’s.
Background

The translations from ICD-9 to ICD-10 are not consistent 1-1 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 the 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 as of October 1, 2015.

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. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed.

CR9751 makes adjustments to the following NCDs:

- NCD 20.7 Percutaneous Transluminal Angioplasty (PTA)
- NCD 20.19 Ambulatory Blood Pressure Monitoring (ABPM)
- NCD 20.33 Transcatheter Mitral Valve Repair (TMVR) Therapy
- NCD 40.1 Diabetes Self-Management Training (DSMT)
- NCD 160.18 Vagus Nerve Stimulation (VNS)
- NCD 180.1 Medical Nutrition Therapy (MNT)
- NCD 190.3 Cytogenetic Studies
- NCD 220.6.17 FDG PET for Solid Tumors
- NCD 220.6.20 PET Beta Amyloid in Dementia/Neurological/ Disorders
- NCD 230.18 Sacral Nerve Stimulation (SNS) for Urinary Incontinence
- NCD 260.1 Adult Liver Transplants


Remember that coding and payment are areas of the Medicare Program that are separate and distinct 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.

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

- Remittance Advice Remark Codes (RARC)

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- N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered; with
  - Claim Adjustment Reason Codes (CARC)
    - 50 - These are non-covered services because this is not deemed a “medical necessity” by the payer;
    - 96 - Non-covered charge(s); or
    - 119 Benefit maximum for this time period has been reached.

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).

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html.

Document History

- November 17, 2016 – This article was revised to reflect the revised CR9571 issued on the same day. CR9571 was revised to change the NCD180.1 effective date in spreadsheet history to 1/1/16, in NCD160.18, remove reactivation of MCS 012L from spreadsheet history, and in NCD220.6.20 to remove reference to 'primary diagnosis' regarding diagnosis code Z00.6 in spreadsheet, and reference FISS new RC for value code D4 in spreadsheet history. In the article, the CR release date, transmittal number and the Web address for CR9571 are revised. All other information remains the same.
- August 19, 2016 – Initial Issuance

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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/home/home

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 appropriate link below for more information: https://www.wpsgha.com/wps/portal/mac/site/policies/news-and-updates

February 2017

There are no new policies/articles for February 2017.

January 2017

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<td>J5/J8</td>
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### RETIRED POLICIES

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

Visit our website at the appropriate link below for more information:

**February 2017**

There are no retired policies/articles for February 2017.

**January 2017**

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<td>J5/J8</td>
<td>MolDX: FDA Approved ALK Companion Diagnostic Tests Coding and Billing Guidelines</td>
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<td>Molecular Diagnostic Testing &amp; Billing and Coding Guidelines for Molecular Diagnostic Testing LCD</td>
<td>L34762</td>
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<td>L34535</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): [http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx)

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

#### February 2017

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<td>Added the following diagnosis codes to Group 4 Patch Tests 95044, 95052: T84.89XS Other specified complication of internal orthopedic prosthetic devices, implant and grafts, sequela Z91.09 Other allergy status, other than to drugs and biological substances</td>
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<td>Added the following paragraph to clarify patch testing for joint replacement patients to the narrative section for Patch Testing. &quot;The clinician should recognize that contact sensitization to metals or bone cement that is used in orthopedic, cardiac, dental, and gynecological implants has been associated with both dermatitis and noncutaneous complications. These complications may include localized pain, swelling, erythema, warmth, implant loosening, decreased range of motion, stent stenosis, and pericardial effusions in the case of cardiac implants. Patch testing to implant or device components has been recommended to help determine the etiology of the adverse reaction.&quot;</td>
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<td>02/01/2017</td>
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<td>For clarification, adding the following sentence to the article text: Further investigation is warranted of the Rezum® procedure for the treatment of BPH and is currently non-covered.</td>
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<tr>
<td>J5/J8</td>
<td>Chemotherapy Drugs and their Adjuncts</td>
<td>L35053</td>
<td>HONC-010</td>
<td>02/01/2017</td>
</tr>
<tr>
<td></td>
<td>Additional diagnosis codes added to: Section C. 13. Daratumumab(Darflex),J9145) (C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79) Effective 11/21/2016-FDA approval date. FDA indications added: Section C. 6 Bevaxizumab(Avastin™) (J9035): Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that is:</td>
<td></td>
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</tr>
</tbody>
</table>
- Platinum-resistant in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, who have received no more than 2 prior chemotherapy regimens
- Platinum-sensitive in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent.

(C48.1, C48.2, C48.8, C56.1, C56.2, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9) FDA approval 12/06/2016, Effective date 12/06/2016.

Section C. 13. Daratumumab (Darzalex) (J9145), 10mg Daratumumab is indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

(C90.00, C90.02, C90.10, C90.12, C90.20, C90.22, C90.30, C90.32, Z85.79) FDA approval 11/21/2016 Effective date 11/21/2016.

Reconsideration request:
Section C. 17. Ipilimumab (Yervoy™) 1mg, (J9228) Per NCCN: Subsequent systemic therapy for patients with performance status 0-2 in combination with nivolumab for small cell lung cancer (SCLC)
- relapse within 6 months following complete or partial response or stable disease with initial treatment
- primary progressive disease

(C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30, C34.32, C34.80, C34.82, C34.90-C34.92, C78.00-C78.02, C79.31, C79.51, C79.52, Z85.118) Effective date: 02/15/2017.

J5/J8 Drug Testing

L34645 PATH-035 01/01/2017

Added code G0659 to Group 1 Codes based on HCPCS correction. (Code G0659 needed to be listed in the Group1 Paragraph instead of Group1 Table due to CMS software issue.)
- G0480 Drug test def 1-7 classes
- G0481 Drug test def 8-14 classes
- G0482 Drug test def 15-21 classes
- G0483 Drug test def 22+ classes
- G0659 Drug test def simple all cl
- 80305 Drug tests presumptive direct optical observation
- 80306 Drug tests presumptive direct optical observation read by instrument
- 80307 Drug tests presumptive by instrument chemistry analyzers

J5/J8 Endoscopic Treatment of GERD

L34659 GI-010 01/01/2017

Removed CPT 43284 and CPT 43285 as non-covered codes. Removed all references to Linx® Reflux Management System procedure and Linx® sources of information.

J5/J8 Erythropoiesis Stimulating Agents (ESAs)

L34633 INJ-023 02/01/2017

Clarification of language regarding Goals of ESA Therapy added to Coverage Indications, Limitations and/or Medical Necessity:
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A: End Stage Renal Disease (ESRD) ON dialysis; removed the word “immediately”. 1. The hemoglobin level prior to initiation of ESA treatment is less than 10 g/dL (or the hematocrit is less than 30%). Group B: Chronic Kidney Disease NOT on dialysis; removed the word “immediately”. 1. The hemoglobin level prior to initiation of ESA treatment is less than 10 g/dL (or the hematocrit is less than 30%). Group C 2. Anemia related to therapy with Zidovudine (AZT) and/or other Nucleoside Reverse Transcriptase Inhibitors (NRTI) therapy; removed the word “immediately”. The hemoglobin level prior to initiation of ESA treatment is less than 10 g/dL (or the hematocrit is less than 30%). Group C 3: Anemia associated with chemotherapeutic medications removed the word “immediately”. The hemoglobin level prior to initiation of ESA treatment is less than 10 g/dL (or the hematocrit is less than 30%). Group C: Indications other than Renal Disease: clarification of language to reflect NCD. Removed unnecessary language of initial paragraph since specific requirements listed individually. Effective 02/01/2017.</td>
<td></td>
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</tr>
<tr>
<td>J5/J8</td>
<td>MolDX-CDD: NSCLC, Comprehensive Genomic Profile Testing</td>
<td>L36803</td>
<td>MolDX-017</td>
<td>02/16/2017</td>
</tr>
<tr>
<td></td>
<td>Registry requirements were removed and the following information was added:</td>
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<td></td>
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<tr>
<td></td>
<td>- Testing is performed by a lab that satisfies the MolDx Contractor’s</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Analytical Performance Specifications for Comprehensive Genomic Profiling</td>
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<tr>
<td></td>
<td>(M00118,v1). Requires submission of specifications by MolDX or entity approved by MolDx.</td>
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<tr>
<td></td>
<td>This contractor recognizes that evidence for clinical utility for CGP in advanced NSCLC patients is limited at the current time. However, this contractor believes the clinical studies currently in progress will identify a number of patients who will test positive for an actionable EGFR, ALK or ROS1 mutations or identify mutations despite prior negative test results in patients who will benefit from targeted therapy. In addition, CGP testing is likely to identify patients who will need referral/genetic counseling for hereditary cancer risk assessment when an APC, MYH, MLH1, MSH2, MSH6, PMS2, EPCAM, POLE, POLD1, BMPR1A, PTEN or STK11 alteration is identified in the test panel. The identification of other genetic genes, although not meeting Medicare’s reasonable and necessary criteria for coverage, will likely direct patients into clinical trials. Continued coverage for CGP test for NSCLC will be dependent on annual review of publications and/or presentations of clinical utility data demonstrating CGP for NSCLC improves patient outcomes and/or directs or changes selection of therapies to improve patient outcomes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: NRAS Genetic Testing</td>
<td>L36797</td>
<td>MolDX-013</td>
<td>02/16/2017</td>
</tr>
<tr>
<td></td>
<td>The following information was added to the policy:</td>
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<tr>
<td></td>
<td>Evidence increasingly suggests that BRAF V600E mutation makes response to panitumumab or cetuximab highly unlikely, as a single agent, or in combination with cytotoxic chemotherapy. In light of the above, KRAS, NRAS and BRAF are covered for metastatic colorectal cancer.</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
(Per NCCN Guidelines 3.2016- BRAF- targeted Therapies: “Approximately half of patients with metastatic cutaneous melanoma harbor an activating mutation of BRAF, an intracellular signaling kinase in the MAPK pathway. Most BRAF-activating mutations occurring in melanomas are at residue V600, usually V600E but occasionally V600K or other substitutions. BRAF inhibitors have been shown to have clinical activity in melanomas with BRAF V600 mutations. Inhibitors of MEK, a signaling molecule downstream of BRAF, may potentiate these effects. Recent efficacy and safety data from large randomized trials testing BRAF and MEK inhibitors have significantly impacted the recommended treatment options for patients with BRAF-mutation positive advanced melanoma.”)

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Non-Coronary Vascular Stents</td>
<td>L35998</td>
<td>CV-049</td>
<td>02/01/2017</td>
</tr>
</tbody>
</table>

Added the following diagnosis codes to Group 9 codes for lower extremity arteries.
- T82.858A - Stenosis of other vascular prosthetic devices, implant and grafts, initial encounter
- T82.858D - Stenosis of other vascular prosthetic devices, implant and grafts, subsequent encounter
- T82.858S - Stenosis of other vascular prosthetic devices, implant and grafts, sequela

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>2017 CPT/HCPCS Code Updates</td>
<td>NA</td>
<td>NA</td>
<td>01/01/2017</td>
</tr>
</tbody>
</table>

The Procedure Codes included in the 2017 CPT/HCPCS Code Updates have been added or deleted from the listed Local Coverage Determination (LCD) Policies for 2017. The new codes are effective for services performed on or after 01/01/2017; the deleted are effective until 12/31/2016 and will not include a 90 day grace period.


<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Drug Administration Coding</td>
<td>A54176</td>
<td>NA</td>
<td>02/14/2017</td>
</tr>
</tbody>
</table>

In addition to the 2017 CPT/HCPCS code update article.

Removed golimumab Simponi® J3590 effective 02/14/2017, this drug was added to the SAD list. Added code J3590 for IV ustekinumab Stelera.

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
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<th>WPS Policy #</th>
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</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>Endoscopic Treatment of GERD</td>
<td>L34659</td>
<td>GI-010</td>
<td>01/01/2017</td>
</tr>
</tbody>
</table>

Please see the 2017 CPT/HCPCS code update article. Coverage Indications, Limitations and/or Medical Necessity Benefits are not available for endoluminal treatment for Gastroesophageal Reflux Disease (GERD) using the Stretta® procedure, the Bard EndoCinch™ Suturing System, Plicator™, EsophyX™, Linx® or similar treatments as these procedures are not considered reasonable and necessary for the diagnosis or treatment of an injury or disease.
The Linx Reflux management system uses an adjustable band of magnetic beads laparoscopically placed around the outside of the esophagus at the level of the sphincter. The magnetic attraction of the beads keeps the sphincter closed to prevent esophageal reflux but allows normal passage of food boluses or emesis.

<table>
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<tr>
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<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>MolDX: Avise PG Assay Billing/Coding Update</td>
<td>A55144</td>
<td>NA</td>
<td>02/16/2017</td>
</tr>
</tbody>
</table>

The following updates have been made to this article:

- Enter Assigned ID in the comment/narrative field for the following Part A claim field/types: Block 80 for the UB04 claim form
- Line SV202-7 for the 837I electronic claim
- Select the appropriate ICD-10-CM code to indicate methotrexate use
  - Z79.899 - Other long term (current) drug therapy
  - Z92.25 - Personal history of immunosupression therapy

Added diagnostic codes to Group 1: M05.011, M05.012, M05.021, M05.022, M05.031, M05.032, M05.041, M05.042, M05.051, M05.052, M05.061, M05.062, M05.071, M05.072, M05.111, M05.112, M05.121, M05.122, M05.131, M05.132, M05.141, M05.142, M05.151, M05.152, M05.161, M05.162, M05.171, M05.172, M05.211, M05.212, M05.221, M05.222, M05.231, M05.232, M05.241, M05.242, M05.251, M05.252, M05.261, M05.262, M05.271, M05.272, M05.311, M05.312, M05.321, M05.322, M05.331, M05.332, M05.341, M05.342, M05.351, M05.352, M05.361, M05.362, M05.371, M05.372, M05.611, M05.612, M05.621, M05.622, M05.631, M05.632, M05.641, M05.642, M05.651, M05.652, M05.661, M05.662, M05.671, M05.672, M05.711, M05.712, M05.721, M05.722, M05.731, M05.732, M05.741, M05.742, M05.751, M05.752, M05.761, M05.762, M05.771, M05.772, M05.811, M05.812, M05.821, M05.822, M05.831, M05.832, M05.841, M05.842, M05.851, M05.852, M05.861, M05.862, M05.871, M05.872, M06.011, M06.012, M06.021, M06.022, M06.031, M06.032, M06.041, M06.042, M06.051, M06.052, M06.061, M06.062, M06.071, M06.072, M06.211, M06.212, M06.221, M06.222, M06.231, M06.232, M06.241, M06.242, M06.251, M06.252, M06.261, M06.262, M06.271, M06.272, M06.311, M06.312, M06.321, M06.322, M06.331, M06.332, M06.341, M06.342, M06.351, M06.352, M06.361, M06.362, M06.371, M06.372, M06.811, M06.812, M06.821, M06.822, M06.831, M06.832, M06.841, M06.842, M06.851, M06.852, M06.861, M06.862, M06.871, M06.872.

Added diagnosis codes to Group 2: Z79.899 and Z92.25.

Added 84999 to CPT/HCPCs section.

Removed unspecified codes from Group 1: M05.40, M05.419, M05.429, M05.439, M05.449, M05.459, M05.469, M05.479, M05.50, M05.519, M05.529, M05.539, M05.549, M05.559, M05.569, M05.579.

| J5/J8    | MolDX: bioTheranostics Cancer TYPE ID® Update | A55147 | NA | 02/16/2017 |

The following information was added to this article:

ICD-10 Codes that are Covered

Group 1 Paragraph:
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy Title</th>
<th>CMS MCD Policy #</th>
<th>WPS Policy #</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Group 1 Codes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C34.31 Malignant neoplasm of lower lobe, right bronchus or lung</td>
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<tr>
<td></td>
<td>Enter DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Line SV202-7 for 837I electronic claim</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Block 80 for the UB04 claim form</td>
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</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: SEPT9 Gene Test Coding and Billing Guidelines</td>
<td>A55206</td>
<td>NA</td>
<td>02/16/2017</td>
</tr>
<tr>
<td></td>
<td>In addition to the 2017 CPT/HCPC code updates, the DEX Z-Code™ identifier and instructions for Part A claim submission were added to this article:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Enter DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:</td>
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<tr>
<td></td>
<td>• Block 80 for the UB04 claim form</td>
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</tr>
<tr>
<td>J5/J8</td>
<td>Self-Administered Drug Exclusion List (SAD List)</td>
<td>A52800</td>
<td>NA</td>
<td>02/15/2017</td>
</tr>
<tr>
<td></td>
<td>The following drugs have been added:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>J3490 Daclizumab (ZINBRYTA™)</td>
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<tr>
<td></td>
<td>J3490 Adalimumab-atto (AMJEVITA™)</td>
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<tr>
<td></td>
<td>J3490 Golimumab (SIMPONI)</td>
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</tr>
</tbody>
</table>
Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9774 updates the Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) lists and instructs Medicare system maintainers to update Medicare Remit Easy Print (MREP) and PC Print. Make sure that your billing staffs are aware of these changes and obtain the updated MREP and PC Print software if they use that software.

Background

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 instructs health plans to be able to conduct standard electronic transactions adopted under HIPAA using valid standard codes. Medicare policy states that CARCs and RARCs, as appropriate, that provide either supplemental explanation for a monetary adjustment or policy information that generally applies to the monetary adjustment, are required in the remittance advice and coordination of benefits transactions.
The Centers for Medicare & Medicaid Services (CMS) instructs contractors to conduct updates based on the code update schedule that results in publication three times a year – around March 1, July 1, and November 1.

CMS provides this CR as a code update notification indicating when updates to CARC and RARC lists are made available on the Washington Publishing Company (WPC) website. Shared System Maintainers (SSMs) have the responsibility to implement code deactivation, making sure that any deactivated code is not used in original business messages and allowing the deactivated code in derivative messages. SSMs must make sure that Medicare does not report any deactivated code on or after the effective date for deactivation as posted on the WPC website. If any new or modified code has an effective date past the implementation date specified in this CR, contractors must implement on the date specified on the WPC website, which is at http://wpc-edi.com/Reference/.

A discrepancy between the dates may arise as the WPC website is only updated three times a year and may not match the CMS release schedule. For this recurring CR, the MACs and the SSMs must get the complete list for both CARC and RARC from the WPC website to obtain the comprehensive lists for both code sets and determine the changes that are included on the code list since the last code update CR (CR 9695).

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

Disclaimer
This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2015 American Medical Association. All rights reserved.
Clarification of Certification Statement Signature and Contact Person Requirements

This article was revised on December 22, 2016, to clarify certain information in the bullet points on pages 3 and 4. All other information remains the same.

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9776 clarifies the certification statement signature requirements for the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) and paper Medicare enrollment applications, and addresses contact person requirements.

CR9776 does not involve any legislative or regulatory policies. Make sure that you are familiar with these requirements.

Background

CR9776 informs the MACs that the Centers for Medicare & Medicaid Services (CMS) is updating Chapter 15 of the “Medicare Program Integrity Manual” in order to clarify the certification statement signature requirements for online and paper Medicare enrollment submissions, and to address contact person requirements. The main points of the updates are summarized below; and you can find the details in the manual’s updated Chapter 15 (Medicare Enrollment), which is an attachment to CR9776.
**Certification Signature Requirements**

A. Paper Submissions

A signed certification statement shall accompany all paper CMS-855 applications, which your MAC will only accept if the signature date is within 120 days of the receipt date of the application. If the provider submits an invalid certification statement or fails to submit a certification statement, your MAC will still proceed with processing the application, however, a valid certification statement will be solicited as part of the development process. This includes certification statements that are: (a) unsigned; (b) undated; (c) contains a copied or stamped signature; (d) was signed (as reflected by the date of signature) more than 120 days prior to the date on which the MAC received the application; (e) for paper Form CMS-855I and Form CMS-855O submissions, someone other than the physician or non-physician practitioner signed the form, except as noted in Section 15.5.14.1; or (f) missing certification statements. **The MAC will send one development request to include a list of all of the missing required data/documentation, including the certification statement.**

The MAC may reject the provider’s application if the provider fails to furnish the missing information on the enrollment application - including all necessary documentation - within 30 calendar days from the date the MAC requested the missing information or documentation. The certification statement may be returned via scanned email, fax or mail to the MAC (as long as an original certification statement signature exist on file).

B. Internet-based PECOS Submissions

A signed certification statement shall accompany all web submitted CMS-855 applications. You may choose to electronically sign the application or submit the paper certification statement to your MAC. Paper certification statements may be submitted by email, fax, or mail (as long as an original certification statement signature exists on file).

You should note that your MAC will not compare the signature on the application with the same provider, authorized or delegated official’s signature on file to ensure that it is the same person; nor will they request the submission of a driver’s license or passport to verify a signature.

Specific form signature requirements follow:

- The enrolling or enrolled physician or non-physician practitioner is the only person who can sign the Form CMS-855I or the Form CMS-855O. (This applies to initial enrollments, changes of information, reactivations, revalidations, voluntary withdrawals, etc.) This includes solely-owned entities listed in section 4A of the Form CMS-855I. A physician or non-physician practitioner may not delegate the authority to sign the Form CMS-855I or Form CMS-855O on his/her behalf to any other person. Note: Exceptions to the above policy may apply in the following scenarios: (1) in the case of death (an executor of the estate), may sign on behalf of the deceased provider, or (2) if an employer is terminating an employment arrangement with a physician assistant, the Authorized or Delegated Official of the
organization may sign the application. These situations would only apply to change of information applications.

- Form CMS-855R (Medicare Enrollment Application - Reassignment of Medicare Benefit), submitted for initial applications, must be signed and dated by the physician or non-physician practitioner and the authorized or delegated official of the provider or supplier; while those submitted to change and/or update the provider or supplier’s Medicare enrollment data (to include updates to the primary practice location) may be signed by either the physician or non-physician practitioner or the authorized or delegated official of the provider or supplier.

- Form CMS-855A (Medicare Enrollment Application - Institutional Providers), CMS-855B (Medicare Enrollment Application - Clinics/Group Practices and Certain Other Suppliers), and CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers), submitted for initial applications, must be signed and dated by an authorized official of the provider or supplier; while those submitted to change, update and/or revalidate the provider or supplier’s Medicare enrollment data may be signed and dated by the authorized or delegated official of the provider or supplier.

The certification statement for the CMS-855A, CMS-855B and CMS-855S Medicare enrollment applications must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in 42 CFR 424.510. This person must also have an ownership or control interest in the provider or supplier, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate; and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.

Your MAC will verify and validate all information collected on the enrollment application, provided that a data source is available. You should remember that:

1. For paper CMS-855 submissions, if you submit an invalid certification statement or do not submit a certification statement, your MAC will treat this as missing information and will request that you submit a correct certification statement, preferably via e-mail or fax. The certification statement may be returned via scanned email, fax or mail to the contractor (as long as an original certification statement signature exist on file).

2. For Internet-based PECOS submissions, if you choose to submit your certification statement via paper rather than through e-signature, you may do so by email, fax or mail (as long as an original certification statement signature exist on file). You must submit the paper certification statement within 20 calendar days of the date on which you submitted your Internet-based PECOS application, otherwise the MAC may reject your application.
3. When submitting the certification statement, only the signature page is required, you do not have to include the additional page containing the certification terms.

4. MACs will not request a driver’s license or passport to verify the signature.

5. Your MAC will send approval letters to the contact person listed on the application via email (if there is no contact person on file, they will send the approval letter to the provider or supplier at their correspondence address).

**Contact Person Requirement Clarifications**

MACs will accept end dates to contact persons via phone, scanned email, fax or mail from the individual provider, the Authorized or Delegated Official or a current contact person. This is an interim process until the Form CMS-855s can be updated to delete contact persons. If any contact person listed on a provider or supplier’s enrollment record requests a copy of their Medicare approval letter or revalidation notice, MACs will send it to the contact person via email, fax or mail.

**Additional Information**

While the above provides the key points of CR9776, providers may wish to review the entire revision to Chapter 15, which is attached to CR9776. CR9776 is available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R689PI.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R689PI.pdf).

42 CFR 424.5120 is available at [http://www.ecfr.gov/cgi-bin/textidx?SID=7abb0c441a8cabde6594ca609fd194c5&mc=true&node=se42.3.424_1510&rgn=div8](http://www.ecfr.gov/cgi-bin/textidx?SID=7abb0c441a8cabde6594ca609fd194c5&mc=true&node=se42.3.424_1510&rgn=div8).

If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).

**Document History**

- December 22, 2016 - The article was revised on December 22, 2016, to clarify certain information in the bullet points on pages 3 and 4.
- December 14, 2016 – Initial issuance
Provider Education

EDUCATION SCHEDULE

WPS GHA Learning Center

WPS GHA Provider Outreach and Education (POE) has transitioned to a new learning portal for your education needs. The WPS GHA Learning Center houses on-demand learning, information about live events, and the ability to receive Certificates of Achievement. These certificates may be submitted for consideration to earn Continuing Education Units (CEUs). For information on how to access, register as a user, and set up a profile for the Learning Center, go to our Learning Center at https://wpsgha.litmos.com/account/login/.

Event Schedule

WPS GHA offers a variety of education in a variety of formats throughout the year. To see our most current listing of seminars, teleconferences, and webinars please visit the WPS GHA Learning Center at: http://wpsgha.litmos.com/online-courses.

New offerings!

New to Medicare Teleconference Series

04/04/17 New to Medicare – Reimbursement Methodologies

The fourth in a series for those working with Medicare for less than 1 year or with questions on the basics of the Medicare program. This teleconference will address information needed by anyone who is beginning to learn the Medicare program with a focus on reimbursement. The agenda will include:

- What are the payment methodologies?
- Time frames for claims submitted under each
- How the methodologies affect each other
- And more

05/02/17 New to Medicare – The Claim

The fifth in a series for those working with Medicare for less than 1 year or with questions on the basics of the Medicare program. This teleconference will address information needed by anyone who is beginning to learn the Medicare program. The agenda will include:

- Electronic vs paper submission
- Overview of system edits and audits
- Correcting claims
- Appeals
- And more

06/06/17 New to Medicare – Find What You Need
The sixth in a series for those working with Medicare for less than 1 year or with questions on the basics of the Medicare program. This teleconference will address information needed by anyone who is beginning to learn the Medicare program with a focus on resources. The agenda will include:

- The CMS website
- The WPS GHA Portal
- Other important websites
- And more

**In the Works**

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

- Appeals
- Chiropractic
- Claims denials
- Documentation
- Evaluation and management
- Medicare secondary payer
- Mental health
- Overlapping claims
- And more

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

**Important Notice Regarding 2017 Seminar Materials**

In an effort to adopt consistent industry trends, beginning in 2017, WPS GHA will offer seminar materials only in an electronic format. Seminar registrants are responsible for printing and bringing their own handouts. To access, choose the Additional References tab in the Learning Center course.

**MEDICARE LEARNING NETWORK (MLN)**

We encourage you to visit the Medicare Learning Network the place for official CMS Medicare fee-for-service provider educational information. There you can find one of our most popular products, MLN Matters national provider education articles. These articles help you understand new or changed Medicare policy and how those changes affect you. A full array of other educational products (including Web-based training courses, hard copy and downloadable publications, and CD-ROMs) are also available and can be accessed at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html). You can also find other important Web sites by visiting the Physician Center Web page at: [http://www.cms.gov/Center/Provider-Type/Physician-Center.html](http://www.cms.gov/Center/Provider-Type/Physician-Center.html), and the All Fee-For-Service Providers Web page at: [https://www.cms.gov/Center/Provider-Type/All-Fee-For-Service-Providers-Center.html](https://www.cms.gov/Center/Provider-Type/All-Fee-For-Service-Providers-Center.html).
In addition to educational products, the MLN also offers providers and suppliers opportunities to learn more about the Medicare program through MLN National Provider Calls. These national conference calls, held by CMS for the Medicare Fee-For-Service provider and supplier community, educate and inform participants about new policies and/or changes to the Medicare program. Offered free of charge, continuing education credits may be awarded for participation in certain National Provider Calls. To learn more about MLN National Provider Calls including upcoming calls, registration information, and links to previous call materials, visit http://www.cms.gov/Outreach-and-Education/Outreach/NPC/index.html.

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 currently under development during this quarter.
- 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.
MLN Matters® Number: MM9945           Related Change Request (CR) #: CR 9945
Related CR Release Date: January 13, 2017   Effective Date: April 1, 2017
Related CR Transmittal #: R3692CP           Implementation Date: April 3, 2017

April 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

Provider Types Affected

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

What You Need to Know

Change Request (CR) 9945 provides the April 2017 quarterly update and instructs MACs to download and implement the April 2017 ASP drug pricing files and, if released by the Centers for Medicare & Medicaid Services (CMS), the revised January 2017, October 2016, July 2016, and April 2016 Average Sales Price (ASP) drug pricing files for Medicare Part B drugs. Medicare will use these files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after April 3, 2017, with dates of service April 1, 2017, through June 30, 2017. MACs will not search and adjust claims previously processed unless brought to their attention.

For claims with a date of service on or after January 1, 2017, and consistent with Section 5004 of the 21st Century Cures Act, which was signed into law on December 13, 2016, payment for infusion drugs furnished through a covered item of Durable Medical Equipment (DME) will be based on Section 1847A of the Social Security Act, meaning that most of the payments will be based on the ASP of these drugs. Payment for DME infusion drugs that do not appear on the ASP Drug Pricing Files will be determined by the MACs in accordance with the “Medicare Claims Processing Manual,” Chapter 17, Section 20.1.3, which is available at https://www.cms.gov/Regulations-and-

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Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Make sure your billing staffs are aware of these changes.

Background

The ASP methodology is based on quarterly data submitted to 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 Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that are in Chapter 4, Section 50 of the “Medicare Claims Processing Manual” at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.

The following table shows how the quarterly payment files will be applied:

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<tr>
<td>January 2017 ASP and ASP NOC</td>
<td>January 1, 2017, through March 31, 2017</td>
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<tr>
<td>October 2016 ASP and ASP NOC</td>
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<tr>
<td>July 2016 ASP and ASP NOC</td>
<td>July 1, 2016, through September 30, 2016</td>
</tr>
<tr>
<td>April 2016 ASP and ASP NOC</td>
<td>April 1, 2016, through June 30, 2016</td>
</tr>
</tbody>
</table>

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9854
Related Change Request (CR) #: CR 9854
Related CR Release Date: December 5, 2016
Effective Date: January 1, 2017
Related CR Transmittal #: R3671CP
Implementation Date: January 3, 2017

CY 2017 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers submitting claims to Medicare Administrative Contractors (MACs) for DMEPOS items or services paid under the DMEPOS fee schedule.

What You Need to Know

Change Request (CR) 9854 provides the calendar year (CY) 2017 annual update for the Medicare DMEPOS fee schedule. The instructions include information on the data files, update factors and other information related to the update of the fee schedule. Make sure your billing staffs are aware of these updates.

Background

The Centers for Medicare & Medicaid Services (CMS) updates the DMEPOS fee schedule on an annual basis in accordance with statute and regulations. The update process for the DMEPOS fee schedule is located in Chapter 23 Section 60 in the “Medicare Claims Processing Manual.”

Payment on a fee schedule basis is required for certain durable medical equipment (DME), prosthetic devices, orthotics, prosthetics, and surgical dressings by the Social Security Act (the Act). Also, payment on a fee schedule basis is a regulatory requirement at 42 CFR Section 414.102 for parenteral and enteral nutrition (PEN), splints, casts and intraocular lenses (IOLs) inserted in a physician’s office.

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The Act mandates adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from competitive bidding programs (CBPs) for DME. The Act provides authority for making adjustments to the fee schedule amounts for enteral nutrients, equipment, and supplies (enteral nutrition) based on information from CBPs. The methodologies for adjusting DMEPOS fee schedule amounts using information from CBPs are established in regulations at 42 CFR Section 414.210(g). Also, program instructions on these changes are available in Transmittal 3551, CR 9642 (MLN Matters article MM9642, dated June 23, 2016, and Transmittal 3416, CR 9431 (MM9431), dated November 23, 2015.

The DMEPOS and PEN fee schedule files contain Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the adjusted fee schedule amounts as well as codes that are not subject to the fee schedule CBP adjustments. Fee schedule amounts that are adjusted using information from CBPs will not be subject to the annual DMEPOS covered item update, but will be updated pursuant to 42 CFR 414.210(g)(8) when information from the CBPs is updated. This update to the adjusted fees includes information from the CBPs that takes effect on January 1, 2017 (Round 1 2017). Pursuant to 42 CFR Section 414.210(g)(4), for items where the single payment amounts (SPAs) from CBPs no longer in effect are used to adjust fee schedule amounts, the SPAs will be increased by an inflation adjustment factor that corresponds to the year in which the adjustment would go into effect (for example, 2017 for this update) and for each subsequent year such as 2018 and 2019.

The ZIP code associated with the address used for pricing a DMEPOS claim determines the rural fee schedule payment applicability for codes with rural and non-rural adjusted fee schedule amounts. ZIP codes for non-continental Metropolitan Statistical Areas (MSA) are not included in the DMEPOS Rural ZIP code file. The DMEPOS Rural ZIP code file is updated on a quarterly basis as necessary. Regulations at Section 414.202 define rural areas to be a geographical area represented by a postal ZIP code where at least 50 percent of the total geographical area of the ZIP code is estimated to be outside any MSA. A rural area also includes any ZIP Code within an MSA that is excluded from a competitive bidding area established for that MSA.

Policy: Fee Schedule and Rural Zip Code Files

The DMEPOS fee schedule file contains fee schedule amounts for non-rural and rural areas. Also, the PEN fee schedule file includes state fee schedule amounts for both enteral nutrition items and national non-rural fee schedule amounts for parenteral nutrition items. The DMEPOS and PEN fee schedules and the rural ZIP code public use files (PUFs) will be available for State Medicaid Agencies, managed care organizations, and other interested parties on the CMS DMEPOS fee schedule website after November 18, 2016.

New Codes Added

The new codes are not to be used for billing purposes until they are effective on January 1, 2017. For gap-filling pricing purposes, deflation factors are applied before updating to the current year. The deflation factors for 2016 by payment category are in the table below.
Codes Deleted

Codes deleted from the DMEPOS fee schedule files effective January 1, 2017, are:

- B9000 - Enteral nutrition infusion pump - without alarm (Enter infusion pump w/o alrm)
- B9000MS - Enteral nutrition infusion pump - without alarm
- E0628 - Separate seat lift mechanism for use with patient owned furniture-electric (Seat lift for pt furn-electr)
- K0901 - Knee orthosis (ko), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf ( Ko single upright pre ots)
- K0902 - Knee orthosis (ko), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf ( Ko double upright pre ots)

Effective January 1, 2017, codes B9000 and E0628 will crosswalk to codes B9002 and E0627 respectively. Payment for necessary maintenance and servicing of B9000 pumps will also crosswalk to B9002MS.

Effective January 1, 2017, the fees for wheelchair accessories and seat and back cushions denoted with the HCPCS modifier ‘KU’ are deleted from the DMEPOS fee schedule file.

The fee schedule amounts associated with the KU modifier were mandated by Section 2 of Patient Access and Medicare Protection Act (PAMPA) effective for dates of service January 1, 2016 through December 31, 2016. The list of HCPCS codes to which this statutory section applied is available in Transmittal 3535, CR 9520 Transmittal 3535, CR 9520, dated June 7, 2016.

Specific Coding and Pricing Issues

Effective January 1, 2017, existing off-the-shelf orthotic (OTS) codes K0901 and K0902 are re-designated as codes L1851 and L1852 respectively. The fee schedule amounts for codes K0901 and K0902 will be applied to the corresponding new codes L1851 and L1852 as part of this update. Attachment B in CR 9854 updates the list of orthotic codes that are
designated as OTS on the CMS [orthotics website](#) to reflect the addition of the two renumbered codes (L1851 and L1852).

As part of this update, the adjusted fee schedule amounts for the following groups of similar items are adjusted in accordance with 42 CFR Section 414.210 (g)(6) to limit the single payment amounts (SPAs) for items without certain features to the weighted average of the SPAs for the items both with and without the features prior to using the SPAs in adjusting the fee schedule amounts:

2. Mattress and overlays (HCPCS codes E0277, E0371, E0372, and E0373)
3. Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823)
4. Seat lift mechanisms (HCPCS codes E0627 and E0629)
5. TENS devices (HCPCS codes E0720 and E0730)
6. Walkers (HCPCS codes E0130, E0135, E0141 and E0143)

CMS is also adjusting the fee schedule amounts for shoe modification codes A5503 through A5507 as part of this update in order to reflect more current allowed service data. Section 1833(o)(2)(C) of the Act required that the payment amounts for shoe modification codes A5503 through A5507 be established in a manner that prevented a net increase in expenditures when substituting these items for therapeutic shoe insert codes (A5512 or A5513).

To establish the fee schedule amounts for the shoe modification codes, the base fees for codes A5512 and A5513 were weighted based on the approximated total allowed services for each code for items furnished during the second quarter of calendar year 2004.

For 2017, CMS is updating the weighted average insert fees used to establish the fee schedule amounts for the shoe modification codes with more current allowed service data for each insert code. The base fees for A5512 and A5513 will be weighted based on the approximated total allowed services for each code for items furnished during the calendar year 2015. The fee schedule amounts for shoe modification codes A5503 through A5507 are being revised to reflect this change, effective January 1, 2017.

**Diabetic Testing Supplies**

The fee schedule amounts for non-mail order diabetic testing supplies (DTS) (without KL modifier) for codes A4233, A4234, A4235, A4236, A4253, A4256, A4258, A4259 are not updated by the covered item update. In accordance with Section 636(a) of the American Taxpayer Relief Act of 2012, the fee schedule amounts for these codes were adjusted in CY 2013 so that they are equal to the single payment amounts for mail order DTS established in implementing the national mail order CBP under Section 1847 of the Act.

The non-mail order payment amounts on the fee schedule file will be updated each time the single payment amounts are updated. This can happen no less often than every time the mail

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order CBP contracts are re-competed. The CBP for mail order diabetic supplies is effective July 1, 2016, to December 31, 2018. The program instructions reviewing these changes are Transmittal 2709, CR 8325 (MM8325), dated May 17, 2013, and Transmittal 2661, CR 8204 (MM8204), dated February 22, 2013. Note that the mail order DTS (KL) fee schedule amounts for all states and territories were removed from the DMEPOS fee schedule file as part of the July 1, 2016, update.

2017 Fee Schedule Update Factor of 0.7 Percent

For CY 2017, an update factor of 0.7 percent is applied to certain DMEPOS fee schedule amounts.

In accordance with the statutory Sections 1834(a)(14) of the Act, certain DMEPOS fee schedule amounts are updated for 2017 by the percentage increase in the consumer price index for all urban consumers (United States city average) or urban consumers (CPI-U) for the 12-month period ending with June of 2016, adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity (MFP). The MFP adjustment is 0.3 percent and the CPI-U percentage increase is 1 percent. Therefore, the 1 percentage increase in the CPI-U is reduced by the 0.3 percentage increase in the MFP resulting in a net increase of 0.7 percent for the update factor.

2017 Update to the Labor Payment Rates

Included below and in Attachment A in CR9854 are the CY 2017 allowed payment amounts for HCPCS labor payment codes K0739, L4205 and L7520. Since the percentage increase in the CPI-U for the twelve month period ending with June 30, 2016, is 1 percent, this change is applied to the 2016 labor payment amounts to update the rates for CY 2017. The 2017 labor payment amounts in Attachment A are effective for claims submitted using HCPCS codes K0739, L4205 and L7520 with dates of service from January 1, 2017, through December 31, 2017.

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2017 National Monthly Fee Schedule Amounts for Stationary Oxygen Equipment

As part of this update, CMS is implementing the 2017 monthly fee schedule payment amounts for stationary oxygen equipment (HCPCS codes E0424, E0439, E1390 and E1391), effective for claims with dates of service from January 1, 2017, through December 31, 2017. As required by statute, the addition of the separate payment classes for oxygen generating portable equipment (OGPE) and stationary and portable oxygen contents must be annually budget neutral. Medicare expenditures must account for these separate oxygen payment classes. Therefore, the fee schedule amounts for stationary oxygen equipment are reduced by a certain percentage each year to balance the increase in payments made for the additional separate oxygen payment classes. For dates of service January 1, 2017, through December 31, 2017, the 2017 monthly fee schedule payment amounts for stationary oxygen equipment range from approximately $67 to $77, incorporating the budget neutrality adjustment factor..

When updating the stationary oxygen equipment amounts, corresponding updates are made to the fee schedule amounts for HCPCS codes E1405 and E1406 for oxygen and water vapor enriching systems. Since 1989, the payment amounts for codes E1405 and E1406 have been established based on a combination of the Medicare payment amounts for stationary oxygen equipment and nebulizer codes E0585 and E0570, respectively.
2017 Maintenance and Servicing Payment Amount for Certain Oxygen Equipment

Also updated for 2017 is the payment amount for maintenance and servicing for certain oxygen equipment. Payment for claims for maintenance and servicing of oxygen equipment was instructed in Transmittal 635, CR 6972 (MM6972), dated February 5, 2010 and Transmittal 717, CR6990 (MM6990), dated June 8, 2010. To summarize, payment for maintenance and servicing of certain oxygen equipment can occur every 6 months, beginning 6 months after the end of the 36th month of continuous use or end of the supplier’s or manufacturer’s warranty, whichever is later for HCPCS codes E1390, E1391, E0433 or K0738, billed with the MS modifier. Payment cannot occur more than once per beneficiary, regardless of the combination of oxygen concentrator equipment and/or transfilling equipment used by the beneficiary for any 6-month period.

Per 42 CFR Section 414.210(5)(iii), the 2010 maintenance and servicing fee for certain oxygen equipment was based on 10 percent of the average price of an oxygen concentrator. For CY 2011 and subsequent years, the maintenance and servicing fee is adjusted by the covered item update for DME as set forth in Section 1834(a)(14) of the Act. Therefore, the 2016 maintenance and servicing fee is adjusted by the 0.7 percent MFP-adjusted covered item update factor to yield CY 2017 maintenance and servicing fee of $69.97 for oxygen concentrators and transfilling equipment.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at MAC Toll-Free Number under - How Does It Work.

For more information regarding the Competitive Bidding Implementation Contractor website refer to the CBIC website.
Calendar Year (CY) 2017 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9909 provides instructions for the Calendar Year (CY) 2017 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. This update applies to Chapter 16, Section 20 of the “Medicare Claims Processing Manual.”

Background

In accordance with Section 1833(h)(2)(A)(i) of the Social Security Act (the Act), the annual update to the local clinical laboratory fees for CY 2017 is 0.70 percent. The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2017 is 1.00 percent (See 42 CFR 405.509(b)(1)).

Section 1833(a)(1)(D) of the Act provides that payment for a clinical laboratory test is the lesser of the actual charge billed for the test, the local fee, or the National Limitation Amount (NLA). The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

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**Key Points of CR9909**

**National Minimum Payment Amounts**

For a cervical or vaginal smear test (pap smear), Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount (described below). However, for a cervical or vaginal smear test (pap smear), payment may also not exceed the actual charge.

The CY 2017 national minimum payment amount is $14.49 ($14.39 times 0.70 percent update for CY 2017). The affected codes for the national minimum payment amount are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, G0476, and P3000.

**National Limitation Amounts (Maximum)**

For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of the local fees. For tests for which the NLAs are first established on or after January 1, 2001, the NLA is 100 percent of the median of the local fees in accordance with Section 1833(h)(4)(B)(viii) of the Act.

**Access to Data File**

Internet access to the CY 2017 clinical laboratory fee schedule data file will be available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html). Other interested parties, such as the Medicaid state agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, should use the Internet to retrieve the CY 2017 clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

**Data File Format**

For each test code, if your system retains only the pricing amount, load the data from the field named “60% Pricing Amt.” For each test code, if your system has been developed to retain the local fee and the NLA, you may load the data from the fields named “60% Local Fee Amt” and “60% Natl Limit Amt” to determine payment. For test codes for cervical or vaginal smears (pap smears), you should load the data from the field named “60% Pricing Amt” which reflects the lower of the local fee or the NLA, but not less than the national minimum payment amount. MACs should use the field “62% Pricing Amt” for payment to qualified laboratories of sole community hospitals.

**Public Comments and Final Payment Determinations**

On July 18, 2016, the Centers for Medicare & Medicaid Services (CMS) hosted a public meeting to solicit input on payment methods for reconsidered CY 2016 codes and new CY 2017 codes. Notice of the meeting was published in the Federal Register on May 13, 2016 and on the CMS web site on approximately May 18, 2016. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html).

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Additional written comments from the public were accepted until October 31, 2016. CMS has posted a summary of the public comments and the rationale for the final payment determinations at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2017-CLFS-Codes-Final-Determinations.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2017-CLFS-Codes-Final-Determinations.pdf).

### Pricing Information

The CY 2017 clinical laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.

The fees for clinical laboratory travel codes P9603 and P9604 are updated on an annual basis. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2017, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2017 clinical laboratory fee schedule also includes codes that have a “QW” modifier to both identify codes and determine payment for tests performed by a laboratory having only a certificate of waiver under the Clinical Laboratory Improvement Amendments (CLIA).

### Organ or Disease Oriented Panel Codes

Similar to prior years, the CY 2017 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the clinical laboratory fee schedule amount or the NLA for each individual test code included in the panel code. The NLA field on the data file is zero-filled.

### Mapping Information

**New codes:**
- G0659 is priced at the same rate as code G0479.
- 80305 is priced at the same rate as code G0477.
- 80306 is priced at the same rate as code G0478.
- 80307 is priced at the same rate as code G0479.
- 81327 is priced at the same rate as code 81287.
- 81413 is priced at the same rate as code 81435.
- 81414 is priced at the same rate as code 81436.
- 81422 is priced at the same rate as code 81436.
- 81439 is priced at the same rate as code 81435.
- 81539 is priced at the same rate as code 0010M.
- 84410 is priced at the same rate as the sum of codes 84402 and 84403.
- 87483 is priced at the same rate as code 87633.
- 87338QW is priced at the same rate as code 87338.
- 87631QW is priced at the same rate as code 87631.
Existing Codes:

- 81420 is priced at the same rate as code 81435.
- G0475 is priced at the same rate as code 87389.
- G0476 is priced at the same rate as code 87624.
- G0480 is priced at the same rate as 4.75 times code 82542.
- G0481 is priced at the same rate as 6.50 times code 82542.
- G0482 is priced at the same rate as 8.25 times code 82542.
- G0483 is priced at the same rate as 10.25 times code 82542.
- G0477, G0478, G0479, 0010M, and 82272QW are all to be deleted.

Laboratory Costs Subject to Reasonable Charge Payment in CY 2017

For outpatients, the following codes are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The inflation-indexed update for CY 2017 is 1.0 percent.

Chapter 23, Sections 80 through 80.8 of the “Medicare Claims Processing Manual” contains instructions for determining the reasonable charge payment. If there is sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

When services described by the HCPCS in the following list are performed for independent dialysis facility patients, Chapter 8, Section 60.3 of the “Medicare Claims Processing Manual” instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital Outpatient Prospective Payment System (OPPS).

Note: Reasonable charge codes P9070, P9071, P9072 and 89337 may be included in the next calendar year's reasonable charge update.

Blood Products

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

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

**Transfusion Medicine**

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**Reproductive Medicine Procedures**

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Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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MLN Matters® Number: MM9912  Related Change Request (CR) #: CR 9912
Related CR Release Date: February 3, 2017  Effective Date: January 1, 2017
Related CR Transmittal #: R1791OTN  Implementation Date: July 3, 2017

Change to Beneficiary Liability and Cost Report Days for Subclause (II) Long Term Care Hospitals (LTCHs)

Provider Types Affected

This MLN Matters® Article is intended for subclause (II) Long Term Care Hospitals (LTCHs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change request (CR) 9912 announces that, effective with cost reporting periods beginning on or after October 1, 2016, for a subclause (II) LTCH, the Medicare payment would only apply to the LTCH’s costs incurred for the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Make sure that your billing staffs are aware of these changes.

Background

In the Fiscal Year (FY) 2015 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule, CMS-1607-F, the Centers for Medicare & Medicaid Services (CMS) established a payment adjustment under the LTCH PPS for hospitals “classified under subclause (II) of subsection (d)(1)(B)(iv)” of the Social Security Act (the Act) (referred to as “subclause (II) LTCHs), effective for cost reporting periods beginning in FY 2015 and beyond.

Under this payment adjustment, payments to subclause (II) LTCHs are adjusted so that their LTCH PPS payments are generally equivalent to an amount determined under the
reasonable cost-based reimbursement rules for both operating and capital-related costs under 42 CFR Part 413. In the FY 2017 IPPS/LTCH PPS Final Rule, CMS revised the policy concerning beneficiary liability, which results in corresponding changes relating to cost report days, for subclause (II) LTCHs (see §412.507).

Section 15008 of the 21st Century Cures Act, enacted December 13, 2016, reclassifies hospitals which had previously been classified as “subclause (II) LTCHs” as their own category of IPPS-excluded hospitals (at section 1886(d)(1)(B)(vi) of the Act). Also, this provision codifies, effective January 1, 2015, the reasonable cost-based payment adjustment CMS implemented in 42 CFR 412.526, and requires Medicare claims be processed as paid on a reasonable cost basis for discharge occurring on or after January 1, 2017.

Under the current policy, for a subclause (II) LTCH, the Medicare payment applies to the LTCH’s costs incurred for all days in the “inlier” period regardless of whether the beneficiary has a benefit day available. This policy, which was implemented in CR9401, will continue to apply for utilization days in cost reporting periods beginning before October 1, 2016, that is, through December 31, 2016, for a subclause (II) LTCH with a calendar year cost reporting period.

Under the revisions in the FY 2017 final rule and consistent with Section 15008 of the 21st Century Cures Act, effective with cost reporting periods beginning on or after October 1, 2016, for a subclause (II) LTCH, the Medicare payment would only apply to the LTCH’s costs incurred for the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). For a subclause (II) LTCH with a calendar year cost reporting period, the revised policy will become effective for utilization days beginning January 1, 2017.

**Note:** Under this revised policy, whether the LTCH discharge would qualify for a high-cost outlier payment will no longer affect beneficiary liability.

### Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).
Transmittal 279, dated December 16, 2016, is being rescinded and replaced by Transmittal 1776, dated, January 27, 2017 to correct one of the items required to be reported by the provider in its election request; i.e., FFY Based on CY Begin Date (YYYY) should be FFY Based on CR Begin Date. In addition, a clarifying phrase was added to the third paragraph under the "Realignment" section of the CR. Also, this CR has been changed from a Pub. 100-06 to a Pub. 100-20. All other information remains the same.

SUBJECT: Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income (SSI) Component of the Disproportionate Share (DSH) Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year (FY) 2004 and earlier, or SSI Ratios for Hospital Cost-reporting Periods for Patient Discharges Occurring before October 1, 2004

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to direct the contractors to inform hospitals of the requirements for making an election for a particular fiscal period covered by the Centers for Medicare & Medicaid Services' (CMS) Ruling 1498-R (as modified by CMS Ruling 1498-R2).

EFFECTIVE DATE: January 19, 2017
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: January 19, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-Only One Per Row.

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III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
One Time Notification
Attachment - One-Time Notification

Pub. 100-20 | Transmittal: 1776 | Date: January 27, 2017 | Change Request: 9896

Transmittal 279, dated December 16, 2016, is being rescinded and replaced by Transmittal 1776, dated January 27, 2017 to correct one of the items required to be reported by the provider in its election request; i.e., FFY Based on CY Begin Date (YYYY) should be FFY Based on CR Begin Date. In addition, a clarifying phrase was added to the third paragraph under the "Realignment" section of the CR. Also, this CR has been changed from a Pub. 100-06 to a Pub. 100-20. All other information remains the same.

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EFFECTIVE DATE: January 19, 2017
*Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: January 19, 2017

I. GENERAL INFORMATION

A. Background: On April 28, 2010, the Administrator of the Centers for Medicare & Medicaid Services (CMS) issued CMS Ruling 1498-R. The Ruling addressed administrative appeals on three different issues related to Medicare Disproportionate Share Hospital (DSH) payment: (1) the Medicare-Supplemental Security Income (SSI) fraction data matching process issue, and the method for recalculating the hospital’s Medicare-SSI fraction by matching Medicare and SSI entitlement data; (2) the exclusion from the Medicare fraction and the numerator of the Medicaid fraction of non-covered inpatient hospital days for patients entitled to Medicare Part A, including days for which the patient’s Part A inpatient hospital benefits were exhausted; and (3) the exclusion from the DSH calculation of labor/delivery room (LDR) inpatient days. On April 22, 2015, the Administrator of CMS issued CMS Ruling 1498-R2, which effectively amended CMS Ruling 1498-R. This modification and amendment of CMS Ruling 1498-R affects a change only with respect to the relief that is available for revised Medicare-SSI fractions, and the interaction between Medicare-SSI fractions suitably revised to address the data matching process issue and the issue of Medicare Part A non-covered or exhausted benefit days (“dual-eligible non-covered days”) for cost reporting periods involving patient discharges before October 1, 2004.

B. Policy: Section 9105 of the Consolidated Omnibus Budget Reconciliation Act of 1985 provides that for discharges occurring on or after May 1, 1986, an additional payment must be made to Inpatient Prospective Payment System (IPPS) hospitals serving a disproportionate share of low income patients. The additional payment is determined by multiplying the federal portion of the Diagnosis-Related Group (DRG) payment by the DSH adjustment factor. (See 42 CFR 412.106).

Prior to the implementation of the FY 2005 IPPS final rule, inpatient days were included in the numerator of the Medicare-SSI fraction only if the inpatient hospital days were “covered” under Medicare Part A and the patient was entitled to SSI benefits. Part A coverage of inpatient days alone was required for inclusion in the denominator of the Medicare-SSI fraction. The FY 2005 IPPS final rule amended the DSH regulations by eliminating the requirement that Part A inpatient hospital days must be covered in order for such days to be included in the Medicare-SSI fraction and made clear that patient days were to be included in that fraction if the patient was entitled to Medicare Part A. See the FY 2005 IPPS final rule (69 FR 49246) (revising 42 CFR 412.106(b)(2)(i)). Under our revised policy, the inpatient days of a person who was entitled to Medicare Part A are included in the numerator of the hospital’s Medicare-SSI fraction (provided that the patient was also entitled to SSI at that time) and in the Medicare-SSI fraction denominator, regardless of whether the individual’s inpatient hospital stay was covered under Part A or whether the patient’s Part A
hospital benefits were exhausted. The FY 2005 IPPS final rule revision to the DSH regulations was effective for patient discharges occurring on or after October 1, 2004 (69 FR 49099).


The CMS Ruling 1498-R2 provided notice of CMS’ determination that CMS Ruling 1498-R shall be amended regarding its remedy for recalculation of certain Medicare DSH payment adjustments. CMS Ruling 1498-R required the Provider Reimbursement Review Board (PRRB) and other Medicare administrative appeals tribunals to remand each qualifying appeal to the appropriate Medicare contractor. CMS Ruling 1498-R further explained how CMS and Medicare contractors were to recalculate the provider’s DSH adjustment resolving any of the three different DSH issues. CMS and the Medicare contractor also were to apply the provisions of CMS Ruling 1498-R, on all three DSH issues, to each qualifying hospital cost reporting period where the contractor had not yet final settled the provider’s Medicare cost report. CMS Ruling 1498-R2 is a modification and amendment of CMS Ruling 1498-R, but only insofar as CMS Ruling 1498-R2 requires an election with respect to the Medicare-SSI component of the DSH payment adjustment for cost reports that involve SSI ratios for federal fiscal year 2004 and earlier, or SSI ratios for hospital cost-reporting periods, but only for those patient discharges occurring before October 1, 2004.

The CMS and the Medicare contractors will resolve each Medicare-SSI and dual-eligible non-covered day appeal remanded by the PRRB to the contractor, or open hospital cost reporting period subject to CMS Ruling 1498-R and the amendment in CMS Ruling 1498-R2 by allowing hospitals to exercise an election. This election is available for hospital cost reporting periods where the Medicare contractor has not yet final settled the provider’s Medicare cost report, as well as appeals remanded to the contractor pursuant to CMS Ruling 1498-R (assuming any such hospital cost reporting period involves SSI ratios for federal fiscal year 2004 and earlier or SSI ratios for hospital cost-reporting periods, but only for those patient discharges occurring before October 1, 2004). The election is also available for hospital cost reporting periods previously reopened specifically on the Medicare-SSI fraction issue – neither CMS Ruling 1498-R nor the amendment in CMS Ruling 1498-R2 required reopening. For a particular hospital cost reporting period or, as applicable, the portion of a particular cost reporting period prior to October 1, 2004, subject to CMS Ruling 1498-R and the amendment in CMS Ruling 1498-R2, hospitals may elect either to:

1. include inpatient days of a person entitled to Medicare Part A in the numerator of the hospital’s Medicare-SSI fraction (provided that the patient was also entitled to SSI) and in that fraction’s denominator, even if the inpatient stay was not covered under Part A or the patient’s Part A hospital benefits were exhausted (that is, elect to have applied a suitably revised Medicare-SSI fraction calculated on the basis of “total days”); or

2. exclude such days where the patient’s Part A hospital benefits were exhausted or otherwise were not in a covered Part A stay from both the numerator and denominator of the Medicare-SSI fraction (that is, elect to have applied a suitably revised Medicare-SSI fraction calculated on the basis of “covered days”).

In summary, a provider may elect whether to receive a suitably revised Medicare-SSI fraction on the basis of “covered days” or “total days” for hospital cost reporting periods that involve SSI ratios for federal fiscal year 2004 and earlier, or SSI ratios for hospital cost reporting periods, but only for those patient discharges occurring before October 1, 2004. CMS Ruling 1498-R2 does not effect any change with respect to the Medicaid fraction of the Medicare DSH payment calculation. The amendment to CMS Ruling 1498-R only allows providers to exercise a choice with respect to the Medicare-SSI fraction, and nothing in the amended Ruling or these instructions shall be interpreted to affect a hospital’s Medicaid fraction of its DSH payment calculation.

The CMS has published on its Web site suitably revised Medicare-SSI fractions that display Medicare-SSI fractions calculated on the basis of “covered days,” as well as “total days.” Before an initial Notice of Program Reimbursement (NPR) or revised NPR pursuant to the amendment to CMS Ruling 1498-R is issued by its Medicare contractor, a hospital’s designated representative should submit to its Medicare
contractor a written request that reflects the hospital’s election of whether, for a particular fiscal period, the hospital’s suitably revised Medicare-SSI fraction will be calculated on the basis of “total days” or “covered days.” The written request must be received by the Medicare contractor within 180 calendar days of the date instructions are posted on the contractor’s Web site. The request to the Medicare contractor must include the following information:

Provider Number
Hospital Name

PRRB Case Number and PRRB Remand Date (if applicable)
Case Name, Docket Number (if applicable)

Hospital’s designated representative (if applicable)

Cost Report Begin Date (YYYYMMDD)
Cost Report End Date (YYYYMMDD)

FFY Based on CR Begin Date (YYYY)

Provider Election (“Total” or “Covered”)

SSI ratio selected (Numerical value from CMS website)

If the hospital’s request does not contain all of the required information or if the hospital does not make an election for a particular fiscal period covered by CMS Ruling 1498-R (as modified by CMS Ruling 1498-R2) in this time frame, the Medicare contractor shall contact the hospital via letter, using a method that tracks delivery and receipt, to obtain the required information and if the provider does not respond within 30 days of the date of the letter, the Medicare contractor shall recalculate the provider’s DSH adjustment using the higher of the two revised Medicare-SSI fractions.

Realignment

42 CFR 412.106(b)(3) allows the hospital the opportunity to request to have their Medicare-SSI fraction realigned based on its cost reporting period (as opposed to the federal fiscal year).

For cost reporting periods subject to CMS Ruling 1498-R and the amendment in CMS Ruling 1498-R2, CMS will furnish (at the hospital’s written request and at no cost to the hospital) patient-level data concerning the number of the hospital’s “covered” and “total” Medicare-SSI days, and the number of the hospital’s “covered” and “total” Medicare days. Hospitals with cost reporting periods that ended before December 8, 2004, that did not receive an initial NPR, must appeal the issue of the calculation of their Medicare-SSI days to the PRRB subsequent to receipt of an initial NPR in order to receive their data at no cost. Such data will be provided on the federal fiscal year basis for the relevant cost reporting period, or, if the hospital does not report on the federal fiscal year basis, the two federal fiscal years in which the hospital’s cost reporting period falls.

If a provider previously submitted a realignment request for an open cost report, or for a cost report with an SSI appeal or SSI remand that uses a federal fiscal year 2004 or earlier Medicare-SSI fraction, the contractor shall send a notice to the provider to inform them that the realignment request no longer applies since the provider will first receive an initial/resvied NPR with a revised Medicare-SSI fraction calculated based on the federal fiscal year. After receiving its revised Medicare-SSI fraction, the provider may request
realignment, based on the revised Medicare-SSI fraction, within the normal timeframes.

The hospital must submit a written request to its contractor if it elects to receive the suitably revised Medicare-SSI fractions on the basis of its cost reporting period. The request must be on provider letterhead and signed by authorized hospital personnel. The request must specify whether the provider elects to have its realigned Medicare-SSI fraction generated on the basis of “total days” or “covered days.” Hospitals requesting that CMS recalculate their SSI ratios on the basis of their cost reporting period shall send their Medicare contractor the following information:

Provider Number
Hospital Name
PRRB Case Number and PRRB Remand Date (if applicable)
Case Name, Docket Number (if applicable)
Hospital’s designated representative (if applicable)
Cost Report Begin Date (YYYYMMDD)
Cost Report End Date (YYYYMMDD)
FFY Based on CR Begin Date (YYYY)
Provider Election (“Total” or “Covered”)

If the hospital’s realignment request does not contain all of the required information, notably if the request does not contain an election of “total” or “covered” with regard to the SSI ratio, the Medicare contractor shall contact the hospital via letter, using a method that tracks delivery and receipt, to obtain the required information and if the provider does not respond within 30 days of the date of the letter, the Medicare contractor shall inform CMS that no election was provided. In this instance, CMS will provide a realigned Medicare SSI ratio using the higher of the two revised Medicare-SSI fractions for the hospital’s cost reporting period.

If a provider submitted a realignment request within 3 years of the NPR where there is no SSI appeal or SSI remand, the provider will receive its requested realignment using the original SSI ratio.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>9896.1</td>
<td>Using the policy in this CR, contractors shall inform hospitals of the election available for hospital cost reporting periods that involve SSI ratios for federal</td>
<td>A/B MAC MAC</td>
<td>X</td>
</tr>
</tbody>
</table>

Page 117 of 161
fiscal year 2004 and earlier, or SSI ratios for hospital realignment requests to use its cost reporting periods, but only for those patient discharges occurring before October 1, 2004.

### III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>9896.2</td>
<td>CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</td>
<td>X</td>
</tr>
</tbody>
</table>

### IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

<table>
<thead>
<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Section B: All other recommendations and supporting information: N/A

### V. CONTACTS

**Pre-Implementation Contact(s):** Emily Lipkin, 410-786-3633 or emily.lipkin@cms.hhs.gov (Medicare DSH Policy), Dorothy Braunsar, 410-786-4037 or dorothy.braunsar@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

### VI. FUNDING
Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0
January 2017 Update of the Ambulatory Surgical Center (ASC) Payment System

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9923 updates the ASC payment system, the payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), the ASC Payment Indicator (PI) file, and the CY 2017 ASC payment rates for covered surgical and ancillary services (ASCFS file). Make sure that your billing staffs are aware of these changes that are effective on January 1, 2017.

Background

CR9923 describes changes to, and billing instructions for, various payment policies implemented in the January 2017 ASC payment system update, including:

1. The CY 2017 payment rates for separately payable drugs and biologicals along with descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), and
2. The CY 2017 ASC payment rates for covered surgical and ancillary services (ASCFS file). It also includes the CY2017 ASC Code pair file, and as appropriate, also includes updates to the Healthcare Common Procedure Coding System (HCPCS).

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Many ASC payment rates under the ASC payment system are established using payment rate information in the Medicare Physician Fee Schedule (MPFS). The payment files provided in CR9923 reflect the most recent changes to CY 2017 MPFS payment.

Key Updates

1. New Device Pass-Through Policies

Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the Outpatient Prospective Payment System (OPPS), categories of devices are eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices not described by existing (or previously existing) categories of devices.

Medicare implemented this policy in the 2008 revised ASC payment system. Therefore, additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the OPPS.

In the CY2017 OPPS/ASC final rule with comment period that was published in the Federal Register on November 14, 2016, CMS adopted a policy to revise the pass-through payment time period by having the pass-through start date begin with the date of first payment and by allowing pass-through status to expire on a quarterly basis, such that the duration of device pass-through payment will be as close to 3 years as possible. This policy is applicable in both the OPPS and ASC payment systems. Refer to the CY 2017 OPPS/ASC final rule with comment period at https://www.gpo.gov/fdsys/pkg/FR-2016-11-14/pdf/2016-26515.pdf for complete details about these policy changes for device pass-through that will become effective on January 1, 2017.

The three device categories that are currently eligible for pass-through payment in the OPPS and ASC payment systems are: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); (2) HCPCS code C2613 (Lung biopsy plug with delivery system); and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). These codes and their ASC payment indicator are listed in Addendum BB at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

2. Argus Retinal Prosthesis Add-on Code (C1842)

Effective October 1, 2013, and expiring December 31, 2015, one device, listed in Table 1 (C1841 - Retinal prosthesis, includes all internal and external components) was eligible for pass-through payment in the OPPS and ASC payment systems. After pass-through status expires for a medical device, the payment for the device is packaged into the payment for the associated procedure.

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Effective January 1, 2016, in the OPPS and ASC payment systems, payment for the
device described by HCPCS code C1841 is packaged into payment for CPT code 0100T.
Due to current ASC systems limitations, CMS cannot implement the identical policy in
ASCs. As an administrative workaround to the field limit on ASC payments equal to or
greater than $100,000, CMS is creating a second device code; HCPCS code C1842, and
splitting payments in half across C1841 and C1842. Therefore, effective January 1,
2017, HCPCS code C1842 (Long descriptor - Retinal prosthesis, includes all internal and
external components; add on to C1841; short descriptor - Retinal prosth, add-on) must
be reported with both C1841 and 0100T when a retinal prosthesis is implanted in the
ASC (see Table 1 below).

Since CMS’s device payment will be equally split between C1841 and C1842. ASCs
must split the submitted device charges equally between C1841 and C1842, to ensure
that Medicare pays what they intended to pay. Likewise, when appropriate, the use of
the FB modifier (Item provided without cost to provider, supplier or practitioner
(examples, but not limited to: covered under warranty, replaced due to defect, free
samples)) and FC modifier (Partial credit received for replaced device) would apply to
both C1841 and C1842.

Table 1 – Argus Retinal Prosthesis Add-on Code (C1842)

<table>
<thead>
<tr>
<th>CY 2017 HCPCS Code</th>
<th>CY 2017 Long Descriptor</th>
<th>CY 2017 Short Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1842</td>
<td>Retinal prosthesis, includes all internal and external components; add on to C1841</td>
<td>Retinal prosth, add-on</td>
<td>J7</td>
</tr>
</tbody>
</table>

3. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2017 HCPCS Codes and Dosage Descriptors for Certain Drugs,
Biologicals, and Radiopharmaceuticals

For CY 2017, several new HCPCS codes have been created for reporting drugs and
biologics in the ASC payment system, where there have not previously been specific
codes available. These new codes are listed in Table 2, below.
Table 2
New CY 2017 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th>CY 2017 HCPCS Code</th>
<th>CY 2017 Long Descriptor</th>
<th>CY 2017 Short Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>A9587</td>
<td>Gallium ga-68, dotatate, diagnostic, 0.1 millicurie</td>
<td>Gallium ga-68</td>
<td>K2</td>
</tr>
<tr>
<td>A9588</td>
<td>Fluciclovine f-18, diagnostic, 1 millicurie</td>
<td>Fluciclovine f-18</td>
<td>K2</td>
</tr>
<tr>
<td>C9140</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.</td>
<td>Afstyla factor viii recomb</td>
<td>K2</td>
</tr>
<tr>
<td>J0570</td>
<td>Buprenorphine implant, 74.2 mg</td>
<td>Buprenorphine implant 74.2mg</td>
<td>K2</td>
</tr>
<tr>
<td>J7175</td>
<td>Injection, factor x, (human), 1 i.u.</td>
<td>Inj, factor x, (human), 1iu</td>
<td>K2</td>
</tr>
<tr>
<td>J7179</td>
<td>Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf;vro</td>
<td>Vonvendi inj 1 iu vwf;vro</td>
<td>K2</td>
</tr>
<tr>
<td>J9034</td>
<td>Injection, bendamustine hcl (Bendeka), 1 mg</td>
<td>Inj., bendeka 1 mg</td>
<td>K2</td>
</tr>
</tbody>
</table>

b. Other Changes to CY 2017 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have changes in their HCPCS and CPT code descriptors that will be effective in CY 2017. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2016, and replaced with permanent HCPCS codes in CY 2017. ASCs should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the CY 2017 HCPCS and CPT codes.

Table 3, below, notes those drugs, biologicals, and radiopharmaceuticals that have changes in their HCPCS/CPT code, their long descriptor, or both. Each product’s CY 2016 HCPCS/CPT code and long descriptor are noted in the two left hand columns and the CY 2017 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.
## Table 3
Other CY 2017 HCPCS Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C9461</td>
<td>Choline C11, diagnostic, per study dose</td>
<td>A9515</td>
<td>Choline c-11, diagnostic, per study dose up to 20 millicuries</td>
</tr>
<tr>
<td>C9121</td>
<td>Injection, argatroban, per 5 mg</td>
<td>J0883</td>
<td>Injection, argatroban, 1 mg (for non-esrd use)</td>
</tr>
<tr>
<td>C9137</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.</td>
<td>J7207</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.</td>
</tr>
<tr>
<td>C9138</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwig), 1 I.U.</td>
<td>J7209</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), (nuwig), 1 i.u.</td>
</tr>
<tr>
<td>C9139</td>
<td>Injection, factor ix, albumin fusion protein (recombinant), idelvion, 1 i.u.</td>
<td>J7202</td>
<td>Injection, factor ix, albumin fusion protein, (recombinant), idelvion, 1 i.u.</td>
</tr>
<tr>
<td>C9349</td>
<td>Puraply, and puraply antimicrobial, any type, per square centimeter</td>
<td>Q4172</td>
<td>Puraply or puraply am, per square centimeter</td>
</tr>
<tr>
<td>C9470</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
<td>J1942</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
</tr>
<tr>
<td>C9471</td>
<td>Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg</td>
<td>J7322</td>
<td>Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>C9472</td>
<td>Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)</td>
<td>J9325</td>
<td>Injection, talimogene laherparepvec, per 1 million plaque forming units</td>
</tr>
<tr>
<td>C9473</td>
<td>Injection, mepolizumab, 1 mg</td>
<td>J2182</td>
<td>Injection, mepolizumab, 1 mg</td>
</tr>
<tr>
<td>C9474</td>
<td>Injection, irinotecan liposome, 1 mg</td>
<td>J9205</td>
<td>Injection, irinotecan liposome, 1 mg</td>
</tr>
<tr>
<td>C9475</td>
<td>Injection, necitumumab, 1 mg</td>
<td>J9295</td>
<td>Injection, necitumumab, 1 mg</td>
</tr>
<tr>
<td>C9476</td>
<td>Injection, daratumumab, 10 mg</td>
<td>J9145</td>
<td>Injection, daratumumab, 10 mg</td>
</tr>
<tr>
<td>C9477</td>
<td>Injection, elotuzumab, 1 mg</td>
<td>J9176</td>
<td>Injection, elotuzumab, 1 mg</td>
</tr>
<tr>
<td>C9478</td>
<td>Injection, sebelipase alfa, 1 mg</td>
<td>J2840</td>
<td>Injection, sebelipase alfa, 1 mg</td>
</tr>
<tr>
<td>C9479</td>
<td>Instillation, ciprofloxacin otic suspension, 6 mg</td>
<td>J7342</td>
<td>Installation, ciprofloxacin otic suspension, 6 mg</td>
</tr>
<tr>
<td>C9480</td>
<td>Injection, trabectedin, 0.1 mg</td>
<td>J9352</td>
<td>Injection, trabectedin, 0.1 mg</td>
</tr>
</tbody>
</table>

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c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2017

For CY 2017, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals continues to be made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In addition, in CY 2017, a single payment of ASP + 6 percent continues to be made for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available.

Effective January 1, 2017, payment rates for many drugs and biologicals have changed from the values published in the CY 2017 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2016. In cases where adjustments to payment rates are necessary, CMS is not publishing the updated payment rates in this Change Request. However, all ASC payable drugs and biologicals effective January 1, 2017, including those that were updated as a result of the new ASP calculations, can be found in the January 2017 ASC Addendum BB.

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

Some drugs and biologicals based on ASP methodology may have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the first date of the quarter at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html).

Suppliers who think they may have received an incorrect payment for drugs and biologicals impacted by these corrections may request their MAC to adjust the previously processed claims.

e. Biosimilar Biological Product Payment Policy

Effective January 1, 2017, the payment rate for biosimilars, approved for payment in the ASC payment system, will be the same as the payment rate in the OPPS and physician office setting; calculated as the Average Sales Price (ASP) of the biosimilar(s) described by the HCPCS code + 6 percent of the ASP of the reference product. Payment will be made at the single ASP + 6 percent rate.

You should remember that ASC claims for separately paid biosimilar biological products are required to include a modifier (see table 4, below) that identifies the specific product’s manufacturer. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code but are made by different manufacturers.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
<th>FDA Approval Date</th>
<th>Modifier</th>
<th>Modifier Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5101</td>
<td>Inj filgrastim g-csf biosim</td>
<td>Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram</td>
<td>K2</td>
<td>03/06/2015</td>
<td>ZA-Novartis/Sand oz</td>
<td>01/01/2016</td>
</tr>
<tr>
<td>Q5102</td>
<td>Inj., infliximab biosimilar</td>
<td>Injection, Infliximab, Biosimilar, 10 mg</td>
<td>K2</td>
<td>04/05/2016</td>
<td>ZB-Pfizer/Hospira</td>
<td>04/05/2016</td>
</tr>
</tbody>
</table>

Table 4
Biosimilar Biological Product Payment and Required Modifiers

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f. Billing and Payment for New Drugs, Biologicals, or Radiopharmaceuticals Approved by the Food and Drug Administration (FDA) but Before Assignment of a Product-Specific HCPCS Code

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

Diagnostic radiopharmaceuticals and contrast agents are policy packaged under both the OPPS and ASC payment system unless they have been granted pass-through status. Therefore, new diagnostic radiopharmaceuticals and contrast agents are an exception to the above policy and should not be billed with C9399 prior to the approval of pass-through status but, instead, are packaged in the ASC setting with payment already included in the surgical procedure performed, and are not billed.

g. Skin Substitute Procedure Edits

The payment for skin substitute products that do not qualify for hospital OPPS pass-through status are packaged into the OPPS payment for the associated skin substitute application procedure. This policy is also implemented in the ASC payment system.

The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes. Table 5, below, lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable. ASCs should not separately bill for packaged skin substitutes (ASC PI=N1). High cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278. All OPPS pass-through skin substitute products (ASC PI=K2) should be billed in combination with one of the skin application procedures described by CPT code 15271-15278.

Table 5
Skin Substitute Product Assignment to High Cost/Low Cost Status for CY 2016

<table>
<thead>
<tr>
<th>CY 2017 HCPCS Code</th>
<th>CY 2017 Short Descriptor</th>
<th>CY 2017 SI</th>
<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9363</td>
<td>Integra Meshed Bil Wound Mat</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4100</td>
<td>Skin Substitute, NOS</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4101</td>
<td>Apligraf</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4102</td>
<td>Oasis Wound Matrix</td>
<td>N1</td>
<td>Low</td>
</tr>
</tbody>
</table>

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</tr>
</thead>
<tbody>
<tr>
<td>Q4103</td>
<td>Oasis Burn Matrix</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4104</td>
<td>Integra BMWD</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4105</td>
<td>Integra DRT</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4106</td>
<td>Dermagraft</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4107</td>
<td>GraftJacket</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4108</td>
<td>Integra Matrix</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4110</td>
<td>Primatrix</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4111</td>
<td>Gammagraft</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4115</td>
<td>Alloskin</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4116</td>
<td>Alloderm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4117</td>
<td>Hyalomatrix</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4121</td>
<td>Theraskin</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4122</td>
<td>Dermacell</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4123</td>
<td>Alloskin</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4124</td>
<td>Oasis Tri-layer Wound Matrix</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4126</td>
<td>Memoderm/derma/tranz/integup</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4127</td>
<td>Talymed</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4128</td>
<td>Flexhd/Allopatchhd/Matrixhd</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4131</td>
<td>Epifix</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4132</td>
<td>Grafix Core</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4133</td>
<td>Grafix Prime</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4134</td>
<td>hMatrix</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4135</td>
<td>Mediskin</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4136</td>
<td>Ezderm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4137</td>
<td>Amnioexcel or Biodexcel, 1 cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4138</td>
<td>Biodfence DryFlex, 1 cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4140</td>
<td>Biodfence 1 cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4141</td>
<td>Alloskin ac, 1 cm</td>
<td>N1</td>
<td>High</td>
</tr>
</tbody>
</table>

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<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4143*</td>
<td>Repriza, 1cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4146*</td>
<td>Tensix, 1CM</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4147</td>
<td>Architect ecm, 1cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4148</td>
<td>Neox 1k, 1cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4150</td>
<td>Allowrap DS or Dry 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4151</td>
<td>AmnioBand, Guardian 1 sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4152</td>
<td>Dermapure 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4153</td>
<td>Dermavest 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4154</td>
<td>Biovance 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4156</td>
<td>Neox 100 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4157*</td>
<td>Revitalon 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4158*</td>
<td>MariGen 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4159</td>
<td>Affinity 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4160</td>
<td>NuShield 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4161</td>
<td>Bio-Connekt per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4162</td>
<td>Amnio bio and woundex flow</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4163*</td>
<td>Amnion bio and woundex sq cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4164</td>
<td>Helicoll, per square cm</td>
<td>N1</td>
<td>High</td>
</tr>
<tr>
<td>Q4165</td>
<td>Keramatrix, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4166*</td>
<td>Cytal, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4167*</td>
<td>Truskin, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4168*</td>
<td>Amnioband, 1 mg</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4169*</td>
<td>Artacent wound, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4170*</td>
<td>Cygnus, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4171*</td>
<td>Interfyl, 1 mg</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4172</td>
<td>PuraPly, PuraPly antimic</td>
<td>K2</td>
<td>High</td>
</tr>
<tr>
<td>Q4173*</td>
<td>Palingen or palingen xplus, per sq cm</td>
<td>N1</td>
<td>Low</td>
</tr>
<tr>
<td>Q4175*</td>
<td>Miroderm, per square cm</td>
<td>N1</td>
<td>Low</td>
</tr>
</tbody>
</table>

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*HCPCS codes Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, and Q4175 were assigned to the low cost group in the CY 2017 OPPS/ASC final rule with comment period. Upon submission of updated pricing information, Q4143, Q4146, Q4157, Q4158, and Q4163 are assigned to the high cost group for CY 2017.

h. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group – Retroactive Change

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The start date on this change is retroactive to October 1, 2016. ASCs should not separately bill for packaged skin substitutes (ASC PI=N1). The product is listed in Table 6 below.

Table 6

Updated Skin Substitute Product Assignment to High Cost Status Retroactive to October 1, 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
<th>Low/High Cost Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4158</td>
<td>MariGen 1 square cm</td>
<td>N1</td>
<td>High</td>
</tr>
</tbody>
</table>

4. Coverage Determinations

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

5. CY 2017 Wage Index

In the CY2017 OPPS/ASC final rule with comment period, we informed readers that generally, the Office of Management and Budget (OMB) issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. Please refer to page 79562 of the final rule for...
more details. OMB Bulletin No. 15–01 made the following changes that are relevant to the ASC wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new Core Based Statistical Area (CBSA) 21420 called Enid, OK.

- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.

- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

These changes are effective January 1, 2017. For CY 2017, the final CY 2017 ASC wage indexes fully reflect the new OMB labor market area delineations. The final CY2017 ASC wage indices are included in Attachment B of CR 9923.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers who submit claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice (HH&H) MACs for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

Provider Action Needed

This article is based on Change Request (CR) 9930 which describes changes to the OPPS to be implemented in the January 2017 update. Make sure your billing staffs are aware of these changes.

Background

Change Request (CR) 9930 describes changes and billing instructions for various payment policies being implemented in the January 2017 OPPS update. The January 2017 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer will reflect the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions identified in CR 9930.

Key Changes in CR9930

Key changes to and billing instructions for various payment policies implemented in the January 2017 OPPS updates are as follows:
New Device Pass-Through Policies

a. New Device Pass-Through Categories
The Social Security Act (Section 1833(t)(6)(B)) requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least 2, but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Social Security Act requires that the Centers for Medicare & Medicaid Services (CMS) create additional categories for transitional pass-through payment of new medical devices that are not described by existing or previously existing categories of devices.

b. Policy
In the Calendar Year (CY) 2017 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) final rule with comment period that was published in the Federal Register on November 14, 2016, CMS adopted a policy to revise the pass-through payment time period by having the pass-through start date begin with the date of first payment and by allowing pass-through status to expire on a quarterly basis, such that the duration of device pass-through payment will be as close to 3 years as possible.

In addition, in calculating the pass-through payment, the “Implantable Devices Charged to Patients Cost-to-Charge Ratio (CCR)” will replace the hospital-specific CCR, when available and device offsets will be calculated from the HCPCS payment rate, instead of the APC payment rate (81 FR 79655 through 79657). Refer to the CY 2017 OPPS/ASC final rule with comment period for complete details of these policy changes for device pass-through that will become effective on January 1, 2017. Effective January 1, 2017, there are three device categories eligible for pass-through payment: (1) HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); (2) HCPCS code C2613 (Lung biopsy plug with delivery system); and (3) HCPCS code C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system). Also, refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html for the most current device pass-through information.

c. Transitional Pass-Through Payments for Designated Devices
Certain designated new devices are assigned to APCs and identified by the OCE as eligible for payment based on the reasonable cost of the new device, reduced by the amount included in the APC for the procedure that reflects the packaged payment for device(s) used in the procedure. OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All related payment calculations will be returned on the same APC line and identified as a designated new device. Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html for the most current OPPS HCPCS Offset File.

Device Intensive Procedures
Effective January 1, 2017, CMS will assign device-intensive status at the HCPCS code level for all procedures requiring the implantation of a medical device, in which the individual HCPCS level device offset is greater than 40 percent. All new procedures requiring the insertion of an implantable medical device will be assigned a default device offset percentage of at least 41 percent, and be assigned device intensive status, until claims data is available. In certain rare instances, CMS may temporarily assign a higher offset percentage, if warranted, with additional information. Effective January 1, 2017, CMS will no longer assign device-intensive status based upon the APC level device offset percentage.

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In light of this policy change, CMS is modifying Sections 20.6.4 and 61.2 of Chapter 4 of the "Medical Claims Processing Manual."

**Argus Retinal Prosthesis Add-on Code (C1842)**

Effective January 1, 2017, CMS is creating HCPCS code C1842 (Retinal prosthesis, includes all internal and external components; add-on to C1841) and assigning it a status indicator (SI) of N. HCPCS code C1842 was created to resolve a claims processing issue for ASCs and should not be reported on institutional claims by hospital outpatient department providers.

Additionally, although HCPCS code C1842 was not included in the CY 2017 Annual HCPCS file, the code has been included in the January 2017 I/OCE. Therefore, MACs will add this code to their HCPCS system.

**Services Eligible for New Technology APC Assignment and Payments**

Under OPPS, services eligible for payment through New Technology APCs are those codes that are assigned to the series of New Technology APCs published in Addendum A of the latest OPPS update. OPPS considers any HCPCS code assigned to the APCs below to be a “new technology procedure or service.” As of January 1, 2017, the range of New Technology APCs include:

- APCs 1491 through 1500
- APCs 1502 through 1537
- APCs 1539 through 1585
- APCs 1589 through 1599
- APCs 1901 through 1906

The application for consideration as a New Technology procedure or service is available at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html). Under the “Downloads” section, refer to the document titled “For a New Technology Ambulatory Payment Classification (APC) Designation Under the Hospital Outpatient Prospective Payment System (OPPS)” for information on the requirements for submitting an application.

The list of HCPCS codes and payment rates assigned to New Technology APCs are in Addendum B of the latest OPPS update regulation each year at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html).

**Expiration of modifier “L1” for unrelated lab tests in the OPPS**

As a result of the CY 2014 OPPS policy to package laboratory services in the hospital outpatient setting, the “L1” modifier was used on type of bill (TOB) 13x to identify unrelated laboratory tests that were ordered for a different diagnosis and by a different practitioner than the other OPPS services on the claim.

In the CY 2016 OPPS final rule, CMS established status indicator “Q4,” which conditionally packaged clinical diagnostic laboratory services. Status indicator “Q4” designates packaged APC payment when billed on the same claim as a HCPCS code assigned status indicator “J1,” “J2,” “S,” “T,” “V,” “Q1,” “Q2,” or “Q3.” The “Q4” status indicator was created to identify 13X bill type claims where there are only laboratory HCPCS codes that appear on the clinical laboratory fee schedule (CLFS); to automatically change their status indicator to “A”; and to pay them separately at the CLFS payment rates. In the CY 2017 OPPS/ASC final rule with comment period, CMS

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finalized a policy to eliminate the L1 modifier. Beginning January 1, 2017, CMS is discontinuing the use of the “L1” modifier to identify unrelated laboratory tests on claims.

**Conditional packaging change to apply at claim level**

When conditional packaging was initially adopted under the OPPS, it was based on the date of service associated with other items and services furnished on the claim. When CMS established the comprehensive APCs in the CY 2015 OPPS, packaging was applied on a claim basis. To promote consistency and ensure appropriate packaging under OPPS policy, CMS finalized a change in the CY 2017 OPPS to apply conditional packaging for status indicators “Q1” and “Q2” on a claim basis.

**Exception for laboratory packaging in the OPPS for Advanced Diagnostic Laboratory Tests (ADLTs)**

Beginning in the CY 2014 OPPS, CMS established that laboratory tests for molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 are not packaged in the OPPS.

In the CY 2017 OPPS, CMS is expanding the laboratory packaging exclusion that currently applies to Molecular Pathology tests (described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479) to all laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) that meet the criteria of the Social Security Act (Section 1834A(d)(5)(A)).

**FX Modifier (X-ray Taken Using Film)**

In accordance with provisions allowed under Section 1833(t)(16)(F)(iv) of the Social Security Act, CMS has established a new modifier “FX” to identify imaging services that are X-rays taken using film. Effective January 1, 2017, hospitals are required to use this modifier on claims for imaging services that are X-rays.

The use of this modifier will result in a payment reduction of 20 percent in CY 2017 for the X-ray services taken using film when the service is paid separately. The use of the FX modifier and subsequent reduction in payment under the OPPS is applicable to all imaging services that are X-rays taken using film. All imaging services that are X-rays are listed in Addendum B of the CY 2017 OPPS/ASC Final Rule. CMS is updating the "Medicare Claims Processing Manual", Chapter 4, Section 20.6.13, to include this new modifier.

**Computed Tomography (CT) Modifier (“Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR–29–2013 standard”)**

In accordance with the Social Security Act (Section 1834(p)), CMS established modifier “CT”, effective January 1, 2016, to identify CT scans that are furnished on equipment that does not meet the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013, entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management.” Hospitals are required to use this modifier on claims for CT scans described by applicable HCPCS codes that are furnished on non-NEMA Standard XR-29-2013-compliant equipment. The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes).

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Effective January 1, 2017, the use of this modifier will result in a payment reduction of 15 percent for the applicable CT services when the service is paid separately. The 15 percent payment reduction will also be applied to the APC payment for the HCPCS codes listed above that are subject to the multiple imaging composite policy. This includes procedures assigned to the two APCs (8005 and 8006) in the CT and CT angiography (CTA) imaging family.

Billing for Items and Services Furnished at Off-Campus Hospital Outpatient Departments

In accordance with the Social Security Act (Section 1833(t)(21)), as added by Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), CMS has established a new modifier “PN” (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay nonexcepted items and services billed on an institutional claim. Effective January 1, 2017, non-excepted off-campus provider-based departments of a hospital are required to report this modifier on each claim line for non-excepted items and services. The use of modifier “PN” will trigger a payment rate under the Medicare Physician Fee Schedule. CMS expects the PN modifier to be reported with each nonexcepted item and service including those for which payment will not be adjusted, such as separately payable drugs, clinical laboratory tests, and therapy services.

Excepted off-campus provider-based departments of a hospital must continue to report existing modifier “PO” (Services, procedures and/or surgeries provided at off-campus provider-based outpatient departments) for all excepted items and services furnished. Use of the off-campus provider-based department (PBD) modifier became mandatory beginning January 1, 2016.

CMS would not expect off-campus PBDs to report both the PO and PN modifiers on the same claim line. However, if services reported on a claim reflect items and services furnished from both an excepted and a nonexcepted off-campus PBD of the hospital, the PO modifier should be used on the excepted claim lines and the PN modifier should be used on the nonexcepted claim lines.

Neither the PO nor the PN modifier is to be reported by the following hospital departments:

- A dedicated emergency department as defined in existing regulations at 42 CFR 489.24(b)
- A PBD that is “on the campus,” or within 250 yards, of the hospital or a remote location of the hospital as defined under 42 CFR 413.65

Partial Hospitalization Program (PHP)
a. Update to PHP Per Diem Costs

The CY 2017 OPPS/ASC final rule with comment period replaces the existing two-tiered APC structure for PHPs with a single APC by provider type for providing three or more services per day. Specifically, CMS is replacing existing Community Mental Health Center (CMHC) APCs 5851 (Level 1 Partial Hospitalization (3 services)) and 5852 (Level 2 Partial Hospitalization (4 or more services)) with a new CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)), and replacing existing hospital-based PHP APCs 5861 (Level 1 Partial Hospitalization (3 services)) and 5862 (Level 2 Partial Hospitalization (4 or more services)) with a new hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)).

b. CMHC Provider-Level Outlier Cap

The CY 2017 OPPS/ASC final rule with comment period implements a CMHC outlier payment cap to be applied at the provider level. In any given year, an individual CMHC will receive no more than 8 percent of its CMHC total per diem payments in outlier payments. The provider-level cap on...
CMHC outlier payments would be managed by the claims processing system. The existing outlier reconciliation process remains in place to adjust outlier payments at final cost report settlement, based on changes in the provider’s CCR.

c. PHP Payments under Section 603 (Off-Campus Policy)
The Social Security Act (Section 1861(ff)(3)(A)) specifies that a PHP is a program furnished by a hospital, to its outpatients, or by a CMHC. The Social Security Act (Section 1833(t)(1)(B)(i)) provides the Secretary with the authority to designate the outpatient department services to be covered under the OPPS. As a part of the OPPS, hospital-based (HB), PHPs are affected by this new legislation. CMHCs are not affected because they are not a hospital or a department/unit of a hospital. The CY 2017 OPPS/ASC final rule with comment adopts payment for non-excepted hospital-based PHPs under the MPFS, paying the CMHC per diem rate for APC 5853, for providing 3 or more PHP services per day.

Changes to Policies related to Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)
a. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) (C-APC 5244)
Effective January 1, 2017, CMS is assigning procedures described by CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) to newly established comprehensive APC (C-APC) 5244 (Level 4 Blood Product Exchange and Related Services). CPT code 38240 will be assigned status indicator “J1”. The assignment of CPT code 38240 to C-APC 5244 and status indicator “J1” will allow for all other OPPS payable services and items reported on the claim (including donor acquisition costs) to be deemed adjunctive services representing components of a comprehensive service and result in a single prospective payment through C-APC 5244 for the comprehensive service based on the costs of all reported services on the claim.

b. New Revenue Code 0815 for Allogeneic Stem Cell Acquisition Services
Effective January 1, 2017, hospitals are required to report revenue code 0815 when billing donor acquisition costs associated with allogeneic hematopoietic stem cell transplantation (HSCT). CMS is also implementing a code edit (edit 100) effective January 1, 2017, that will require donor acquisition charges for allogeneic HSCT reported with revenue code 0815 to be included on a claim with CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor). Donor acquisition charges for allogeneic HSCT are described in the "Medicare Claims Processing Manual", Chapter 4, Section 231.11. Revenue code 0819 is no longer required for the reporting of donor acquisition charges for allogeneic HSCT. CMS is updating the "Medicare Claims Processing Manual", Chapter 4, Section 231.11 and Chapter 3, Section 90.3.1 to reflect the new billing guidelines for allogeneic HSCT.

Drugs, Biologicals, and Radiopharmaceuticals
a. New CY 2017 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals
For CY 2017, several new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. These new codes are listed in Table 1 below.
Table 1 – New CY 2017 HCPCS Codes Effective for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>90682</td>
<td>Influenza virus vaccine, quadrivalent (RIV4), derived from recombinant DNA, hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use</td>
<td>L</td>
<td></td>
</tr>
<tr>
<td>90750</td>
<td>Zoster (shingles) vaccine (HZV), recombinant, sub-unit, adjuvanted, for intramuscular injection</td>
<td>E1</td>
<td></td>
</tr>
<tr>
<td>A9587</td>
<td>Gallium ga-68, dotatate, diagnostic, 0.1 millicurie</td>
<td>G 9056</td>
<td></td>
</tr>
<tr>
<td>A9588</td>
<td>Fluciclovine f-18, diagnostic, 1 millicurie</td>
<td>G 9052</td>
<td></td>
</tr>
<tr>
<td>A9597</td>
<td>Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>A9598</td>
<td>Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>C9140</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.</td>
<td>G 9043</td>
<td></td>
</tr>
<tr>
<td>J0570</td>
<td>Buprenorphine implant, 74.2 mg</td>
<td>G 9058</td>
<td></td>
</tr>
<tr>
<td>J1130</td>
<td>Injection, diclofenac sodium, 0.5 mg</td>
<td>E2</td>
<td></td>
</tr>
<tr>
<td>J7175</td>
<td>Injection, factor x, (human), 1 i.u.</td>
<td>K 1857</td>
<td></td>
</tr>
<tr>
<td>J7179</td>
<td>Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco</td>
<td>G 9059</td>
<td></td>
</tr>
<tr>
<td>J9034</td>
<td>Injection, bendamustine hcl (Bendeka), 1 mg</td>
<td>G 1861</td>
<td></td>
</tr>
<tr>
<td>Q4166</td>
<td>Cytal, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4167</td>
<td>Truskin, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4168</td>
<td>Amnioband, 1 mg</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4169</td>
<td>Artacent wound, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4170</td>
<td>Cygnus, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4171</td>
<td>Interfyl, 1 mg</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4173</td>
<td>Palingen or palingen xplus, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4174</td>
<td>Palingen or promatrx, 0.36 mg per 0.25 cc</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Q4175</td>
<td>Miroderm, per square centimeter</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

b. Other Changes to CY 2017 HCPCS and CPT Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Many HCPCS and CPT codes for drugs, biologicals, and radiopharmaceuticals have undergone changes in their HCPCS and CPT code descriptors that will be effective in CY 2017. In addition, several temporary HCPCS C-codes have been deleted effective December 31, 2016, and replaced with permanent HCPCS codes in CY 2017. Hospitals should pay close attention to accurate billing for units of service consistent with the dosages contained in the long descriptors of the active CY 2017 HCPCS and CPT codes.

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Table 2 (below) notes the drugs, biologicals, and radiopharmaceuticals that have undergone changes in their HCPCS/CPT code, their long descriptor, or both. Each product’s CY 2016 HCPCS/CPT code and long descriptor are noted in the two left hand columns. The CY 2017 HCPCS/CPT code and long descriptor are noted in the adjacent right hand columns.

**Table 2 – Other CY 2017 HCPCS and CPT Code Changes for Certain Drugs, Biologicals, and Radiopharmaceuticals**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C9461</td>
<td>Choline C 11, diagnostic, per study dose</td>
<td>A9515</td>
<td>Choline c-11, diagnostic, per study dose up to 20 millicuries</td>
</tr>
<tr>
<td>A9599</td>
<td>Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose</td>
<td>A9599</td>
<td>Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose, not otherwise specified</td>
</tr>
<tr>
<td>C9121</td>
<td>Injection, argatroban, per 5 mg</td>
<td>J0883</td>
<td>Injection, argatroban, 1 mg (for non-esrd use)</td>
</tr>
<tr>
<td>C9121</td>
<td>Injection, argatroban, per 5 mg</td>
<td>J0884</td>
<td>Injection, argatroban, 1 mg (for esrd on dialysis)</td>
</tr>
<tr>
<td>C9137</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.</td>
<td>J7207</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), pegylated, 1 i.u.</td>
</tr>
<tr>
<td>C9138</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), 1 I.U.</td>
<td>J7209</td>
<td>Injection, factor viii, (antihemophilic factor, recombinant), (nuwiq), 1 i.u.</td>
</tr>
<tr>
<td>C9139</td>
<td>Injection, factor ix, albumin fusion protein (recombinant), idelvion, 1 i.u.</td>
<td>J7202</td>
<td>Injection, factor ix, albumin fusion protein, (recombinant), idelvion, 1 i.u.</td>
</tr>
<tr>
<td>C9349</td>
<td>Puraply, and puraply antimicrobial, any type, per square centimeter</td>
<td>Q4172</td>
<td>Puraply or puraply am, per square centimeter</td>
</tr>
<tr>
<td>C9470</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
<td>J1942</td>
<td>Injection, aripiprazole lauroxil, 1 mg</td>
</tr>
<tr>
<td>C9471</td>
<td>Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg</td>
<td>J7322</td>
<td>Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg</td>
</tr>
<tr>
<td>C9472</td>
<td>Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)</td>
<td>J9325</td>
<td>Injection, talimogene laherparepvec, per 1 million plaque forming units</td>
</tr>
<tr>
<td>C9473</td>
<td>Injection, mepolizumab, 1 mg</td>
<td>J2182</td>
<td>Injection, mepolizumab, 1 mg</td>
</tr>
<tr>
<td>C9474</td>
<td>Injection, irinotecan liposome, 1 mg</td>
<td>J9205</td>
<td>Injection, irinotecan liposome, 1 mg</td>
</tr>
<tr>
<td>C9475</td>
<td>Injection, necitumumab, 1 mg</td>
<td>J9295</td>
<td>Injection, necitumumab, 1 mg</td>
</tr>
<tr>
<td>C9476</td>
<td>Injection, daratumumab, 10 mg</td>
<td>J9145</td>
<td>Injection, daratumumab, 10 mg</td>
</tr>
<tr>
<td>C9477</td>
<td>Injection, elotuzumab, 1 mg</td>
<td>J9176</td>
<td>Injection, elotuzumab, 1 mg</td>
</tr>
<tr>
<td>C9478</td>
<td>Injection, sebelipase alfa, 1 mg</td>
<td>J2840</td>
<td>Injection, sebelipase alfa, 1 mg</td>
</tr>
</tbody>
</table>

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### c. Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective January 1, 2017

For CY 2017, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals continues to be made at a single rate of ASP plus 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In addition, in CY 2017, a single payment of ASP plus 6 percent continues to be made for pass-through drugs, biologicals and radiopharmaceuticals to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Effective January 1, 2017, payment rates for many drugs and biologicals have changed from the values published in the CY 2017 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from the third quarter of CY 2016. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2017 Fiscal Intermediary Standard System (FISS)

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release. CMS is not publishing the updated payment rates in this CR implementing the January 2017 update of the OPPS. However, the updated payment rates effective January 1, 2017, are available in the January 2017 update of the OPPS Addendum A and Addendum B at [http://www.cms.gov/HospitalOutpatientPPS/](http://www.cms.gov/HospitalOutpatientPPS/).

d. 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-ServicePayment/HospitalOutpatientPPS/OPPS­Restated-Payment-Rates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/OPPS­Restated-Payment-Rates.html). Providers may resubmit claims that were impacted by adjustments to previous quarter’s payment files.

e. Biosimilar Biological Product Payment Policy
Effective January 1, 2017, the payment rate for a biosimilar biological product under the OPPS will continue to be the same as the payment rate in the physician office setting, (that is, calculated as the ASP of the biosimilar(s) described by the HCPCS code plus 6 percent of the ASP of the reference product). Biosimilar biological products are also be eligible for transitional pass-through payment; however, pass-through payment will be made to the first eligible biosimilar biological product to a reference product. Subsequent biosimilar biological products to a reference product will not meet the newness criterion, and therefore, will be ineligible for pass-through payment.

As a reminder, OPPS claims for separately paid biosimilar biological products are required to include a modifier (see Table 3, below) that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code but are made by different manufacturers.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
<th>HCPCS Code Effective Date</th>
<th>HCPCS Modifier</th>
<th>HCPCS Modifier Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5101</td>
<td>Inj filgrastim g­csf biosim</td>
<td>Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram</td>
<td>G</td>
<td>1822</td>
<td>03/06/2015</td>
<td>ZA-Novartis/ Sandoz</td>
<td>01/01/2016</td>
</tr>
<tr>
<td>Q5102</td>
<td>Inj., infliximab biosimilar</td>
<td>Injection, Infliximab, Biosimilar, 10 mg</td>
<td>K</td>
<td>1847</td>
<td>04/05/2016</td>
<td>ZB-Pfizer/ Hospira</td>
<td>04/01/2016</td>
</tr>
</tbody>
</table>

f. Billing and Payment for New Drugs, Biologicals, or Radiopharmaceuticals Approved by the Food and Drug Administration (FDA) but Before Assignment of a Product-Specific HCPCS Code
Hospital outpatient departments are allowed to bill for new drugs, biologicals, and therapeutic radiopharmaceuticals that are approved by the FDA on or after January 1, 2004, for which pass-through status has not been approved and a C-code and APC payment have not been assigned using...
the “unclassified” drug/biological HCPCS code C9399 (Unclassified drugs or biological). Drugs, biologicals, and therapeutic radiopharmaceuticals that are assigned to HCPCS code C9399 are contractor priced at 95 percent of AWP.

Diagnostic radiopharmaceuticals and contrast agents are policy packaged under the OPPS unless they have been granted pass-through status. Therefore, new diagnostic radiopharmaceuticals and contrast agents are an exception to the above policy and should not be billed with C9399 prior to the approval of pass-through status but, instead, should be billed with the appropriate “A” NOC code as described below.

1. Diagnostic Radiopharmaceuticals – All new diagnostic radiopharmaceuticals are assigned to either HCPCS code A9597 (Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified), HCPCS code A9598 (Positron emission tomography radiopharmaceutical, diagnostic, for non-tumor identification, not otherwise classified), HCPCS code A9599 (Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose), or HCPCS code J3490 (Unclassified drugs) (applicable to all new diagnostic radiopharmaceuticals used in non-beta-amyloid PET imaging). HCPCS code A9597, A9598, A9599, or J3490, whichever is applicable, should be used to bill a new diagnostic radiopharmaceutical until the new diagnostic radiopharmaceutical has been granted pass-through status and a C-code has been assigned. HCPCS codes A9597, A9598, A9599, and J3490 are assigned status indicator “N” and, therefore, the payment for a diagnostic radiopharmaceutical assigned to any of these HCPCS codes is packaged into the payment for the associated service.

2. Contrast Agents – All new contrast agents are assigned HCPCS code A9698 (Non-radioactive contrast imaging material, not otherwise classified, per study) or A9700 (Supply of injectable contrast material for use in echocardiography, per study). HCPCS code A9698 or A9700 should be used to bill a new contrast agent until the new contrast agent has been granted pass-through status and a C-code has been assigned. HCPCS code A9698 is assigned status indicator “N” and, therefore, the payment for a drug assigned to HCPCS code A9698 is packaged into the payment for the associated service. The status indicator for A9700 will change from SI=B (Not paid under OPPS) to SI=N (Payment is packaged into payment for other services) and, therefore, the payment for a drug assigned to HCPCS code A9700 is packaged into the payment for the associated service.

g. Skin Substitute Procedure Edits
The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. The skin substitute products are divided into two groups: 1) high cost skin substitute products and 2) low cost skin substitute products for packaging purposes. Table 4 lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable. CMS will implement an OPPS edit that requires hospitals to report all high-cost skin substitute products in combination with one of the skin application procedures described by CPT codes 15271-15278 and to report all low-cost skin substitute products in combination with one of the skin application procedures described by HCPCS codes C5271-C5278. All pass-through skin substitute products are to be reported in combination with one of the skin application procedures described by CPT codes 15271-15278.
### Table 4 – Skin Substitute Product Assignment to High Cost/Low Cost Status for CY 2016

<table>
<thead>
<tr>
<th>CY 2017 HCPCS Code</th>
<th>CY 2017 Short Descriptor</th>
<th>CY 2017 SI</th>
<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9363</td>
<td>Integra Meshed Bil Wound Mat</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4100</td>
<td>Skin Substitute, NOS</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4101</td>
<td>Apligraf</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4102</td>
<td>Oasis Wound Matrix</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4103</td>
<td>Oasis Burn Matrix</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4104</td>
<td>Integra BMWD</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4105</td>
<td>Integra DRT</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4106</td>
<td>Dermagraft</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4107</td>
<td>GraftJacket</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4108</td>
<td>Integra Matrix</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4110</td>
<td>Primatrix</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4111</td>
<td>Gammagraft</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4115</td>
<td>Alloskin</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4116</td>
<td>Alloderm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4117</td>
<td>Hyalomatrix</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4121</td>
<td>Theraskin</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4122</td>
<td>Dermacell</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4123</td>
<td>Alloskin</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4124</td>
<td>Oasis Tri-layer Wound Matrix</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4126</td>
<td>Memoderm/derma/tranz/integup</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4127</td>
<td>Talymed</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4128</td>
<td>Flexhd/Allopatchhd/Matrixhd</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4131</td>
<td>Epifix</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4132</td>
<td>Grafix Core</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4133</td>
<td>Grafix Prime</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4134</td>
<td>hMatrix</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4135</td>
<td>Mediskin</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4136</td>
<td>Ezderm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4137</td>
<td>Amnioexcel or Biodexcel, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4138</td>
<td>Biodfence DryFlex, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4140</td>
<td>Biodfence 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4141</td>
<td>Alloskin ac, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4143*</td>
<td>Repriza, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>CY 2017 HCPCS Code</th>
<th>CY 2017 Short Descriptor</th>
<th>CY 2017 SI</th>
<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4146*</td>
<td>Tensix, 1CM</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4147</td>
<td>Architect ecm, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4148</td>
<td>NeoX 1k, 1cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4150</td>
<td>Allowrap DS or Dry 1 sq cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4151</td>
<td>AmnioBand, Guardian 1 sq cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4152</td>
<td>Dermapure 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4153</td>
<td>Dermavest 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4154</td>
<td>Biovance 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4156</td>
<td>NeoX 100 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4157*</td>
<td>Revitalon 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4158*</td>
<td>MariGen 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4159</td>
<td>Affinity 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4160</td>
<td>NuShield 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4161</td>
<td>Bio-Connekt per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4162</td>
<td>Amnio bio and woundex flow</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4163*</td>
<td>Amnion bio and woundex sq cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4164</td>
<td>Helicoll, per square cm</td>
<td>N</td>
<td>High</td>
</tr>
<tr>
<td>Q4165</td>
<td>Keramatrix, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4166*</td>
<td>Cytal, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4167*</td>
<td>Truskin, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4168*</td>
<td>AmnioBand, 1 mg</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4169*</td>
<td>Artacent wound, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4170*</td>
<td>Cygnus, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4171*</td>
<td>Interfly, 1 mg</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4172</td>
<td>PuraPly, PuraPly antimic</td>
<td>G</td>
<td>High</td>
</tr>
<tr>
<td>Q4173*</td>
<td>Palingen or palingen xplus, per sq cm</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Q4175*</td>
<td>Miroderm, per square cm</td>
<td>N</td>
<td>Low</td>
</tr>
</tbody>
</table>

*HCPCS codes Q4166, Q4167, Q4168, Q4169, Q4170, Q4171, Q4173, and Q4175 were assigned to the low cost group in the CY 2017 OPPS/ASC final rule with comment period. Upon submission of updated pricing information, Q4143, Q4146, Q4157, Q4158, and Q4163 are assigned to the high cost group for CY 2017.

**h. Reassignment of Skin Substitute Products from the Low Cost Group to the High Cost Group – Retroactive Change**

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The start date on this change is retroactive to October 1, 2016. The product is listed in Table 5 below.

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Table 5 – Updated Skin Substitute Product Assignment to High Cost Status
Retroactive to October 1, 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Status Indicator</th>
<th>Low/High Cost Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4158</td>
<td>MariGen 1 square cm</td>
<td>N</td>
<td>High</td>
</tr>
</tbody>
</table>

Changes to OPPS Pricer Logic

a. Rural sole community hospitals and essential access community hospitals (EACHs) will continue to receive an additional 7.1 percent payment for most services in CY 2017. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items, and services paid at charges reduced to cost, and items paid under the pass-through payment policy in accordance with the Social Security Act (Section 1833(t)(13)(B)), as added by Section 411 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

b. New OPPS payment rates and copayment amounts will be effective January 1, 2017. 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 2017 inpatient deductible of $1,316. For most OPPS services, copayments are set at 20 percent of the APC payment rate.

c. For hospital outlier payments under OPPS, there will be no change in the multiple threshold of 1.75 for 2017. This threshold of 1.75 is multiplied by the total line-item APC payment to determine eligibility for outlier payments. This factor also is used to determine the outlier payment, which is 50 percent of estimated cost less 1.75 times the APC payment amount. The payment formula is (cost-(APC payment x 1.75))/2.

d. The fixed-dollar threshold for OPPS outlier payments increases in CY 2017 relative to CY 2016. The estimated cost of a service must be greater than the APC payment amount plus $3,825 in order to qualify for outlier payments.

e. For outliers for CMHCs (bill type 76x), there will be no change in the multiple threshold of 3.4 for 2017. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 5853 to determine eligibility for outlier payments. This multiple amount is also used to determine the outlier payment, which is 50 percent of estimated costs less 3.4 times the APC payment amount. The payment formula is (cost-(APC 5853 payment x 3.4))/2.

f. Continuing CMS established policy for CY 2017, the OPPS Pricer will apply a reduced update ratio of 0.980 to the payment and copayment for hospitals that fail to meet their hospital outpatient quality data reporting requirements or that fail to meet CMS validation edits. The reduced payment amount will be used to calculate outlier payments.
g. Effective January 1, 2017, CMS is adopting the FY 2017 IPPS post-recategorization wage index values with application of out-commuting adjustment authorized by Section 505 of the MMA to non-IPPS hospitals discussed below.

h. Effective January 1, 2014, for claims with APCs, which require implantable devices and have significant device offsets (greater than 40 percent), a device offset cap will be applied based on the credit amount listed in the “FD” (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code “FD”, which reduces the APC payment for the applicable procedure, will be capped by the device offset amount for that APC. The offset amounts for the above referenced APCs are available on the CMS website.

i. Effective January 1, 2017 conditional packaging for status indicators “Q1” and “Q2” will apply at the claim level rather than the date-of-service level.

j. The Payment Rate field in the Pricer file will be expanded from 7 digits to 8 digits to accommodate APC payment rates greater than or equal to $100,000.

**Update the Outpatient Provider Specific File (OPSF) for New Core-Based Statistical Area (CBSA) and Wage Indices for Non-IPPS Hospitals Eligible for the Out-Commuting Adjustment Authorized by Section 505 of the MMA**

CR9930 provides instructions to the MACs for updating the OPSF, effective 2017. This includes updating the CBSA in the provider records, as well as updating the “special wage index” value for those providers who qualify for the Section 505 adjustment as annotated in Table 6 in Attachment A of CR 9930.

**NOTE:** Although the Section 505 adjustment is static for each qualifying county for 3 years, the special wage index will need to be updated (using the final wage index in Table 6, Attachment A in CR9930) because the post-recategorization CBSA wage index has changed. Also, note that payment for Distinct Part Units (DPUs) located in an acute care hospital is based on the wage index for the labor market area where the hospital is located, even if the hospital has a reclassified wage index. If the DPU falls in a CBSA eligible to receive the section 505 out-commuting adjustment, the DPU’s final wage index should consist of the geographic wage index plus the appropriate out-commuting adjustment.

a) **Updating the OPSF for Expiration of Transitional Outpatient Payments (TOPs)**

Cancer and children's hospitals are held harmless under the Social Security Act (Section 1833(t)(7)(D)(ii)) and continue to receive hold harmless TOPs permanently. For CY 2017, cancer hospitals will continue to receive an additional payment adjustment.

b) **Updating the OPSF for the Hospital Outpatient Quality Reporting (HOQR) Program Requirements**

Effective for OPPS services furnished on or after January 1, 2009, Subsection (d) hospitals that have failed to submit timely hospital outpatient quality data as required in the Social Security Act (Section 1833(t)(17)(A)) will receive payment under the OPPS that reflects a 2 percentage point deduction from the annual OPPS update for failure to meet the HOQR program requirements. This reduction will not apply to hospitals not required to submit quality data or hospitals that are not paid under the OPPS.

c) **Updating the OPSF for the Outpatient CCR**
As stated in Pub. 100-04, "Medicare Claims Processing Manual", Chapter 4, Section 50.1, MACs must maintain the accuracy of the data and update the OPSF as changes occur in data element values, including changes to provider CCRs. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are available at [www.cms.gov/HospitalOutpatientPPS/](http://www.cms.gov/HospitalOutpatientPPS/) under “Annual Policy Files.”

d) Application of the Out Migration Adjustment for IPPS hospitals that also receive OPPS Payment

CR9930 provides instructions to the MACs regarding the application of the out migration adjustment for hospitals located in a county eligible for the out migration adjustment, if the hospital is NOT located in a rural county deemed as a Lugar county (only applicable to 1886(d) hospitals), or the hospital has NOT been approved to reclassify as rural under Section 1886(d)(8)(E) of the Social Security Act ([42 CFR 412.103](http://www.cm...)) or the hospital does NOT have an MGCRB reclassification.

**Note:** Hospitals that are LUGAR (and did not waive their LUGAR status) or qualify for MGCRB or 412.103 reclassification are not eligible for the out migration adjustment.

e) Updating the OPSF for Hospitals Reclassified as Rural Hospitals Under Section 412.103 and Hospitals Reclassified under the Medicare Geographic Classification Review Board (MGCRB)

An urban hospital that reclassifies as a rural hospital under Section 412.103 is considered rural for all OPPS purposes. Prior to April 21, 2016, the regulations at Section 412.230(a)(5)(ii) and Section 412.230(a)(5)(iii) prohibited hospitals from simultaneously receiving an urban to rural reclassification under Section 412.103 and a reclassification under the MGCRB. Also, the regulations did not allow a LUGAR hospital to keep its LUGAR status if it was approved for an urban to rural reclassification under Section 412.103. The court decisions in Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services, 794 F.3d 383 (3d Cir. 2015) and Lawrence + Memorial Hospital v. Burwell, No. 15-164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) ruled as unlawful the regulation precluding a hospital from maintaining simultaneous MGCRB and Section 412.103 reclassifications.

Therefore, on April 18, 2016, CMS issued an interim final rule with comment period (CMS-1664-IFC) amending the regulations to conform to the court decisions. The IFC is effective April 21, 2016, and was finalized on August 2, 2016. The IFC allows hospitals nationwide that have an MGCRB reclassification or LUGAR status during FY 2016 and subsequent years the opportunity to simultaneously seek urban to rural reclassification under Section 412.103 for IPPS payment and other purposes, and keep their existing MGCRB reclassification or LUGAR status.

At any point during a calendar year, MACs may be notified by the CMS Regional Offices of hospitals located in an urban CBSA that are approved to reclassify as rural under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103). The regulations at Section 412.103(a)(c) provide the CMS Regional Offices with up to 60 days to review and approve an urban to rural reclassification request. If the request is approved by CMS Regional Office, the approval is effective as of the filing date of the request (typically specified in the CMS Regional Office’s approval letter).
Instructions for Updating the OPSF if a Hospital is Approved for an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (§ 412.103) with an Effective Date of April 21, 2016 and After for CY 2016

CR9930 provides instruction to MACs for updating the OPSF when a hospital is approved for an urban to rural reclassification under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103) with an effective date of April 21, 2016, and after for CY 2016.

Instructions for Updating the OPSF for Treatment of Certain Urban Hospitals Reclassified as Rural Hospitals Under Section 412.103 in CY 2017 but with no other Reclassifications

An urban hospital that reclassifies as a rural hospital under Section 412.103 is considered rural. In order to ensure correct payment under the OPPS, the rural CBSA (2-digit State code) in the Wage Index Location CBSA and the special payment indicator field must be updated. CR9930 provides instructions to MACs to make that update.

Instructions for Updating the OPSF if a Hospital is Approved for an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103) with an Effective Date of January 1, 2017, and After for CY 2017

CR9930 provides instructions to the MACs for updating the OPSF using Table 7 in the attachment to CR9930.

Instructions for Updating the OPSF if a Hospital Cancels an Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Social Security Act (Section 412.103)

For a hospital that notifies the CMS Regional Office that it wishes to cancel its urban to rural reclassification under Section 1886(d)(8)(E) of the Social Security Act (42 CFR 412.103), CR9930 provides instructions to the MACs for updating their OPSF.

CR9930 also provides instructions to the MACs for updating the OPSF for hospitals that have both a MGCRB reclassification/LUGAR status and a Section 412.103 urban to rural reclassification and cancel their Urban to Rural reclassification under Section 1886 (d)(8)(E) of the Social Security Act (412.103) in the middle of the Fiscal Year.

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


You may refer to [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html) for the most current OPPS HCPCS Offset File.

If you have any questions, please contact your MAC at their toll-free number. That number is available at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/).
July 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

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 MACs and Durable Medical Equipment MACs (DME/MACs) for Part B drug services to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9612 informs MACs to download and implement the July 2016 ASP drug pricing files and, if released by the Centers for Medicare & Medicaid Services (CMS), the April 2016, January 2016, October 2016 and July 2015, ASP drug pricing files for Medicare Part B drugs. Medicare will use these files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 5, 2016, with dates of service July 1, 2016, through September 30, 2016. Make sure that your billing staffs are aware of these changes.

Background

The ASP methodology is based on quarterly data submitted to 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 the "Medicare Claims Processing Manual" (Chapter 4 (Part B Hospital (Including Inpatient Hospital Part B and OPPS)), Section 50 (Outpatient PRICER)).

Disclaimer

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The following table shows how the quarterly payment files will be applied:

<table>
<thead>
<tr>
<th>Files</th>
<th>Effective Dates of Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2016 ASP and ASP NOC</td>
<td>July 1, 2016, through September 30, 2016</td>
</tr>
<tr>
<td>April 2016 ASP and ASP NOC</td>
<td>April 1, 2016, through June 30, 2016</td>
</tr>
<tr>
<td>January 2016 ASP and ASP NOC</td>
<td>January 1, 2016, through March 31, 2016</td>
</tr>
<tr>
<td>October 2015 ASP and ASP NOC</td>
<td>October 1, 2015, through December 31, 2015</td>
</tr>
<tr>
<td>July 2015 ASP and ASP NOC</td>
<td>July 1, 2015, through September 30, 2015</td>
</tr>
</tbody>
</table>

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.
October 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

**Provider Types Affected**

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

**What You Need to Know**

Change Request (CR) 9724 provides the October 2016 quarterly update and instructs MACs to download and implement the October 2016 ASP drug pricing files and, if released by CMS, the July 2016, April 2016, January 2016, and October 2015, ASP drug pricing files for Medicare Part B drugs. Medicare will use these files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 3, 2016, with dates of service October 1, 2016, through December 31, 2016. MACs will not search and adjust claims that have already been processed unless brought to their attention. Make sure your billing staffs are aware of these changes.

**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 Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that are in Chapter 4, Section 50 of the “Medicare Claims Processing Manual” at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.

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</table>

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html).
Rural Health Clinic and Federally Qualified Health Center - Medicare Benefit Policy Manual Chapter 13 Update

Provider Types Affected

This MLN Matters® Article is intended for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9864 requires Medicare Administrative Contractors to be aware of the updates to the “Medicare Benefit Policy Manual” - Chapter 13. Make sure that your billing staffs are aware of these changes.

Background

The 2017 update of the “Medicare Benefit Policy Manual,” Chapter 13 - Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services, provides information on requirements and payment policies for RHCs and FQHCs, as authorized by Section 1861(aa) of the Social Security Act. The Centers for Medicare & Medicaid Services (CMS) has revised Chapter 13 to include that beginning January 1, 2017, the FQHC PPS base rate will be updated by the FQHC Market Basket, and that services furnished by auxiliary personnel incident to a transitional care management (TCM) or chronic care management (CCM) visit may be furnished under general supervision instead of direct supervision, as finalized in the CY 2017 Physician Fee Schedule Final Rule. All other revisions serve to clarify existing policy. The key revised areas include the following sections:
- Section 70.3 revised to include that beginning in 2017, the FQHC PPS base rate will be updated by the FQHC Market Basket.
- Section 110.3 revised to clarify information on payment for Graduate Medical Education in RHCs and FQHCs.
- Section 110.4 revised to include that services furnished by auxiliary personnel incident to a TCM visit may be furnished under general supervision.
- Section 110.5 revised to include that services furnished by auxiliary personnel incident to a CCM visit may be furnished under general supervision.
- Section 130.3 updated to remove the payment restriction for an RHC owned by a physician assistant.
- Section 160 updated to remove services furnished incident to a clinical social worker service.
- Section 180 revised to include speech-language pathology services.
- Section 220.4 revised to clarify copayment for FQHC preventive services under the FQHC Prospective Payment System (PPS).

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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Summary of Policies in the Calendar Year (CY) 2017 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, and CT Modifier Reduction List

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9844 provides a summary of policies in the Calendar Year (CY) 2017 MPFS Final Rule and announces the Telehealth Originating Site Facility Fee payment amount. Make sure that your billing staffs are aware of these updates.

Background

Section 1848(b)(1) of the Social Security Act (the Act) requires the Secretary of Health and Human Services to establish by regulation a fee schedule of payment amounts for physicians’ services for the subsequent year. The Centers for Medicare & Medicaid Services (CMS) issued a final rule on November 2, 2016, that updates payment policies and Medicare payment rates for services furnished by physicians and Non-Physician Practitioners (NPPs) that are paid under the MPFS in CY 2017.

The final rule (CMS-1654-F) also addresses public comments on Medicare payment policies proposed earlier in 2016. The proposed rule, “Revisions to Payment Policies under

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the Physician Fee Schedule and Other Revisions to Part B for CY 2017,” was published in the Federal Register on July 15, 2016.

The key changes are as follows:

**CT Modifier Reduction Changes from 5 percent to 15 percent**

As required by Medicare law, effective January 1, 2016, a payment reduction of 5 percent applies to Computed Tomography (CT) services furnished using equipment that is inconsistent with the CT equipment standard and for which payment is made under the MPFS. The payment reduction increases to 15 percent in 2017 and subsequent years. See MLN Matters Article MM9250 at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9250.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9250.pdf) for more details.

**Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures**

As required by Medicare law, CMS revised the MPPR of the PC of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount. The MPPR on the Technical Component (TC) of imaging remains at 50 percent.

Currently, CMS makes full payment for the PC of the highest-priced procedure and payment at 75 percent for the PC of each additional procedure, when furnished by the same physician (or physician in the same group practice) to the same patient, in the same session on the same day. See MLN Matters Article MM9647 at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9647.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9647.pdf) for more details.

**Telehealth Origination Site Facility Fee Payment Amount Update**

Section 1834(m)(2)(B) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31, 2002, at $20. For telehealth services provided on or after January 1 of each subsequent CY, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in Section 1842(i)(3) of the Act. The MEI increase for 2017 is 1.2 percent. Therefore, for CY 2017, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge, or $25.40. (The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.)

**Access to Telehealth Services**

CMS is adding the following services to the list of those that can be furnished to Medicare beneficiaries under the telehealth benefit:

- ESRD-related services CPT codes 90967 through 90970
- Advance care planning CPT codes 99497 through 99498
- Telehealth consultation HCPCS codes G0508 through G0509

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Note: For the ESRD-related services, the required clinical examination of the catheter access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by a physician, Clinical Nurse Specialist (CNS), Nurse Practitioner (NP), or Physician Assistant (PA). For the complete list of telehealth services, visit [http://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html](http://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html).

**New Place of Service (POS) Code for Telehealth**

The new POPS is 02 with a description of the location where health services and health related services are provided or received, through telecommunication technology.

**X-ray Reduction for Film**

As required by Medicare law, Medicare reduces payment amounts under the MPFS by 20 percent for the TC (and the TC of the global fee) of imaging services that are X-rays taken using film, effective January 1, 2017, and after.

To implement this provision, CMS has created Modifier FX (X-ray taken using film). Beginning in 2017, claims for X-rays using film must include Modifier FX, which will result in the applicable payment reduction. See MLN Matters Article MM9727 at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9727.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9727.pdf) for more details.

**Primary Care, Care Management, and Cognitive Services**

CMS is finalizing the following coding and payment changes for CY 2017 to improve payment for various primary care, care management, and cognitive services. Each of these codes is included in the 2017 HCPCS update and payment information is included in the routine annual update files:

- Separate payment for existing codes describing prolonged Evaluation and Management (E/M) services without direct patient contact by the physician (or other billing practitioner) (CPT codes 99358, 99359), and increased payment for prolonged E/M services with direct patient contact by the physician (or other billing practitioner) (CPT code 99354) adopting the RUC-recommended values. CPT codes 99358 and 99359 are listed in the “Medicare Claims Processing Manual” as non-payable (Chapter 12, Section 30.6.15.2). As of January 1, 2017, these codes are separately payable under the MPFS and changes to the manual are forthcoming.

- The MPFS includes new coding and payment for Behavioral Health Integration (BHI) services including substance use disorder treatment, specifically three new codes to describe services furnished using the psychiatric Collaborative Care Model (CoCM) (HCPCS codes G0502, G0503, G0504) and one new code to describe services furnished using other BHI care models (HCPCS code G0507).

- Separate payment for complex Chronic Care Management (CCM) services (CPT codes 99487, 99489), reduced administrative burden for CCM (CPT codes 99487,
99489, 99490), and a new add-on code to the CCM initiating visit to account for the work of the billing practitioner in assessing the beneficiary and establishing the CCM care plan (HCPCS code G0506).


Implementation of Alternative Medicare Physician Fee Schedule (PFS) Locality Configuration for California

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA 2014) was signed into law and Section 220(h) of the legislation adds Section 1848(e) (6) of the Act, which now requires, for services furnished on or after January 1, 2017, that the locality definitions for California be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California’s locality structure increases its number of localities from 9 under the current locality structure to 27 under the MSA based locality structure. However, both the current localities and the MSA based localities are comprised of various component counties, and in some localities only some of the component counties are subject to the blended phase-in and hold harmless provisions required by Section 1848(e)(6)(B) and (C) of the Act. Although the modifications to California’s locality structure increase the number of localities from 9 under the current locality structure, to 27 under the MSA-based locality structure, for purposes of payment, the actual number of localities under the MSA based locality structure would be 32 to account for instances where unique locality numbers are needed.

Additionally, for some of these new localities, PAMA requires that the geographic practice cost index GPCI values that would be realized under the new MSA based locality structure are gradually phased in (in one-sixth increments) over a period of 6 years.

Update to the Methodology for Calculating GPCIs in the U.S. Territories

CMS is revising the methodology used to calculate GPCIs in the U.S. territories, whereby Puerto Rico will be assigned the national average of 1.0 to each GPCI, as is currently done in the Virgin Islands in an effort to provide greater consistency in the calculation of the territories’ GPCIs. This change is included in the routine PFS update files.

Data Collection Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to Accurately Value Global Packages

CMS finalized a data collection strategy to gather information needed to value global surgical services. Practitioners in Florida, Kentucky, Louisiana, Nevada, New Jersey, North Dakota, Ohio, Oregon and Rhode Island are required, beginning July 1, 2017, to report claims showing that a visit occurred during the post-operative period for select global services. Practitioners who only practice in settings of fewer than 10 practitioners are not required to...
report, but may do so voluntarily. Such visits will be reported using CPT code 99024. The requirement to report will only apply to specified high-volume/high-cost services. The list of services for which reporting is required will be available on the CMS website. Practitioners who are not required to report are able to report voluntarily and encouraged to do so. If reporting voluntarily, reporting should be done for all visits relating to all codes on the list of applicable codes.

In addition a survey of practitioners will be conducted to gather data on service furnished in the post-operative period.

To the extent that these data result in proposals to revalue any global packages, that revaluation will be done through notice and comment rulemaking at a future time.

CPT code 99024 is currently included on the PFS with a procedure status indicator of “B.”

Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure
The CPT Editorial Panel created CPT codes for separately reporting moderate sedation services, which corresponded to elimination of Appendix G from the CPT Manual, effective January 1, 2017. Appendix G of the CPT Manual identified services where moderate sedation was considered an inherent part of the procedural service. The MPFS Final Rule established valuations for the new moderate sedation CPT codes and revaluation of certain procedural services previously identified in Appendix G. These coding and payment changes provide for payment for moderate sedation services only in cases where moderate sedation services are furnished.

Additional Information

The final 2017 MPFS rule is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-f.html.

If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

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