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- 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.

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Comprehensive ESRD Care (CEC) Model Telehealth - Implementation

MLN Matters Number: MM10314 Revised
Related Change Request (CR) Number: 10314
Related CR Release Date: June 27, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R198DEMO
Implementation Date: October 1, 2018

Note: This article was revised on June 28, 2018, to reflect a revised CR10314 issued on June 27. In the article, the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) and participating in the Comprehensive ESRD Care (CEC) Model for telehealth services provided to Medicare End-Stage Renal Disease (ESRD) beneficiaries associated with the CEC Model.

PROVIDER ACTION NEEDED

Change Request (CR) 10314 details the CEC Model telehealth program and how it will be implemented. Make sure your billing staffs are aware of this initiative.

BACKGROUND

Section 1115A) of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act (ACA) (42 USC 1315a) authorizes the Center for Medicare and Medicaid Innovation (CMMI) to test innovate health care payment and service-delivery models that have the potential to lower Medicare, Medicaid, and the Child Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries’ care.

The CEC Model is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with ESRD. Through the CEC Model, the Centers for Medicare & Medicaid Services (CMS) will partner with health care providers and suppliers to test the effectiveness of a new payment and service delivery model in providing beneficiaries with person-centered, high-quality care. The Model builds on Accountable Care Organization (ACO) experience from the Pioneer ACO Model, Next Generation ACO Model, and the Medicare Shared Savings Program to test ACOs for ESRD beneficiaries.
More than 600,000 Americans have ESRD and require life-sustaining dialysis treatments several times per week. Many beneficiaries with ESRD suffer from poorer health outcomes, often the result of underlying disease complications and multiple co-morbidities. These can lead to high rates of hospital admission and readmissions, as well as a mortality rate that is higher than that of the general Medicare population.

According to United States Renal Data System, in 2014, ESRD beneficiaries comprised less than 1 percent of the Medicare population, but accounted for an estimated 7.2 percent of total Medicare Fee-For-Service (FFS) spending, totaling more than $32.8 billion.

Because of their complex health needs, beneficiaries often require visits to multiple providers and follow multiple care plans, all of which can be challenging for beneficiaries if care is not coordinated. The CEC Model seeks to create incentives to enhance care coordination and to create a person-centered, coordinated care experience, and to ultimately improve health outcomes for this population.

In the CEC Model, dialysis clinics, nephrologists and other providers collaborate to create an ESRD Seamless Care Organization (ESCO) to coordinate care for matched beneficiaries. ESCOs are accountable for clinical quality outcomes and financial outcomes measured by Medicare Part A and B spending, including all spending on dialysis services for their aligned ESRD beneficiaries. This model encourages dialysis providers to think beyond their traditional roles in care delivery and supports them as they provide patient-centered care that will address beneficiaries’ health needs, both in and outside of the dialysis clinic.

The CEC Model includes separate financial arrangements for larger and smaller dialysis organizations. Large Dialysis Organizations (LDOs), defined as having 200 or more dialysis facilities, will be eligible to receive shared savings payments. These LDOs will also be liable for shared losses and will have higher overall levels of risk compared with their smaller counterparts.

Non-Large Dialysis Organizations (Non-LDOs) include chains with fewer than 200 dialysis facilities, independent dialysis facilities, and hospital-based dialysis facilities. Non-LDOs will have the option of participating in a one-sided track where they will be able to receive shared savings payments, but will not be liable for payment of shared losses, or participating in a track with higher risk and the potential for shared losses. The one-sided track is offered in recognition of the Non-LDOs more limited resources.

The CEC Model began on October 1, 2015, and will run until December 31, 2020. The CEC Model conducted a solicitation in 2016 to add more ESCOs for Performance Year 2 of the model, beginning on January 1, 2017. The CEC Model has no current plans for another round of solicitations.

The CEC Model LDO payment track and Non-LDO two-sided payment track are considered Advance Payment Models (APMs) regarding the Quality Payment Program.

The CEC Model will implement design elements with implications for the FFS system for its third
performance year that includes benefit enhancements to give ACOs the tools to direct care and engage beneficiaries in their own care. The model also offers increased monitoring to account for different financial incentives and the provision of enhanced benefits. The model’s quality requirements are similar to Shared Savings Program (SSP) and Pioneer, modified as needed to take into account unique aspects of dialysis care, in keeping with the agencies initiatives to unify and streamline quality measurement and requirements.

**Telehealth Waiver**

In order to emphasize high-value services and support the ability of ESCOs to manage the care of beneficiaries, CMS plans to design policies and use the authority under Section 1115A of the Social Security Act (Section 3021 of the Affordable Care Act) to conditionally waive certain Medicare payment requirements as part of the CEC Model.

CMS will make available to qualified ESCOs a waiver of the originating site requirement for services provided via telehealth. This benefit enhancement will allow beneficiaries to receive qualified telehealth services in non-rural locations and locations that are not specified by statute, such as homes and dialysis facilities. The waiver will apply only to eligible aligned beneficiaries receiving services from ESCO providers.

An aligned beneficiary will be eligible to receive telehealth services through this waiver if the services are otherwise qualified with respect to:

1. The service provided, as designated by Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes, and
2. The remote site.

MACs will apply claims processing edit logic, audit, medical review, Medicare Secondary Payor, and fraud and abuse activities, appeals and overpayment processes for CEC claims in the same manner as normal FFS claims.

Notwithstanding these waivers, all telehealth services must be furnished in accordance with all other Medicare coverage and payment criteria, and no additional reimbursement will be made to cover set-up costs, technology purchases, training and education, or other related costs. In particular, the services allowed through telehealth are limited to those described under Section 1834(m)(4)(F) of the Act, and subsequent additional services specified through regulation with the exception that claims **will not** be allowed for the following telehealth services rendered to aligned beneficiaries located at their residence:

- Follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals or Skilled Nursing Facilities (SNFs) - HCPCS codes G0406-G0408.
- Subsequent hospital care services, with the limitation of 1 telehealth visit every 3 days - CPT codes 99231-99233.
- Subsequent nursing facility care services, with the limitation of 1 telehealth visit every 30 days - CPT codes 99307-99310.
- Telehealth consultations, emergency department or initial inpatient - HCPCS codes G0425-G0427.
• Telehealth Consultation, Critical Care, initial - HCPCS code G0508.
• Telehealth Consultation, Critical Care, subsequent - HCPCS code G0509.
• Prolonged service in the inpatient or observation setting requiring unit/floor time beyond the usual service - CPT codes 99356-99357.

MACs will be ready to process Part B CEC claims for dates of service on or after October 1, 2018. MACs will process CEC telehealth claims (Place of Service (POS) 02) when providers are ESCO providers and beneficiaries are aligned to the same ESCO for the Date of Service (DOS) on the claims and contains the demo code 85 and one of the following CPT or HCPCS codes:

90785, 90791, 90792, 90832, 90833, 90834, 90836, 90837, 90838, 90839, 90840, 90845, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, 96116, 96150, 96151, 96152, 96153, 96154, 96160, 96161, 97802, 97803, 97804, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99354, 99355, 99406, 99407, 99495, 99496, 99497, 99498, G0108, G0109, G0270, G0396, G0397, G0420, G0421, G0438, G0439, G0442, G0443, G0444, G0445, G0446, G0447, G0459, G0506, G9481, G9482, G9483, G9484, G9485, G9486, G9487, G9488, G9489

For Part A CEC claims when providers are ESCO providers and beneficiaries are aligned to the same ESCO for the Date of Service (DOS) on the claims submitted on Type of Bill (TOB) 12X, 13X, 22X, 23X, 71X, 72X, 76X, 77X, or 85X and contains the demo code 85 and one of the following CPT or HCPCS codes:

90785, 90791, 90792, 90832, 90833, 90834, 90836, 90837, 90838, 90839, 90840, 90845, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, 96116, 96150, 96151, 96152, 96153, 96154, 96160, 96161, 97802, 97803, 97804, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99354, 99355, 99406, 99407, 99495, 99496, 99497, 99498, G0108, G0109, G0270, G0396, G0397, G0420, G0421, G0438, G0439, G0442, G0443, G0444, G0445, G0446, G0447, G0459, G0506, G9481, G9482, G9483, G9484, G9485, G9486, G9487, G9488, G9489

MACs will not process as CEC telehealth claims that contain the following codes. Claims that contain these codes can be processed following existing claims processing logic:

• HCPCS codes G0406 – G0408.
• CPT codes 99231 – 99233.
• CPT codes 99307 – 99310.
• HCPCS codes G0425-G0427
• HCPCS code G0508
• HCPCS code G0509
• CPT codes 99356-99357

MACs will treat CEC payments the same as Medicare patients for cost reporting purposes.
Providers submitting electronic 837 claims should enter DEMO 85 in the REF segment 2300 Loop Demonstration Project Identifiers and providers will include Qualifier P4. Providers submitting a paper claim should enter demo 85 in the treatment authorization field.

Providers should be aware that MACs will return claims if you append demo code 85, and:

- You are not on the CEC participant provider list with a telehealth record type; or
- DOS “from date” is prior to your telehealth effective date, or
- DOS “from date” is after your telehealth termination date, or
- The DOS “from date” is prior to the beneficiary’s effective date; or
- The DOS “from date” is after the beneficiary’s termination date, or
- The DOS “from date” is more than 90 days after the beneficiary’s termination date; or
- The beneficiary was not aligned to the same ESCO with which you are participating, as identified by ESCO ID; or
- The claim is for Part A and the TOB is other than 12X, 13X, 22X, 23X, 71X, 72X, 76X, 77X, and 85X,
- Other, non-telehealth services are billed on the same claim. In these cases, none of the services on the claim are processed.

In returning Part B claims, your MAC will use the following messaging:

- Claims Adjustment Reason Code (CARC) 16: (Claim/service lacks information or has submission/billing error(s) which is needed for adjudication) and
- Remittance Advice Remark Code (RARC) N763 (The demonstration code is not appropriate for this claim; resubmit without a demonstration code.)
- Group Code: CO (Contractual Obligation)

For Part A claims, your MAC will just return the claim to the provider (RTP).

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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International Classification of Diseases, Tenth Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)

MLN Matters Number: MM10859
Related CR Number: 10859
Related CR Release Date: August 10, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R2122OTN
Implementation Date: January 7, 2019, shared edits, September 28, 2018, local edits

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10859 constitutes a maintenance update of International Classification of Diseases, Tenth Revision (ICD-10) conversions and other coding updates specific to national coverage determinations (NCDs). These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received. Please follow the link below for the NCD spreadsheets included with this CR: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR10859.zip. Make sure that your billing staffs are aware of these changes.

BACKGROUND

Previous NCD coding changes appear in ICD-10 quarterly updates that are available at https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html, along with other CRs implementing new NCD policy. Edits to ICD-10, and other coding updates specific to NCDs, will be included in subsequent quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

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

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

CR10859 makes coding and clarifying adjustments to the following NCDs:

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

Note/Clarification: A/B MACs shall use default Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) messages where appropriate: Remittance Advice Remark Codes (RARC) N386 with Claim Adjustment Reason Code (CARC) 50, 96, and/or 119. See latest CAQH CORE update. When denying claims associated with the NCDs referenced in CR10859, except where otherwise indicated, A/B MACs shall use:

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

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

**ADDITIONAL INFORMATION**

The official instruction, CR10859, issued to your MAC regarding this change is available at

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

## DOCUMENT HISTORY

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<tr>
<th>Date of Change</th>
<th>Description</th>
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Medical Review of Evaluation and Management (E/M) Documentation

MLN Matters Number: MM10627  Related Change Request (CR) Number: 10627
Related CR Release Date: July 13, 2018  Effective Date: August 14, 2018
Related CR Transmittal Number: R808PI  Implementation Date: August 14, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10627 establishes a new Section (6.8) in Chapter 6 of the “Medicare Program Integrity Manual” (Pub. 100-08), titled, “Medical Review of Evaluation and Management (E/M) Documentation.” Please make sure your billing staffs are aware of this new content.

BACKGROUND

CR10627 establishes Section 6.8 (Medical Review of Evaluation and Management (E/M) Documentation) with subsection 6.8.1 (Medical Review of E/M Documentation Provided by Student). These sections provide direction to Medicare’s medical review contractors on how to review claims where a medical student documented the E/M service. This is a follow-up instruction to CR10412 (published in February 2018), which allowed teaching physicians to verify a student’s E/M visit notes rather than re-documenting them.


The new section of the “Medicare Program Integrity Manual” states the following:

The “Medicare Claims Processing Manual”, Chapter 12, Section 100.1.1 (B) states the teaching physician must personally perform (or re-perform) the physical exam and medical decision
making activities of the E/M service being billed, but may verify any student documentation of them in the medical record rather than re-documenting this work. If the teaching physician chooses to rely on the medical student documentation and chooses not to re-document the E/M services, contractors shall consider this requirement met if the teaching physician signs and dates the medical student’s entry in the medical record.”

**ADDITIONAL INFORMATION**


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

**DOCUMENT HISTORY**

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Claim Submission

Claim Status Category and Claim Status Codes Update

MLN Matters Number: MM10777 Related Change Request (CR) Number: 10777
Related CR Release Date: June 1, 2018 Effective Date: October 1, 2018
Related CR Transmittal Number: R4066CP Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10777 updates, as needed, the Claim Status and Claim Status Category Codes used for the Accredited Standards Committee (ASC) X12 276/277 Health Care Claim Status Request and Response and ASC X12 277 Health Care Claim Acknowledgment transactions. Make sure your billing staffs are aware of these updates.

BACKGROUND

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

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

The codes sets are available at http://www.wpc-edi.com/reference/codelist/healthcare/claim-status-category-codes/ and http://www.wpc-edi.com/reference/codelist/healthcare/claim-status-codes/. Included in the code lists are specific details, including the date when a code was added, changed, or deleted.
All code changes approved during the June 2018 committee meeting shall be posted on these sites on or about July 1, 2018.

The Centers for Medicare & Medicaid Services (CMS) will issue future updates to these codes, as needed. MACs must update their claims systems to ensure that the current version of these codes is used in their claim status responses.

These code changes are used in editing of all ASC X12 276 transactions processed on or after the date of implementation and to be reflected in the ASC X12 277 transactions issued on and after the date of implementation of CR 10777.

The CMS’ Medicare contractors must comply with the requirements contained in the current standards adopted under HIPAA for electronically submitting certain health care transactions, among them the ASC X12 276/277 Health Care Claim Status Request and Response. These contractors must use valid Claim Status Category Codes and Claim Status Codes when sending ASC X12 277 Health Care Claim Status Responses. They must also use valid Claim Status Category Codes and Claim Status Codes when sending ASC X12 277 Healthcare Claim Acknowledgments. References in CR 10777 to "277 responses" and "claim status responses" encompass both the ASC X12 277 Health Care Claim Status Response and the ASC X12 277 Healthcare Claim Acknowledgment transactions.

**ADDITIONAL INFORMATION**

The official instruction, CR10777, issued to your MAC regarding this change is available at

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients

MLN Matters Number: MM10474 Revised  Related Change Request (CR) Number: 10474
Related CR Release Date: May 24, 2018  Effective Date: July 1, 2018
Related CR Transmittal Number: R4062CP  Implementation Date: July 2, 2018

Note: This article was revised on May 25, 2018, to reflect the revised CR10474 issued on May 24 to correct the code description for ICD-10-CM D68.32. In the article, the code description is corrected and 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 providers who submit claims to Medicare Administration Contractors (MACs) for inpatient services to Medicare beneficiaries with hemophilia.

WHAT YOU NEED TO KNOW

Change Request (CR) 10474 provides updates to diagnosis codes required in order to allow add-on payments under the Inpatient Prospective Payment System (IPPS) for blood clotting factor administered to hemophilia inpatients. The add-on payment criteria for blood clotting factors administered to hemophilia inpatients will be updated July 1, 2018, by terminating International Classification of Diseases, Clinical Modification (ICD-CM) code D68.32, effective with that date. The list of ICD-CM codes that will continue to receive the add-on payment can be found in Section 20.7.3, of Chapter 3 of the “Medicare Claims Processing Manual”. Make sure your billing staffs are aware of this update.

BACKGROUND

The September 1, 1993, IPPS final rule (58 FR 46304) states that payment will be made for the blood clotting factor only if an ICD-CM diagnosis code for hemophilia is included on the bill.

Effective July 1, 2018, code D68.32 (Hemorrhagic disorder due to extrinsic circulating anticoagulants) is TERMINATED. Therefore, providers that include diagnosis code D68.32 on inpatient claims with discharge dates after July 1, 2018, will not receive the add-on payment.
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/Medicare/Medicare-Contracting/FFSProvCustSvcGen/MAC-Website-List.html.

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<td>March 2, 2018</td>
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E/M Service Documentation Provided By Students (Manual Update)

MLN Matters Number: MM10412 Revised Related Change Request (CR) Number: 10412
Related CR Release Date: May 31, 2018 Effective Date: January 1, 2018
Related CR Transmittal Number: R4068CP Implementation Date: March 5, 2018

Note: This article was revised on June 1, 2018, to reflect an updated Change Request (CR) that corrected typos in the CR and part of the manual update under Section 100.1.1. The transmittal number, CR released date and link to the transmittal also changed. All other information is unchanged.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

CR 10412 revises the Medicare Claims Processing Manual to allow the teaching physician to verify in the medical record any student documentation of components of E/M services, rather than re-documenting the work. Make sure your billing staffs are aware of the changes.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is revising the Medicare Claims Processing Manual, Chapter 12, Section 100.1.1, to update policy on Evaluation and Management (E/M) documentation to allow the teaching physician to verify in the medical record any student documentation of components of E/M services, rather than re-documenting the work. Students may document services in the medical record. However, the teaching physician must verify in the medical record all student documentation or findings, including history, physical exam and/or medical decision making. The teaching physician must personally perform (or re-perform) the physical exam and medical decision making activities of the E/M service being billed, but may verify any student documentation of them in the medical record, rather than re-documenting this work.
ADDITIONAL INFORMATION


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

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Internet Only Manual (IOM) Update to Publication 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100

MLN Matters Number: MM10809  Related Change Request (CR) Number: CR 10809
Related CR Release Date: July 20, 2018  Effective Date: October 23, 2018
Related CR Transmittal Number: R244BP  Implementation Date: October 23, 2018

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare contractors (Regional Home Health Intermediaries (RHHIs), Durable Medical Equipment Medicare Administrative Contractors (DME/MACs) and A/B Medicare Administrative Contractors (A/B MACs)) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10809 which informs MACs about an update to the Medicare Benefit Policy Manual, Chapter 11, Section 100, extending renal dialysis services paid under Section 1881(b)(14) of the Social Security Act to beneficiaries with Acute Kidney Injury (AKI), effective January 1, 2017. This revision does not represent a policy change. Specifically, the manual has been updated to state that Erythropoietin Stimulating Agents (ESAs) are included in the bundled payment amount for treatments administered to patients with AKI. The Non-ESRD HCPCS codes should be used (J0881, J0883, J0885, J0888, Q0138). The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636.

Make sure 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.

ADDITIONAL INFORMATION

The official instruction, CR10809, issued to your MAC regarding this change is available at

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

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July 2018 Integrated Outpatient Code Editor (I/OCE) Specification Version 19.2

MLN Matters Number: MM10699 Revised
Related CR Release Date: June 15, 2018
Related CR Transmittal Number: R4074CP
Related Change Request (CR) Number: 10699
Effective Date: July 1, 2018
Implementation Date: July 2, 2018

Note: This article was revised on June 18, 2018, to reflect an updated Change Request (CR) that made revisions to the Summary of Changes and Summary of Modifications documents. In the article "Service Not Paid by Medicare (edit 13)" was added in the table on page 3. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

CR 10699 provides the I/OCE instructions and specifications for the I/OCE that will be utilized under the Outpatient Prospective Payment System (OPPS) and non-OPPS for hospital outpatient departments, community mental health centers, all non-OPPS providers, and for limited services when provided in a home health agency not under the Home Health PPS (HH PPS) or to a hospice payment for the treatment of a non-terminal illness. Please make sure your billing staffs are aware of these updates.

BACKGROUND

CR10699 informs the Part A/B MACs Part A, the A/B MACs Part Home Health and Hospice (HHH) and the Fiscal Intermediary Shared System (FISS) that the I/OCE is being updated for July 1, 2018. The I/OCE routes all institutional outpatient claims (which includes non-OPPS hospital claims) through a single I/OCE.

The I/OCE is used under the OPPS and non-OPPS for hospital outpatient departments, community mental health centers, all non-OPPS providers, and for limited services when provided in a home health agency not under HH PPS or to a hospice patient for the treatment of a non-terminal illness.
The modifications of the I/OCE for the July 2018 V19.2 release are summarized in the table below. Readers should also read through the entire specifications document and note the highlighted sections, which also indicate changes from the prior release of the software. The I/OCE specifications will be posted on the Centers for Medicare & Medicaid Services (CMS) website at [http://www.cms.gov/OutpatientCodeEdit/](http://www.cms.gov/OutpatientCodeEdit/).

Table 1: July 2018 I/OCE Modifications

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<tr>
<th>Effective Date</th>
<th>Edits Affected</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/2018</td>
<td>18</td>
<td>Implement new program logic retroactively (1/1/18) to allow Anesthesia code 01402 (Status Indicator (SI) = C) reported with procedure code 27447 to package by changing its SI from C to N. If 01402 is reported with any other procedure the SI remains a C and will process as usual.</td>
</tr>
<tr>
<td>1/1/2016</td>
<td>38</td>
<td>Update program logic retroactively (1/1/16) to exclude procedures with SI=J2 from satisfying edit 38.</td>
</tr>
<tr>
<td>4/1/2018</td>
<td>106,107,108</td>
<td>Update logic for Add-on Code Editing to apply the applicable edits on both add-on procedure line items, if reporting multiple add-on codes without one or both primary procedures.</td>
</tr>
<tr>
<td>7/1/2018</td>
<td>6,20,22,40,106,107,108</td>
<td>Update the program logic to include edits (6, 20, 22, 40, 106, 107, and 108) to applicable bill types retroactively to the edits activation date. This includes the documentation update to the edits applied by bill type tables, see table for updates.</td>
</tr>
<tr>
<td>7/1/2018</td>
<td>6,22</td>
<td>Implement logic to include a condition in which lines submitted on a 32x bill type (HHA) with revenue code 0023 do not have edit 6 or 22 applied.</td>
</tr>
<tr>
<td>7/1/2018</td>
<td>22</td>
<td>Add the following new modifier to the valid modifier list QQ – Qualified cdsm consulted</td>
</tr>
<tr>
<td>7/1/2018</td>
<td></td>
<td>Update the Add-on Code Editing section to include additional conditions for editing. This includes an update to the Edit Descriptions and Reason for Edit Generation table.</td>
</tr>
<tr>
<td>7/1/2018</td>
<td></td>
<td>Update the I/OCE Execution and Processing Flowchart to include Rural Health Clinic (RHC) in the Federally Qualified Health Center (FQHC) objects mentioned in processing.</td>
</tr>
<tr>
<td>7/1/2018</td>
<td></td>
<td>Update to Hospice Processing section to note the logic that is discontinued by edit 61 and 72 being removed from bill type 81x and 82x (1/1/14).</td>
</tr>
<tr>
<td>7/1/2018</td>
<td></td>
<td>Update the Pass-through Device Processing section to change language from device-intensive procedure pairing to procedure and pass-through device pairings.</td>
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</table>
### Effective Date | Edits Affected | Modification
--- | --- | ---
7/1/2018 | Make all HCPCS/APC/SI changes as specified by CMS (quarterly data files).<br>7/1/2018 | Update the following lists for the release (see quarterly data files):<br>- Add on Type I (edit 106)<br>- Add on Type II (edit 107)<br>- Add on Type III (edit 108)<br>- Comprehensive Ambulatory Payment Classification (APC) Ranking<br>- Comprehensive APC Exclusions<br>- Procedure and Sex Conflict (edit 8)<br>- RHC CG Modifier not Payable<br>- Skin Substitute Product (edit 86)<br>- Non-covered service (edit 9)<br>- **Service Not Paid by Medicare (edit 13)**<br>7/1/2018 | Implement version 24.2 of the National Correct Coding Initiative (NCCI) (as modified for applicable outpatient institutional providers).

### ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).
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New Physician Specialty Code for Undersea and Hyperbaric Medicine

MLN Matters Number: MM10666
Related Change Request (CR) Number: 10666
Related CR Release Date: July 13, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number:
R4087CP, R306FM
Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

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

WHAT YOU NEED TO KNOW

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

BACKGROUND

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

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

Existing enrolled providers who want to update their specialty to reflect the new specialty must submit a change of information application to their Medicare Administrative Contractor (MAC). Providers may submit an enrollment application to initially enroll or update their specialty within 60 days of the implementation date of the new specialty.
MACs will recognize Undersea and Hyperbaric Medicine (D4) as a valid specialty type for the following edits:

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

**ADDITIONAL INFORMATION**


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MLN Matters Number: MM10624  Revised  Related Change Request (CR) Number: 10624
Related CR Release Date: July 5, 2018  Effective Date: July 1, 2018
Related CR Transmittal Number: R4083CP  Implementation Date: July 2, 2018

Note: This article was revised on July 6, 2018, to reflect a revised CR issued on July 5. The article is revised to show the Type of Service Code for CPT code 90739 remains as V. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is the same.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10624 informs MACs of updated drug/biological HCPCS codes. The HCPCS code set is updated on a quarterly basis. The July 2018 HCPCS file includes six new HCPCS codes: Q9991, Q9992, Q9993, Q9995, Q5105, and Q5106. Please make sure your billing staffs are aware of these updates.

BACKGROUND

The July 2018 HCPCS file includes six new HCPCS codes, which are payable by Medicare, effective for claims with dates of service on or after July 1, 2018. Part B payment for HCPCS code Q9995 will include the clotting factor furnishing fee. These codes are:

- **Q9991**
  - Short Description: Buprenorph x 100 mg or less
  - Long Description: Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg
  - Type of Service (TOS) Code: 1
  - Medicare Physician Fee Schedule Data Base (MPFSD) Status Indicator: E

- **Q9992**
  - Short Description: Buprenorphpine x r over 100 mg
Long Description: Injection, buprenorphine extended-release (sublocade), greater than 100 mg
- TOS Code: 1
- MPFSDB Status Indicator: E

**Q9993**
- Short Description: Inj., triamcinolone ext rel
- Long Description: Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
- TOS Code: 1,P
- MPFSDB Status Indicator: E

**Q9995**
- Short Description: Inj. emicizumab-kxwh, 0.5 mg
- Long Description: Injection, emicizumab-kxwh, 0.5 mg
- TOS Code: 1
- MPFSDB Status Indicator: E

**Q5105**
- Short Description: Inj Retacrit esrd on dialysi
- Long Description: Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units
- TOS Code: 1, L
- MPFSDB Status Indicator: E

**Q5106**
- Short Description: Inj Retacrit non-esrd use
- Long Description: Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units
- TOS Code: 9
- MPFSDB Status Indicator: E

In addition to the new codes, the TOS code for CPT Code 90739 remains as V.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).
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<td>June 26, 2018</td>
<td>The article was revised to reflect a revised CR issued on June 26. In the article, the new codes of Q5105 and Q5106 are added. The Type of Service Code for CPT code 90739 is updated to 1, V. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is the same.</td>
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<td>May 14, 2018</td>
<td>This article was revised to reflect a revised CR issued on May 11. In the article, a sentence is added to show that Part B payment for Q9995 includes the clotting factor furnishing fee. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information is the same.</td>
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Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes – October 2018 Update

MLN Matters Number: MM10834  Related Change Request (CR) Number: 10834
Related CR Release Date: August 10, 2018  Effective Date: July 12, 2018
Related CR Transmittal Number: R4114CP  Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

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

WHAT YOU NEED TO KNOW

The HCPCS code set is updated on a quarterly basis. Change Request (CR) 10834 informs MACs of the October 2018 addition of one new HCPCS code. Effective with dates of service on or after July 12, 2018, the Q5108 is payable by Medicare. The short descriptor for Q5108 is Injection, fulphila and the long descriptor is Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg. The Type of Service (TOS) Codes for Q5108 are 1, P and the Medicare Physician Fee Schedule Database (MPFSDB) Status Indicator is E. Note that MACs should hold claims for Q5108 until CR10834 is implemented.

ADDITIONAL INFORMATION


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

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Quarterly Influenza Virus Vaccine Code Update - January 2019

MLN Matters Number: MM10871
Related Change Request (CR) Number: 10871
Related CR Release Date: August 3, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4100CP
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

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

BACKGROUND

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

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

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

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

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

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

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

ADDITIONAL INFORMATION


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Revisions to the Telehealth Billing Requirements for Distant Site Services

MLN Matters Number: MM10583 Revised
Related Change Request (CR) Number: 10583
Related CR Release Date: June 21, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R2095OTN
Implementation Date: October 1, 2018

Note: This article was revised on June 21, 2018, to reflect a revised CR10583 issued on June 20. In the article, the criteria that allows the GT modifier to be present on Method II CAH claim lines is revised. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

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

BACKGROUND

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

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

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

ADDITIONAL INFORMATION


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System Changes to Implement Epoetin Alfa Biosimilar, Retacrit for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) Claims

MLN Matters Number: MM10839
Related Change Request (CR) Number: 10839
Related CR Release Date: August 3, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R245BP and R4105CP
Implementation Date: January 7, 2019

PROVIDER TYPES AFFECTED

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

WHAT YOU NEED TO KNOW

Change Request (CR) 10839 updates the list of supplies, drugs, and labs included in the End Stage Renal Disease (ESRD) consolidated billing list and therefore included in the base rate payment for Acute Kidney Injury (AKI). This includes erythropoietin stimulating agents billed with the ESRD-specific Healthcare Common Procedure Coding System (HCPCS) or the non-ESRD specific HCPCS.

CR10839 adds Q5106 (Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units) to the list established in CR9987. Claims that include Q5106 with dates of service between July 1, 2018, and December 31, 2018 will need to be reprocessed. Make sure 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 Acute Kidney Injury (AKI), effective January 1, 2017.

CRs9598 (see https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/mm9598.pdf) and 9814 (see https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-
MLN/MLNMattersArticles/Downloads/mm9814.pdf) implemented the initial requirements for this legislation.

MACs will not separately pay HCPCS code Q5106 (not found on the consolidated billing list) for AKI claims for Dates of Service (DOS) on or after July 1, 2018.

AKI claims are on Type of Bill 72X, submitted with condition code 84, CPT code G0491 and one of the following ICD-10 diagnosis codes:

1. N17.0 Acute kidney failure with tubular necrosis
2. N17.1 Acute kidney failure with 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

**Note:** Line should be indicated as covered and lines billed with modifier AY will not receive separate payment.

MACs will mass adjust AKI claims where HCPCS code Q5106 is present for DOS on or after July 1, 2018, through December 31, 2018. Mass adjustment should be completed within 90 days of the implementation date of CR10839.

**ADDITIONAL INFORMATION**


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

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Update of Internet Only Manual (IOM), Medicare Claims Processing Manual, Publication 100-04, Chapter 18 - Preventive and Screening Services, and Chapter 35 - Independent Diagnostic Testing Facility (IDTF)

MLN Matters Number: MM10735
Related Change Request (CR) Number: 10735
Related CR Release Date: June 8, 2018
Effective Date: July 9, 2018
Related CR Transmittal Number: R4071CP
Implementation Date: July 9, 2018

PROVIDER TYPES AFFECTED

This MLN Matters article is intended for Independent Diagnostic Testing Laboratories (IDTFs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change Request (CR) 10735 updates Medicare Claims Processing Manual, Chapter 18 - Preventive and Screening Services and Chapter 35 - Independent Diagnostic Testing Facility (IDTF) to include requirements and payment policies for screening mammography services furnished by IDTFs. CR10735 does not convey any policy changes. Instead, it just documents current policy in the Medicare Claims Processing Manual.

BACKGROUND

If an IDTF furnishes any type of mammography service (screening or diagnostic), it must have a Food and Drug Administration (FDA) certification to perform such services. However, an entity that only performs diagnostic mammography services should not be enrolled as an IDTF.

Screening mammographies (including those that are self-referred) are payable by Medicare when performed in and by an IDTF entity.

ADDITIONAL INFORMATION

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Update to Medicare Claims Processing Manual, Chapter 24, Section 90

MLN Matters Number: MM10559
Related Change Request (CR) Number: 10559
Related CR Release Date: August 3, 2018
Effective Date: November 5, 2018
Related CR Transmittal Number: R4096CP
Implementation Date: November 5, 2018

PROVIDER TYPE AFFECTED

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

WHAT YOU NEED TO KNOW

This article is based on Change Request (CR) 10559 which reduces confusion and clarifies the Administrative Simplification Compliance Act (ASCA) waiver process guideline in the Medicare Claims Processing Manual, Chapter 24, Section 90. CR10559 combines two sections (90.3.2 and 90.3.3) into one new Section 90.3.2 with a new title and description.

BACKGROUND

Section 3 of the ASCA, Pub. L. 107-105, and the implementing regulation at 42 CFR 424.32 (see https://www.ecfr.gov/cgi-bin/text-idx?SID=c41b2cb8b72f75bd58ae2a26094f4cfe&mc=true&node=pt42.3.424&rgn=div5#se42.3.4_132), require providers to submit all initial claims for reimbursement under Medicare, (except for small providers), electronically as of October 16, 2003, with limited exceptions.

Medicare is prohibited from paying claims submitted in a non-electronic manner that do not meet the limited exception criteria. The issuance of waivers under this limited exception criteria to is discussed in Chapter 24, Section 90 of the Medicare Claims Processing Manual.

A provider may submit a waiver request to their MAC claiming other types of “unusual circumstances” outside of their control prevent submission of electronic claims. It is the responsibility of the provider to submit appropriate documentation including request application with Provider name, address, email, and phone number to establish the validity of a waiver request in this situation. Requests received without documentation and above stated information to fully explain and justify why enforcement of the requirement would be against equity and
good conscience in these cases will be denied. If the MAC agrees that the waiver request has merit, the MAC sends the request to the Centers for Medicare & Medicaid Services (CMS) for review and issuance of the CMS decision.

If the MAC does not consider an “unusual circumstance” to be met, and does not recommend CMS approval, the MAC must issue a form letter to the provider. As required by the Privacy Act of 1974, letters issued to a provider to announce a waiver decision must be addressed to the organizational name of a provider and not to an individual (whether a sole practitioner, employee, or an owner of the provider organization). The organizational name is generally a corporate name under which the provider is registered as a Medicare provider or that is used to obtain an Employer Identification Number (EIN).

**ADDITIONAL INFORMATION**


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

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Updates to the Medicare Claims Processing Manual, Chapter 24, ASCA Waiver Review Form of Letters, Exhibits A-H

MLN Matters Number: MM10858
Related Change Request (CR) Number: CR 10858
Related CR Release Date: August 3, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R4102CP
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10858 provides an update to the language contained in the Form Letters the MACs use to inform certain providers of Administrative Simplification Compliance Act (ASCA) waiver reviews. The CR gives you clear directions for communicating with your MACs regarding ASCA waiver review-related questions when you receive a review Form Letter. Make sure your billing staffs are aware of these directions.

BACKGROUND

Section 3 of the ASCA, PL107-105, and the implementing regulation at 42 CFR 424.32, requires that you, on or after October 16, 2003, submit electronically (with limited exceptions); all of your initial claims for reimbursement under Medicare. You should be aware that Medicare cannot pay for claims: 1) That do not meet the limited exception criteria; and 2) Which you submit non-electronically. The issuance of waivers under this limited exception criteria to providers has been delegated to the MACs by the Centers for Medicare & Medicaid Services (CMS). Refer to https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm3440.pdf for additional information about this requirement, including a list of these exception criteria.

Based on discussions with MACs to streamline the communication process with your MACs, CMS has made minor modifications to the ASCA waiver review letters that will improve this communication. CR10858 provides these modifications; specifically, the addition of the statement: “If you have questions, please contact your MAC Customer Service.”

You will find the updated Claims Processing Manual, Chapter 24 (General EDI and EDI Support Requirements, Electronic Claims, and Mandatory Electronic Filing of Medicare Claims), as an
attachment to CR10858. It documents the changes mentioned above for the waiver review Exhibits of Form Letters (A-H).

ADDITIONAL INFORMATION


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

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User CR: FISS to Add Additional Search Features to Provider Direct Data Entry (DDE) Screen

MLN Matters Number: MM10542
Related Change Request (CR) Number: 10542
Related CR Release Date: August 10, 2018
Effective Date: January 1, 2019
Related CR Transmittal Number: R2112OTN
Implementation Date: January 7, 2019

PROVIDER TYPE AFFECTED

MLN Matters® Article 10542 is a one-time notice that highlights the improved claim search capability in Fiscal Intermediary Shared System (FISS) for providers who use DDE and submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10542 allows providers who use DDE to look up the claims associated with an Accounts Receivable (AR) by using the invoice number on the AR to find the Document Control Number (DCN), and then using the DCN to look up the claims. This update will improve provider customer service, allowing providers to find the claim associated with the AR and reconcile it back to their patient accounts. Please make certain your billing staff is aware of this enhancement. Detailed instructions on how to use the new feature will be provided closer to implementation.

BACKGROUND

CR 10542 gives providers the ability to find the claims associated with a receivable through DDE screens. Providers will use a new look up feature in DDE to use the invoice number on the receivable to find the DCN. Then, they can use the DCN to find the associated claims.

ADDITIONAL INFORMATION


If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.
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A55639 CHEMOTHERAPY AGENTS FOR NON-ONCOLOGICAL CONDITIONS UPDATED AND REFORMATTED


The article has been updated and reformatted to support Article Guidance on Non-Oncological Conditions. The following changes will be viewable October 1, 2018, on the Medicare Coverage Database:

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

These medications were removed as they are applicable to oncologic conditions and do not support the article guidance for non-oncological conditions. This article is related to LCD L37205 Chemotherapy Drugs and their Adjuncts. Please refer to the LCD (https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37205) for coverage for chemotherapy agents.

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

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

Please refer to NCCN Radiation Therapy Compendium™ for guidance.

Removed Group 3 Paragraph and associated information:
J9151 Daunorubicin citrate, liposomal formulation (DaunoXome) 10 mg,
J9165 Diethylstilbestrol diphosphate 250 mg,
J9270 Plicamycin (Mithracin) 2.5 mg, and
Q2017 Teniposide (Vumon) 50 mg.
Removed Group 3 Codes:
[C00.0 - C96.0] Malignant neoplasms of lip, oral cavity and pharynx- Multifocal and lutosystemic (disseminated) Langerhans-cell histiocytosis
[C96.21 - D46.9] Aggressive systemic mastocytosis - myelodysplastic syndrome, unspecified
[D47.09 - D49.9] Other mast cell neoplasms of uncertain behavior – Neoplasm of unspecified behavior of unspecified site
[E34.0 - E34.9] Carcinoid syndrome-Endocrine disorder, unspecified.

Group Paragraphs and Group Codes corrected for numerical order.
Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2018

MLN Matters Number: MM10873
Related Change Request (CR) Number: 10873
Related CR Release Date: July 20, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R4092CP
Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

This article is based on Change Request (CR) 10873 which informs MACs about the changes that will be included in the October 2018 quarterly release of the edit module for clinical diagnostic laboratory services. Make sure that your billing staffs are aware of these changes.

BACKGROUND

CR 10873 announces the changes that will be included in the October 2018 quarterly release of the edit module for clinical diagnostic laboratory services. The National Coverage Determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee, and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12 - 190.34) were processed uniformly throughout the nation, effective April 1, 2003.

In accordance with Chapter 16, Section 120.2, Publication 100-04, the laboratory edit module is updated quarterly as necessary to reflect ministerial coding updates and substantive changes to the NCDs developed through the NCD process. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes.
CR 10873 communicates requirements to Shared System Maintainers (SSMs) and contractors, notifying them of changes to the laboratory edit module to update it for changes in laboratory NCD code lists for October 2018. Please access the link below for the NCD spreadsheet of changes included with CR 10873:


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

### ADDITIONAL INFORMATION


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

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### INFORMATION ON WEBSITE

WPS GHA publishes Local Coverage Determinations (LCDs) and Coverage Articles on its website:  

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

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### NEW POLICIES/ARTICLES

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

Visit our website at the link below for more information:  

#### September 2018

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<tr>
<td>J5/J8</td>
<td>Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)</td>
<td>A56062</td>
<td>NA</td>
<td>08/01/2018</td>
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#### July 2018
### RETIRED POLICIES/ARTICLES

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

Visit our website at the link below for more information:

**September 2018** – There are no retired policies/articles for September 2018

**August 2018**

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<tr>
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<td>Billing and Coding for Rezum® Procedure</td>
<td>A55353</td>
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**July 2018** – There are no retired policies/articles for July 2018

### REVISED POLICIES/ARTICLES

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Visit our website at the link below for more information:

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<td>Category III Codes</td>
<td>L35490</td>
<td>PHYS-084</td>
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Under Utilization Guidelines, deleted the following sentence "Services described by CPT codes 0075T and 0076T are allowed when provided in accordance with NCD 20.7, Percutaneous Transluminal Angioplasty."  


The following information has been added to this LCD:

**Coverage Indications, Limitations and/or Medical Necessity**

MSI/MMR testing is also covered for adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR): solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.

**Step 2: Added and/or Deficient Mismatch Repair (MMR) by Immunohistochemistry (IHC)**

Changed medically necessary to medically acceptable in the sentence below: Molecular testing for MLH1, MSH2, MSH6 and PMS2 genes by NGS is covered as medically acceptable for the identification of LS by this contractor.

**IHC and/or MSI Testing**

Added:

- For patients with unresectable or metastatic solid tumors, either MSI or IHC or a multigene NGS or other multi-analyte methodology panel inclusive of MSI microsatellite loci, and MLH1, MSH2, MSH6 and PMS2 genes is medically reasonable and necessary.

**MMR Germline Gene Mutation Testing Exception**

Updated the third bullet: Diagnosis of any Lynch-associated cancer prior to Medicare eligibility AND tumor sample no longer available AND meets either Revised Bethesda guidelines or has at least a personal 5% estimated likelihood to be mutation positive, as calculated by an established available risk model (e.g., PREMM, MMRpredict, MMRpro).

If targeted gene testing is not possible, testing of the four MMR genes can be performed concurrently followed by testing for EPCAM, or per a testing strategy deemed appropriate by the physician.

Corrected the step numbers in the paragraph below:

**Step 5B: MSH2 Testing**

When IHC shows loss of MSH2 and MSH6, genetic testing should start with analysis of the MSH2 gene, given its frequency of germ-line mutation in LS. If MSH2 germ-line mutation is identified, then LS is diagnosed, and further testing of the patient is not medically necessary.
However, if genetic testing for germ-line mutations in *MSH2* is negative, analysis for deletion in the *EpCAM* gene should be performed (Step 6). If *EpCAM* is also negative, genetic testing of MSH6 should be performed (Step 5C). The presence of MSI and the loss of *MSH2/MSH6* strongly indicate an MMR germ-line defect.

The title of this article has been changed from Immunohistochemistry (IHC) Indications for Gastric Pathology to Special Stains and Immunohistochemistry (IHC) Indications for Gastric Pathology.

### August 2018

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<td>J5/J8</td>
<td>Erythropoiesis Stimulating Agents (ESAs) and Billing and Coding Guidelines</td>
<td>L34633</td>
<td>INJ-023</td>
<td>07/01/2018</td>
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Added: CR 10818, Quarterly Update to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Effective July 1, 2018, CR 10781, July 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS), Effective July 1, 2018 and CR 10624 Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes, Effective July 1, 2018.

CPT/HCPCS Codes

Group 1 Paragraph:
Removed J3590
Added Q5106

Group 1 Codes:
Added Q5105: Injection, epoetin alfa, biosimilar (for ESRD on dialysis) 100 units
Added Q5106: Injection, epoetin alfa, biosimilar (for non-ESRD use) 1000 units

Removed Group 2 Paragraph:
Removed J3590 for Epoetin alfa-epbx (biosimilar) FDA approval/effective date 05/15/2018 and Group 2 codes: removed J3590: unclassified biologics.

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph, A. End Stage Renal Disease (ESRD)
Removed J3590
Added Q5105.

Group 2 Paragraph, Chronic Kidney Disease NOT on dialysis
Removed J3590
Added Q5106.
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<td>Group 4 Paragraph, C. Indications other than Renal Disease, 1. Anemia related to therapy with Zidovudine (AZT) Removed J3590 Added Q5106. Group 11 Paragraph, 5. Prophylactic pre-operative use for reduction of allogeneic blood transfusions prior to elective hip and knee replacement surgery Removed J3590 Added Q5106. Removed NOC drug billing: Removed refer to the Not Otherwise Classified (NOC) Billing requirements contained within the Billing &amp; Coding Guidelines for claims submitted with J3590 unclassified biologics, effective 05/15/2018. Billing and Coding Guidelines for Erythropoiesis Stimulating Agents (ESAs) updated: Removed Not Otherwise Classified (NOC) Billing verbiage: Removed J3590 for Epoetin alfa-epbx (biosimilar) FDA approval/effective date 05/15/2018. Removed Office/Clinic: Providers submit NOC codes in the 2400/SV101-2 data element in the 5010 professional claim transaction (837P). When billing an NOC code, providers are required to provide a description in the 2400/SV101-7 data element. The 5010 TR3 Implementation Guide instructs: &quot;Use SV101-7 to describe non-specific procedure codes.&quot; (Do not use the 2400 NTE segment to describe non-specific procedure codes with 5010.) The SV101-7 data element allows for 80 bytes (i.e., characters, including spaces) of information. In order for WPS GHA to correctly reimburse NOC drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Item 19 of the CMS 1500 form: - The name of the drug, - The total dosage (plus strength of dosage, if appropriate), and - The method of administration. Important: List one unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Medicare determines the proper payment of NOC drugs and biologicals by the narrative information, not the number of units billed. Medicare will reject as unprocessable claims for NOC drugs and biologicals if any of the information above is missing, or if the NOC code is billed with more than one unit of service. (Note: The remittance notice will include remark code M123, &quot;Missing/incomplete/invalid name, strength, or dosage of the drug furnished,&quot; even if the rejection is due to the number of units billed.)</td>
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</table>
Pricing for NOC J-codes is determined by the information provided on the Average Sales Price (ASP) NOC pricing file. If the ASP NOC file lists the strength for a drug on the file, this indicates that the drug comes in different strengths. Medicare payment varies depending on the strength given. When billing Medicare for an NOC J-code, you can determine if the drug comes in different strengths by accessing the ASP NOC pricing files on the CMS website.


### J5/J8

**High Intensity Focused Ultrasound (HIFU) in the Treatment of Recurrent Prostate Cancer**

For clarification added the following statement to the narrative section of the Article Guidance:

> It should primarily serve as a billing and coding guideline.

Added the National Comprehensive Cancer Network (NCCN) to the Sources of Information section.

### J5/J8

**MolDX: Molecular Diagnostic Tests (MDT)**

The following changes have been made to this LCD.

**Added CPT codes:**
- 0012M Onc mrna 5 gen rsk urthl ca
- 0013M Onc mrna 5 gen recr urthl ca
- 0035U Neuro csf prion prtn qual
- 0036U Xome tum & nml spec seq alys
- 0037U Trgt gen seq dna 324 genes
- 0038U Vitamin d srn microsamp quan
- 0039U Dna antb 2strand hi avidity
- 0040U Bcr/abl1 gene major bp quan
- 0041U B brgdrferi antb 5 prtn igm
- 0042U B brgdrferi antb 12 prtn igg
- 0043U Tbrf b grp antb 4 prtn igm
- 0044U Tbrf b grp antb 4 prtn igg

**Removed CPT codes:**
- 87999 Microbiology procedure
- 88199 Cytopathology procedure
- 88299 Cytogenetic study
- 88399 Surgical pathology procedure
- 89398 Unlisted reprod med lab proc

Moved 0024U-0034U codes from the Group 1 paragraph into the Group 1 Codes section.

Replaced McKesson Diagnostic Exchange with DEXTM Diagnostics Exchange.
### Contract Policy/Article Title

<table>
<thead>
<tr>
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<tr>
<td>J5/J8</td>
<td>MolDX: ThermoFisher Oncomine Dx Target Test for Non-Small Cell Lung Cancer, Coding and Billing Guidelines</td>
<td>A55846</td>
<td>NA</td>
<td>08/01/2018</td>
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<td></td>
<td>Removed CPT code 81445 and added 0022U effective for dates of service after 10/01/2017. 0022U TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, NON-SMALL CELL LUNG NEOPLASIA, DNA AND RNA ANALYSIS, 23 GENES, INTERROGATION FOR SEQUENCE VARIANTS AND REARRANGEMENTS, REPORTED AS PRESENCE/ABSENCE OF VARIANTS AND ASSOCIATED THERAPY(IES) TO CONSIDER</td>
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<tr>
<td>J5/J8</td>
<td>Non-Invasive Cerebrovascular Studies</td>
<td>L35753</td>
<td>CV-045</td>
<td>08/01/2018</td>
</tr>
</tbody>
</table>
|          | Added to the following ICD-10 codes to Group 1: I69.351 Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side  
I69.352 Hemiplegia and hemiparesis following cerebral infarction affecting left dominant side  
I69.353 Hemiplegia and hemiparesis following cerebral infarction affecting right non-dominant side  
I69.354 Hemiplegia and hemiparesis following cerebral infarction affecting left non-dominant side  
Added the following ICD-10 code to Group 2. I67.89 Other cerebrovascular disease |
| J5/J8    | Not Otherwise Classified Chemotherapy Agents (NOC) | A55640    | NA    | 04/01/2018     |
|          | Formatting change due to CR 10515: OPPS April Quarterly Update effective 04/01/2018. CPT/HCPCS Code, Group 1 Paragraph: Removed 1 mg from: J9999/C9467 Rituximab and hyaluronidase human/Rituxan Hycela (FDA approval 06/22/2017), C9467 effective 04/01/2018 per CR 10515: OPPS. Group 1 Code table: Added C9467 Injection, Rituximab and hyaluronidase human, 10 mg. |

### July 2018

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<td>J5/J8</td>
<td>Category III Codes</td>
<td>L35490</td>
<td>PHYS-084</td>
<td>07/01/2018</td>
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<tr>
<td></td>
<td>Created a Group 5 Paragraph for CPT codes: The following lists Category III services determined by WPS GHA to be reasonable and medically necessary. Coverage will only be allowed when the service is delivered in clinical situations meeting medical necessity.</td>
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</table>

Created a Group 5 table of Codes for CPT codes.

**Group 5 Codes:**

0398T Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame replacement when performed.

Created a Group 6 Paragraph: The following ICD-10 Codes are used to support medical necessity with CPT code 0398T.

Created a Group 6 table of diagnosis codes:

G25.0 Essential tremor

Added the following information to the Utilization Guidelines: 0398T Magnetic resonance image guided high intensity focused ultrasound (MRgFUS) is for the treatment of idiopathic essential tremor patients with medication-refractory tremor.

**Criteria for Medical Necessity:**

1. Essential tremor refractory to medical therapy, i.e., tremor refractory to at least two trials of medical therapy which has included at least one first-line agent.
2. Moderate to severe postural or intention tremor of the dominant hand [defined by a score greater than or equal to 2 on the Clinical Rating Scale for Tremor (CRST)].
3. Disabling essential tremor, i.e., a score of 2 or more on any of the eight items in the disability subsection of the CRST.

**Exclusion from Coverage:**

1. Treatment of head or voice tremor
2. Bilateral thalamotomy
3. Following conditions:
   a. A neurodegenerative condition
   b. Unstable cardiac disease
   c. Coagulopathy
   d. Risk factors for deep-vein thrombosis
   e. Severe depression, i.e., a score greater than or equal to 20 on the Patient Health Questionnaire 9 (PHQ-9)
   f. Cognitive impairment defined by a score of less than 24 on the Mini-Mental Status Examination.
   g. Previous brain procedure (transcranial magnetic stimulation, deep brain stimulation, stereotactic lesioning, or electroconvulsive therapy).
   h. A skull density ratio (the ratio of cortical to cancellous bone) less than 0.45.
   i. Contraindications for MRI

Updated the Analysis of Evidence section:

**Level of Evidence for 0398T**

- Quality - Moderate
- Strength - Moderate
Weight – Moderate

While more trials would be helpful, the evidence submitted in the reconsideration request does indicate that this may have a role in avoiding more invasive interventions. The evidence submitted also allows the establishment of indications for coverage and exclusions from coverage.

Updated the Summary of Evidence and Bibliography sections for 0398T.

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<td>J5/J8</td>
<td>Erythropoiesis Stimulating Agents (ESAs) and Billing and Coding Guidelines</td>
<td>L34633</td>
<td>INJ-023</td>
<td>05/15/2018</td>
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</table>

Updated CMS National Coverage Policy Section:
Added: CR 10318 ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs), January 18, 2018. NCD 110.21 Erythropoiesis Stimulating Agents (ESAs in Cancer).

Coverage Guidance
Added 5. Epoetin alfa-epbx (biosimilar) (epoetin alfa-epbx), FDA approved as a biosimilar to Epogen/Procrit (epoetin alfa) for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis, use of zidovudine in patients with HIV infection, and the effects of concomitant myelosuppressive chemotherapy. It is also approved for the reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery. Effective 05/15/2018.

Group A: End Stage Renal Disease (ESRD) ON dialysis: added Epoetin alfa-epbx (biosimilar).

Group B: Chronic Kidney Disease NOT on dialysis: added Epoetin alfa-epbx (biosimilar).

Group C: Indications other than Renal Disease
Added 7. Prophylactic pre-operative use for reduction of allogenic blood transfusions prior to elective noncardiac or nonvascular surgery. Epoetin alfa-epbx (biosimilar) is covered for use in specific patients who are at high risk for perioperative blood loss prior to surgery to reduce risk of transfusion:

- who are undergoing elective, noncardiac or nonvascular surgery;
- have anemia with a hemoglobin > 10 to < 13 gm/dL;
- are not candidates for autologous blood transfusion;

The recommended Epoetin alfa-epbx (biosimilar) regimens are:

- 300 Units/kg per day subcutaneously for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery.
- 600 Units/kg subcutaneously in 4 doses administered 21, 14, and 7 days before surgery and on the day of surgery.

The components listed above must be documented in the medical record.
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<tr>
<td></td>
<td>Deep venous thrombosis prophylaxis is recommended during Epoetin alfa-epbx (biosimilar) therapy.</td>
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<td></td>
<td>CPT/HCPCS Codes</td>
<td>Group 1 Paragraph and Group 1 Codes</td>
<td>Added J3590.</td>
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<tr>
<td></td>
<td>Created Group 2 Paragraph:</td>
<td>Use J3590 for Epoetin alfa-epbx (biosimilar) FDA approval/effective date 05/15/2018 and</td>
<td>Group 2 codes: J3590: unclassified biologics.</td>
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<tr>
<td></td>
<td>ICD-10 Codes that Support Medical Necessity</td>
<td>Group 1 Paragraph, A. End Stage Renal Disease (ESRD)</td>
<td>Added J3590.</td>
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<tr>
<td></td>
<td>Group 2 Paragraph, Chronic Kidney Disease NOT on dialysis</td>
<td>Added J3590</td>
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<td>Group 4 Paragraph, C. Indications other than Renal Disease, 1. Anemia related to therapy with Zidovudine (AZT)</td>
<td>Added J3590 and</td>
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<td>Group 11 Paragraph, 5. Prophylactic pre-operative use for reduction of allogeneic blood transfusions prior to elective hip and knee replacement surgery</td>
<td>Added J3590.</td>
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<td>Added NOC drug billing: Please refer to the Not Otherwise Classified (NOC) Billing requirements contained within the Billing &amp; Coding Guidelines for claims submitted with J3590 unclassified biologics, effective 05/15/2018.</td>
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<tr>
<td></td>
<td>Billing and Coding Guidelines for Erythropoiesis Stimulating Agents (ESAs) updated:</td>
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<td></td>
<td>Not Otherwise Classified (NOC) Billing:</td>
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<td></td>
<td>Use J3590 for Epoetin alfa-epbx (biosimilar) FDA approval/effective date 05/15/2018.</td>
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<td>Office/Clinic: Providers submit NOC codes in the 2400/SV101-2 data element in the 5010 professional claim transaction (837P). When billing an NOC code, providers are required to provide a description in the 2400/SV101-7 data element. The 5010 TR3 Implementation Guide instructs: &quot;Use SV101-7 to describe non-specific procedure codes.&quot; (Do not use the 2400 NTE segment to describe non-specific procedure codes with 5010.) The SV101-7 data element allows for 80 bytes (i.e., characters, including spaces) of information.</td>
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<td>In order for WPS GHA to correctly reimburse NOC drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Item 19 of the</td>
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</table>
CMS 1500 form:

- The name of the drug,
- The total dosage (plus strength of dosage, if appropriate), and
- The method of administration.

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

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

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

See [Not Otherwise Classified (NOC) Billing](#) for further information.

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<tr>
<td>J5/J8</td>
<td>MolDX: CDH1 Genetic Testing Coding and Billing Guidelines</td>
<td>A55622</td>
<td>NA</td>
<td>07/01/2018</td>
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<td><strong>Policy/Article Details:</strong></td>
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<tr>
<td></td>
<td>Information on the incidence of Hereditary Diffuse Gastric Cancer has been removed from the introductory paragraph. It now reads as:</td>
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<td></td>
<td>CDH1 testing is utilized in patients with specified cancers as an adjunctive test. CDH1 testing has also been recommended as a screening test for other cancers. However, screening for individuals at risk for cancer is not a Medicare benefit and is statutorily excluded. Coverage has been added for metastatic breast cancer.</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: Myriad’s BRACAnalysis CDx® Coding and Billing Guidelines</td>
<td>A55224</td>
<td>NA</td>
<td>07/01/2018</td>
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<td><strong>Policy/Article Details:</strong></td>
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<tr>
<td></td>
<td>Coverage has been added for metastatic breast cancer.</td>
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<td>The FDA has approved Lynparza® (olaparib), as a new drug treatment for women with advanced ovarian cancer, or metastatic HER2-negative breast cancer, and the companion diagnostic BRACAnalysis CDx®, the laboratory test to detect mutated BRCA genes.</td>
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</tbody>
</table>
According to the FDA, “results of the test are used as an aid in identifying breast and ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants, who are or may become eligible for treatment with Lynparza® (olaparib).”

The following diagnosis codes have been added:

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<thead>
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<tr>
<td></td>
<td>The following diagnosis codes have been added:</td>
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<tr>
<td></td>
<td>C48.0 - C48.2 Malignant neoplasm of retroperitoneum</td>
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<td></td>
<td>Malignant neoplasm of specified parts of peritoneum</td>
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<td></td>
<td>Malignant neoplasm of peritoneum, unspecified</td>
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<tr>
<td></td>
<td>C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum</td>
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<td>C50.011 Malignant neoplasm of nipple and areola, right female breast</td>
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<td>C50.012 Malignant neoplasm of nipple and areola, left female breast</td>
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<td>C50.019 Malignant neoplasm of nipple and areola, unspecified female breast</td>
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<td>C50.021 Malignant neoplasm of nipple and areola, right male breast</td>
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<td>C50.022 Malignant neoplasm of nipple and areola, left male breast</td>
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<td>C50.029 Malignant neoplasm of nipple and areola, unspecified male breast</td>
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<td>C50.111 Malignant neoplasm of central portion of right female breast</td>
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<td>C50.112 Malignant neoplasm of central portion of left female breast</td>
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<td>C50.119 Malignant neoplasm of central portion of unspecified female breast</td>
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<td>C50.121 Malignant neoplasm of central portion of right male breast</td>
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<td>C50.129 Malignant neoplasm of central portion of unspecified male breast</td>
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<td>C50.211 Malignant neoplasm of upper-inner quadrant of right female breast</td>
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<td>C50.212 Malignant neoplasm of upper-inner quadrant of left female breast</td>
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<td>C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast</td>
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<td>C50.221 Malignant neoplasm of upper-inner quadrant of right male breast</td>
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<td>C50.222 Malignant neoplasm of upper-inner quadrant of left male breast</td>
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<td>C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast</td>
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<td>C50.311 Malignant neoplasm of lower-inner quadrant of right female breast</td>
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<td>C50.312 Malignant neoplasm of lower-inner quadrant of left female breast</td>
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<td>C50.319 Malignant neoplasm of lower-inner quadrant of unspecified female breast</td>
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<td>C50.321 Malignant neoplasm of lower-inner quadrant of right male breast</td>
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<td>C50.322 Malignant neoplasm of lower-inner quadrant of left male breast</td>
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<td></td>
<td>C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast</td>
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<td>C50.411 Malignant neoplasm of upper-outer quadrant of right female breast</td>
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<td>C50.412 Malignant neoplasm of upper-outer quadrant of left female breast</td>
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<td>C50.419 Malignant neoplasm of upper-outer quadrant of unspecified female breast</td>
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<td>C50.421 Malignant neoplasm of upper-outer quadrant of right male breast</td>
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<td>C50.422 Malignant neoplasm of upper-outer quadrant of left male breast</td>
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<td>C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast</td>
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**J5/J8 Transcranial Magnetic Stimulation (TMS)**

| L34641 | NEURO-010 | 07/01/2018 |

In the Initial Treatment section updated verbiage in the:
Resistance paragraph from: four to one trial of psychopharmacological agent from two different agent classes for current depressive episode with each agent administered at an adequate course of mono- or poly-drug therapy. And for;
Inability to tolerate paragraph from: four to two trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects.

**Initial Treatment**

Left Prefrontal rTMS of the brain is considered medically necessary for use in an adult who has a confirmed diagnosis of severe major depressive disorder (MDD) single or recurrent episode; and

One or more of the following:

- Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to one trial of psychopharmacologic agents in the current depressive episode from at least two different agent classes. Each agent in the treatment trial must have been administered at an adequate course of mono- or poly-drug therapy; or
- Inability to tolerate psychopharmacologic agents as evidenced by two trials of psychopharmacologic agents from at least two different agent classes, with distinct side effects; or
- History of response to rTMS in a previous depressive episode; or
- If patient is currently receiving electro-convulsive therapy, rTMS may be considered reasonable and necessary as a less invasive treatment option.
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<td>Treatment of Varicose Veins of the Lower Extremities</td>
<td>L34536</td>
<td>GSURG-041</td>
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Added ICD-10 I83.215 Varicose veins of right lower extremity with both ulcer other part of foot and inflammation to Group 1. I83.215 was inadvertently omitted from Group 1 during ICD-9 to ICD-10 transition.
Electronic Data Interchange (EDI)

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

MLN Matters Number: MM10620
Related Change Request (CR) Number: 10620
Related CR Release Date: May 18, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R4057CP
Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10620 updates the Remittance Advice Remark Code (RARC) and Claims Adjustment Reason Code (CARC) lists and instructs Medicare Shared System Maintainers (SSMs) to update Medicare Remit Easy Print (MREP) and PC Print. Be sure your staff are aware of these changes and obtain the updated MREP and PC Print software if they use that software.

BACKGROUND

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

The Centers for Medicare & Medicaid Services (CMS) instructs MACs to conduct updates based on the code update schedule that occurs three times per year – around March 1, July 1, and November 1. CMS provides CR10620 as a code update notification indicating when updates to CARC and RARC lists are made available on the Washington Publishing Company (WPC) website. Medicare's 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 CR 10620, MACs must implement on the date specified on the WPC website available at http://wpc-edi.com/Reference/.

A discrepancy between the dates may arise because the WPC website is only updated three times per year and may not match the CMS release schedule. For CR 10620, MACs and 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 referenced in CR10489.

**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**

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<th>Description</th>
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<tr>
<td>May 18, 2018</td>
<td>Initial article released.</td>
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Program Safeguards

Provider/Supplier Reporting of Adverse Legal Actions

MLN Matters Number: MM10558    Related Change Request (CR) Number: 10558
CR Release Date: June 1, 2018    Effective Date: April 30, 2018
Related CR Transmittal Number: R797PI    Implementation Date: April 30, 2018

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended to update the Medicare provider and supplier community on what Final Adverse Action(s) need to be timely reported to the Centers for Medicare & Medicaid Services (CMS).

WHO SHOULD REPORT FINAL ADVERSE ACTION(S)

- Medicare providers or suppliers with new or unreported Final Adverse Action(s)
- Those individuals listed on an application as having managing control or an ownership interest

WHAT FINAL ADVERSE ACTION(S) SHOULD BE REPORTED

Historically, CMS deemed Medicare Payment Suspensions and CMS-Imposed Medicare Revocations to be reportable Final Adverse Actions. In an effort to reduce provider and supplier burden, CMS NO LONGER requires Medicare Payment Suspensions and CMS-Imposed Medicare Revocations to be reported.

The updated list of reportable Final Adverse Actions is as follows:
- Felony and Misdemeanor conviction(s) within 10 years
- Current or Past Suspension(s)/Revocation(s) of a medical license
- Current or Past Suspension(s) Revocation(s) of an accreditation
- Current or Past Suspension(s) or Exclusion(s) imposed by the U.S. Department of Health and Human Service’s Office of Inspector General (OIG)
- Current or Past Debarment(s) from participation in any Federal Executive Branch procurement or non-procurement program
- Medicaid exclusion(s), revocation(s) or termination(s) of any billing number
- Any other Current or Past Federal Sanction(s)
Please note that all final adverse actions should be reported, regardless of whether any of the records have been expunged or are pending appeal.

WHEN SHOULD FINAL ADVERSE ACTION(S) BE REPORTED

Providers and suppliers shall timely report all new or unreported Final Adverse Actions on any applications submitted to CMS. Final Adverse Actions must be reported by providers and suppliers within time frames specified in 42 CFR § 424.516.

HOW SHOULD FINAL ADVERSE ACTION(S) BE REPORTED

Providers and suppliers shall disclose reportable Final Adverse Legal Actions on any CMS 855 or CMS 20134 application submitted to CMS. As it applies, the sections of the application(s) that providers must complete are:

- Section 3
- Section 5B
- Section 6B
- Section 7

If a final adverse action is disclosed on a CMS-855 application, a provider/supplier must attach all applicable documentation related to the adverse action.

Please note that documentation, concerning the final adverse action, must be furnished regardless of whether the adverse action occurred in a state different from that in which the provider/supplier seeks enrollment or is enrolled.

It is important that you comply with these reporting requirements. Failure to do so could result in the revocation of your Medicare billing privileges.

ADDITIONAL INFORMATION


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

EDUCATION SCHEDULE

WPS GHA Learning Center

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

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

Here are some of the events currently available:

In Person Events

Reducing Overlapping Claims (Part A) - A Collaborative Effort Between WPS GHA and NGS
09/11/2018 - Holyoke, MA - 9:00 AM - 4:00 PM ET
10/23/2018 - Glen Ellyn, IL - 9:00 AM - 4:00 PM CT

Overlapping claims continue to be a top claim rejection for providers. Often, overlapping claims can be prevented by knowing how to properly submit claims in these situations. WPS GHA and NGS would like to invite all Part A providers (billing on a UB-04) to join us in this unique joint event to collaborate and learn with the MACs processing your claims and help reduce your workload.

Reducing Overlapping Claims (Part A)
10/09/2018 - Springfield, MO - 9:00 AM - 4:00 PM CT
11/28/2018 - Puyallup, WA - 9:00 AM - 4:00 PM PT

Overlapping claims continue to be a top claim rejection for providers. Often, overlapping claims can be prevented by knowing how to properly submit claims in these situations. WPS GHA would like to invite all Part A providers (billing on a UB-04) to join us in this event to collaborate with other providers and learn how you can reduce your workload.

SNF Consolidated Billing - A Collaborative Effort Between WPS GHA and NGS
09/12/2018 - Holyoke, MA - 9:00 AM - 4:00 PM ET
10/24/2018 - Glen Ellyn, IL - 9:00 AM - 4:00 PM CT

Do you want to become a "pro" and the go-to person in your office for questions related to SNF Consolidated Billing? WPS GHA and NGS have come together to provide this unique, interactive event for our provider communities. You will learn all the intricacies of SNF
Consolidated Billing during this INTENSIVE day of hands-on training to help you implement strategies and tools needed to become your office’s subject matter expert.

**SNF Consolidated Billing**
10/10/2018 - Springfield, MO - 9:00 AM - 4:00 PM CT
11/29/2018 - Puyallup, WA - 9:00 AM - 4:00 PM PT

Do you want to become a "pro" and the go-to person in your office for questions related to SNF Consolidated Billing? This is a unique, interactive event for ALL PROVIDERS affected by SNF Consolidated billing. You will learn all the intricacies of SNF Consolidated Billing during this intensive day of hands-on training to help you implement strategies and tools needed to become your office’s subject matter expert.

**Teleconferences**

**Waivers to Extend Timely Filing**
09/19/2018 - 11:00 AM - 12:00 PM CT (12:00 PM - 1:00 PM ET)

CMS permits Medicare contractors to extend the time limit for filing a claim if the provider can show good cause for the delay. Find out more about this topic and the proper process for requesting a waiver to extend the deadline for timely filing.

**Medicare Beneficiary Identifier (MBI) Ask-the-Contractor Teleconference (ACT)**
10/30/2018 - 11:00 AM - 12:30 PM CT (12:00 PM - 1:30 PM ET)

Do you have any questions related to the new Medicare numbers also known as the Medicare Beneficiary Identifiers (MBIs)? Would you like to know where to find resources related to the MBIs? This is your chance to ask your MAC questions related to the MBIs.

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

**MEDI CARE LEARNING NETWORK (MLN)**

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

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

QUARTERLY PROVIDER UPDATE

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

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

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


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

UNSOLICITED/ VOLUNTARY REFUNDS

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

SUBJECT: Clarification of Policies Related to Reasonable Cost Payment for Nursing and Allied Health Education Programs

I. SUMMARY OF CHANGES: This CR clarifies policies related to payment for approved provider-operated and certain non-provider-operated nursing and allied health education programs.

EFFECTIVE DATE: August 17, 2018
*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: November 19, 2018

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
SUBJECT: Clarification of Policies Related to Reasonable Cost Payment for Nursing and Allied Health Education Programs

EFFECTIVE DATE: August 17, 2018

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: November 19, 2018

I. GENERAL INFORMATION

A. Background: Under section 1861(v) of the Social Security Act, Medicare has historically paid providers for the program’s share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or is recognized by a national accrediting body. The costs of these programs are excluded from the definition of inpatient hospital operating costs and are not included in the calculation of payment rates for hospitals or hospital units paid under the Inpatient Prospective Payment System (IPPS), Inpatient Rehabilitation Facility (IRF) PPS, or Inpatient Psychiatric Facility (IPF) PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and “passed through” (that is, paid separately on a reasonable cost basis). Existing regulations on NAH education program costs are located at § 413.85. The most recent rulemaking on these regulations was in the January 12, 2001 final rule (66 FR 3358) and in the August 1, 2003 final rule (68 FR 45423—45434).

Payment for Provider-operated Programs

A program is considered to be provider-operated if the hospital meets the criteria specified in § 413.85(f), which means the hospital directly incurs the training costs, controls the curriculum and the administration of the program, employs the teaching staff, and provides and controls both classroom and clinical training (where applicable) of the NAH education program.

Payment for Certain Non-provider-operated Programs

Section 4004(b)(1) of Pub. L. 101-508 provides an exception to the requirement that programs be provider-operated to receive pass-through payments. This section provides that, if certain conditions are met, the costs incurred by a hospital (or by an educational institution related to the hospital by common ownership or control) for clinical training conducted on the premises of the hospital under an approved NAH education program that is not provider-operated by the hospital are treated as pass-through costs and paid on the basis of reasonable cost. Section 4004(b)(2) of Pub. L. 101-508 sets for the conditions that a hospital must meet to receive payment on a reasonable cost basis under section 4004(b)(1). These provisions are codified in the regulations at § 413.85. The most recent rulemaking on these regulations was in the January 12, 2001 final rule (66 FR 3358) and in the August 1, 2003 final rule (68 FR 45423—45434).

B. Policy: I. Clarification Regarding Provider-Operated Programs

The regulations regarding provider-operated programs at § 413.85 are as follows:

(f) Criteria for identifying programs operated by a provider.

(1) Except as provided in paragraph (f)(2) of this section, for cost reporting periods beginning on or after October 1, 1983, in order to be considered the operator of an approved nursing or allied health education program, a provider must meet all of the following requirements:
(i) Directly incur the training costs.

(ii) Have direct control of the program curriculum. (A provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider must provide all of the courses relating to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program.)

(iii) Control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)

(iv) Employ the teaching staff.

(v) Provide and control both classroom instruction and clinical training (where classroom instruction is a requirement for program completion), subject to the parenthetical sentence in paragraph (f)(1)(ii) of this section.

(2) Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in paragraph (f)(1) of this section and to be the operator of the program.

We have received questions about §413.85(f)(2), which states, “Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in paragraph (f)(1) of this section and to be the operator of the program.” We are clarifying our existing policy below; we are not changing policy on this matter.

As the accreditation requirements have evolved and the trend in nursing and allied health education has grown toward degree-issuing programs from colleges or universities, hospitals have tried to restructure their programs and make arrangements with colleges or universities in order to simultaneously provide a degree to their graduates, and meet the provider-operated criteria. However, successfully satisfying the provider-operated criteria in order to qualify for Medicare pass-through payment while simultaneously meeting current accreditation requirements has become extremely difficult, if not impossible, in certain circumstances. It is a reality that many previously provider-operated programs are no longer compliant with all provider-operated criteria at §413.85(f)(1), and should not be receiving Medicare pass-through payments. We stress that in all cases, the burden of proof is on the hospital to demonstrate that its program is meeting the 5 criteria listed at §413.85(f)(1) for provider-operated status. The MAC shall not assume that because the hospital issues the degree, diploma, or certificate of completion, either individually, or jointly with a college/university, that that is sufficient to meet the provider-operated criteria. It is not sufficient. As §413.85(f)(2) states, “Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in paragraph (f)(1) of this section and to be the operator of the program” (emphasis added). This bolded language, “absent evidence to the contrary,” indicates that the hospital must first demonstrate that there is no evidence showing that the program is not provider-operated. The MAC shall review the evidence provided, and be satisfied that all provider-operated criteria at §413.85(f)(1) are met first, and only then shall the MAC approve pass-through payment to the hospital for the program. MACs shall not rely on a degree/diploma/certificate issued by the hospital as evidence that a program is provider-operated.

We have also received questions about the meaning of the parenthetical statement at §413.85(f)(1)(ii), which states “(A provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider must provide all of the courses relating to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program.)” We are clarifying our existing policy.
below; we are not changing policy on this matter.

Regarding arrangements between hospitals and colleges or universities that could be acceptable, the January 12, 2001 Federal Register (66 FR 3363-4) states:

“…sequential operation of a nursing and allied health education program involves providers that enter into agreements with a college or university in which instruction in general academic requirements leading to a degree is provided by the educational institution, and subsequent specialized didactic and clinical training is given by the provider. The provider may receive pass-through payment for the costs of the program that the provider incurs if the provider meets all of the criteria for operating the program, including the requirement at . . . (§413.85(f)(1)(ii) of this final rule) that the provider must directly control the curriculum. We note that under this section of the regulations, there is a provision (also cited at § 413.85(f)(1)(v) of this final rule) which states that a provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider must provide all of the courses related to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program. No costs incurred by the college or university may be claimed as provider costs (emphasis added).”

That is, the hospital is always responsible for meeting the provider-operated criteria; hospital staff, not staff from an educational institution, must be responsible for controlling, managing, and operating the program financially and administratively on a daily basis, such as, but not limited to, enrollment, collection of tuition, human resources matters, and payroll. While §413.85(f)(1)(iii) states that a provider may contract with another entity to perform some administrative functions of day to day operations, the provider must maintain control over all aspects of the contracted functions. The hospital cannot have an arrangement with an educational institution where there are certain functions for which the hospital has no involvement and no oversight. If educational institution personnel are involved, hospital staff must have final decision making authority. In addition, the hospital may contract with an educational institution to provide basic courses required for a degree (e.g., English 101), but the hospital must teach all the courses related to the theory and practice of the particular nursing or allied health specialty.

The January 12, 2001 final rule provides additional guidance on what “direct control” of the curriculum means. Although the accrediting agency often dictates which courses and the order of the courses that must be completed by each student, to the extent where there is some flexibility provided by the accrediting body, it must be the hospital, not another educational institution deciding upon the order of the coursework, and the manner its students will accomplish the coursework that will allow the program to be accredited. In addition, there may be certain courses that are unique to the hospital, and the hospital decides what those courses are and when they are taught. Furthermore, control of the curriculum means the hospital actually provides all of the courses, or, with respect to the basic courses required for completion of the program (e.g., English 101), the hospital arranges for an outside organization to provide those academic courses necessary to complete the course work. (See 66 FR 3364).

II. Clarifications Regarding Payment for Certain Non-provider-Operated Programs

Sections 413.85(g)(1) and (2) specify that pass-through payment for the clinical costs (not classroom costs) of certain nonprovider-operated programs may be made to a hospital if, in part, the hospital claimed and was paid for clinical training costs on a reasonable cost basis during its most recent cost reporting period that ended on or before October 1, 1989. We note that section 4004(b) of Pub. L. 101-508 was intended to apply only to NAH programs which were not provider-operated in 1989, but for which hospitals erroneously claimed and received pass-through payment from Medicare in 1989. We emphasize that this provision allows the hospitals to receive pass-through payment after 1989 for the clinical costs of only those programs that were already not provider-operated in 1989; this provision is not intended to allow for the payment of the clinical costs of programs that became non-provider-operated after 1989. That is, after 1989, hospitals cannot receive pass-through payments under this provision for any other non-provider operated NAH program if the hospital did not receive pass-through payment in 1989. Clinical training costs are defined at
§413.85(c) as “costs of training for the acquisition and use of the skills of a nursing or allied health profession or trade in the actual environment in which these skills will be used by the student upon graduation. Clinical training may involve occasional or periodic meetings to discuss or analyze cases, critique performance, or discuss specific skills or techniques; it involves no classroom instruction.”

We have received questions about the proper way to determine the allowable clinical costs to be paid for the applicable nonprovider-operated programs. We are providing instructions to implement our existing policy below; we are not changing policy on this matter.

§413.85(g)(2)(iii) states:

In any cost reporting period, the percentage of total allowable provider cost attributable to allowable clinical training costs does not exceed the percentage of total cost for clinical training in the provider’s most recent cost reporting period ending on or before October 1, 1989.

To determine whether the limit described in § 413.85(g)(2)(iii) applies to any non-provider operated program claimed in the current cost report and, if so, to compute the appropriate payment for such program or programs, the MAC shall:

1. Obtain the hospital’s most recent cost report ending on or before October 1, 1989 (for ease of reference, we will refer to this cost report as the “1989” cost report).
2. For each current year’s non-provider operated program, determine whether this same program was reported in the 1989 cost report (i.e., Form HCFA-2552-89), Worksheet A, Line 20 and subscripts (nursing school(s)) and lines 23 and 24 and subscripts (Allied Health programs), Column 7). It is important to ensure in this step that the 1989 NAH non-provider operated program is the same as the non-provider program in the current year. For example, the programs would not be the same in 1989 and the current year if the hospital reported a Radiology Technologist non-provider operated program and no other Radiology-type programs in the 1989 cost report but in the current year’s cost report the provider reported only a Nuclear Medicine Technology non-provider operated program. As mentioned in the first paragraph of this section, the hospital is not entitled to receive pass-through payment in the current year for the Nuclear Medicine Technology program because this program does not meet the requirements of § 413.85(g)(2).
3. For each non-provider operated program found to have been reported in both the current and the 1989 cost reports in Step 2, determine whether the program was not operated by the hospital in 1989 but the hospital received pass-through payment for it in that year. (See § 413.85(g)(2)i(iii).)
4. Only for each non-provider operated NAH program reported on Worksheet A, Line 20 and subscripts and Line 23 and subscripts of the current cost report for which the hospital received pass-through payment in 1989 (as determined in Step 3), compute the “1989 percentage” using steps 5 through 7 and the “Current Year Percentage” using steps 8 through 10. Do not complete Steps 5 through 11 for any current year’s non-provider operated NAH programs if the hospital did not receive pass-through payments for the program(s) in 1989 (see Step 3).
5. Numerator - For each program individually, from Form HCFA-2552-89, determine the sum of the costs on lines 20 and 23, 24 and subscripts as applicable, column 7, of Worksheet A.
6. Denominator - determine total allowable hospital costs from the amount on Form HCFA-2552-89, Worksheet A, line 95 Subtotals, column 7. (We note that Worksheet A, Line 95 of the 1989 cost report contains only the “allowable” total provider cost since the non-reimbursable cost centers’ costs are not included on this line. Per § 413.85(g)(2)(iii), the “percentage” is “the percentage of total allowable cost…”)
7. Percentage from 1989 - For each program individually, divide the NAH cost amount from Step 5 by the total allowable hospital cost from Step 6. In accordance with Provider Reimbursement Manual-2 (PRM-2), Section 4000.1, percentages are rounded to 2 decimal places. Current Year Percentage.
8. Using the current year cost report under review, only for programs that were nonprovider-operated in 1989 and are still nonprovider-operated in step 3, refer to Form CMS-2552-10, Worksheet A, line 20 (Nursing School) and line 23 and subscripts (paramedical education programs as applicable),
column 7. Numerator – For each program individually, use the amounts from Worksheet A, lines 20 and subscripts and 23 and subscripts, Column 7. For each program individually, verify that the amount on Worksheet A, line 20 or its subscripts and/or Line 23 or its subscripts, Column 7 relate only to the “clinical costs” of the NAH program. If so, use the amount from this specific line. If the amount in Column 7 for any of the programs contains “clinical training cost and classroom costs”, subtract the “classroom costs” and use the net amount. (We note that for cost reporting periods beginning on or after October 1, 1990, PRM-2, Section 3610 (Form CMSA-2552-96) and Section 4013 (Form CMS-2552-10), specify that “classroom costs” related to non-provider operated NAH programs under § 413.85(g)(2) are not to be reported on Lines 20, 24 (Form CMS-2552-96) and 23 (Form CMS-2552-10).)

9. Denominator - determine total allowable hospital costs from the amount on Form CMS-2552-10, Worksheet A, line 118 Subtotals, column 7. (We note that Worksheet A, Line 118 of the current cost report contains only the “allowable” total provider cost since the non-reimbursable cost centers’ costs are not included on this line. Per § 413.85(g)(2)(iii), the “percentage” is “the percentage of total allowable cost…”).

10. Clinical Percentage from the Current Cost Report – For each program individually, divide the NAH clinical cost amount from step 8 by the total allowable hospital cost from step 9. In accordance with PRM-2, Section 4000.1, percentages are rounded to 2 decimal places.

11. For each program individually, compare the 1989 Percentage (step 7) to the Clinical Percentage from the Current Cost Report (step 10). If for any program, the current year percentage is greater than the 1989 year percentage, do not use the current year percentage; compute the current year’s allowable clinical pass-through payment for the program by using the 1989 percentage. Proceed to pay the Medicare pass-through to the hospital in the current year for the clinical costs. For example, if the 1989 clinical percent was 30 percent, and the current year percent is 40 percent, only 30 percent of the hospital’s current year clinical costs are allowable for Medicare pass-through payment. If for any program, the current year percentage is equal to or less than the 1989 percentage, then 100 percent of the hospital’s current year clinical costs are allowable for Medicare pass-through payment; use the current year percentage.

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></td>
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<td>A/B MAC</td>
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<td>A B H H F I S M C V W C W F</td>
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<tr>
<td>10552.1</td>
<td>The MACs shall note that the policies contained in this notice are clarifications; no changes in policy are being made. These clarified policies shall be applied by hospitals as they file the cost reports and by the MACs during the normal desk review/audit process.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>10552.2</td>
<td>The MAC shall not assume that because the hospital issues the degree, diploma, or certificate of completion, either individually, or jointly with a college/university, that that is sufficient to meet the provider-operated criteria.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>10552.3</td>
<td>MACs shall not rely on a degree/diploma/certificate</td>
<td>X</td>
<td></td>
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</tbody>
</table>
issued by the hospital as evidence that a program is provider-operated.

10552.4 The MAC shall review the evidence provided, request additional documentation as necessary, and be satisfied that all provider-operated criteria at §413.85(f)(1) are met first, and only then may the MAC approve pass-through payment to the hospital for the program.

10552.5 The MAC shall follow the 11 steps under section II of this CR to determine whether the limit described in §413.85(g)(2)(iii) applies to any non-provider operated program claimed in the current cost report and to compute the appropriate payment for such program or programs.

### III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>10552.6</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>
</table>

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

V. CONTACTS

Pre-Implementation Contact(s): Renate Dombrowski, renate-rockwell.dombrowski@cms.hhs.gov, Miechal Kriger, 646-842-2766 or miechal.kriger@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
Global Surgical Days for Critical Access Hospital (CAH) Method II

MLN Matters Number: MM10425 Revised
Related Change Request (CR) Number: 10425
Related CR Release Date: June 22, 2018
Effective Date: July 1, 2018
Related CR Transmittal Number: R2096OTN
Implementation Date: July 2, 2018

Note: This article was revised on June 25, 2018, to reflect a revised CR10425 issued on June 22. In the article, we removed terminated HCPCS codes from edits for visits which are included in the global package. Also, the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

This article is based on Change Request (CR) 10425 which discusses the global surgical days for Method II Critical Access Hospital (CAH) providers. CR 10425 contains no new policy. It improves the implementation of existing Medicare payment policies. Make sure that your billing staffs are aware of these changes.

BACKGROUND

CR10425 is for the global surgical periods for Critical Access Hospital (CAH) Method II providers to mirror the logic historically applied to physicians and non-physician practitioners that bill their own services to Medicare’s Multi-Carrier System (MCS).

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

The global surgical package, also called global surgery, includes all necessary services normally furnished by a surgeon before, during, and after a procedure. Medicare payment for the surgical procedure includes the pre-operative, intra-operative, and post-operative services...
routinely performed by the surgeon or by members of the same group with the same specialty.

Position 13-15 of the MPFS Data Base provides the postoperative periods that apply to each surgical procedure.

The payment rules for surgical procedures apply to codes with entries of 000, 010, 090, and, sometimes, YYY, and are defined below. This field provides the postoperative time frames that apply to payment for each surgical procedure or another indicator that describes the applicability of the global concept to the service.

- **000** = Endoscopic or minor procedure with related preoperative and postoperative relative values on the day of the procedure only included in the fee schedule payment amount; evaluation and management services on the day of the procedure generally not payable.

- **010** = Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable.

- **090** = Major surgery with a (one) 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount.

- **XXX** = Global concept does not apply.

- **YYY** = A/B MAC (Part A) determines whether global concept applies and establishes postoperative period, if appropriate, at time of pricing.

Codes with “YYY” are A/B MAC (Part B)-priced codes, for which A/B MACs (Part B) determine the global period (the global period for these codes will be 0, 10, or 90 days). Note that not all A/B MAC (Part B)-priced codes have a "YYY" global surgical indicator; sometimes the global period is specified.

CAH Method II providers should follow the same guidelines as per Part B physician services that are available in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 12; (Physicians/Nonphysician Practitioners), Section 40 (Surgeons and Global Surgery)).

Note that Medicare will reject line items that contain an E/M CPT code (92012, 92014, 99211-99215, 99217-99223, 99231-99236, 99238, 99239, 99291, 99292, 99315, 99316, and 99347-99350) that is covered by the global period using the following remittance codes:

- Group code of CO - Contractual Obligation
- Claim Adjustment Reason Code 97 – Payment is included in the allowance for another service/procedure
- Remittance Advice Remark Code M144 – Pre-/post-operative care payment is included in the allowance for the surgery/procedure.

MACs, however, will allow E/M services rendered during the global period when submitted with modifier 24 or 25, as appropriate.

**ADDITIONAL INFORMATION**


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

**DOCUMENT HISTORY**

<table>
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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>June 25, 2018</td>
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</tr>
<tr>
<td>January 26, 2018</td>
<td>Initial article released.</td>
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Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2019

MLN Matters Number: MM10880  Related Change Request (CR) Number: 10880
Related CR Release Date: August 3, 2018  Effective Date: October 1, 2018
Related CR Transmittal Number: R4104CP  Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for Inpatient Psychiatric Facilities (IPFs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10880 identifies required changes as part of the annual IPF PPS update established in the Medicare Program; FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2018 (FY 2019) Final Rule. These changes are applicable to discharges occurring from October 1, 2018 through September 30, 2019 (FY 2019), and they relate to Chapter 3, Section 190.49 of the Medicare Claims Processing Manual. This update includes technical corrections and updates to various parts of Section 190 from prior rulemaking. Please make sure your billing staffs are aware of these updates.

BACKGROUND

On November 15, 2004, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a final rule that established the IPF PPS under the Medicare program in accordance with provisions of Section 124 of Public Law 106-113, the Medicare, Medicaid, and State Children’s Health Insurance Program (CHIP) Balanced Budget Refinement Act of 1999 (BBRA).

Payments to IPFs under the IPF PPS are based on a Federal per-diem base rate, which includes both inpatient operating and capital-related costs (including routine and ancillary services), but excludes certain pass-through costs (that is, bad debts and graduate medical education). CMS is required to make updates to this IPF PPS annually.

Market Basket Update:

For FY 2019, CMS is using the 2012-based IPF market basket to update the IPF PPS payment rates (that is, the Federal per-diem base rate and Electroconvulsive Therapy (ECT) payment per treatment). The 2012-based IPF market basket update for FY 2019 is 2.9 percent. However, this
2.9 percent is subject to two reductions required by the Social Security Act (the Act).

1) Section 1886(s)(2)(A)(ii) of the Act requires the application of an “other adjustment” that reduces any update to the IPF market basket update by percentages specified in Section 1886(s)(3) of the Act for Rate Year (RY) beginning in 2010 through the RY beginning in 2019. For the FY beginning in 2018 (that is, FY 2019), Section 1886(s)(3)(E) of the Act requires the reduction to be 0.75 percentage points. CMS implemented that provision in the FY 2019 IPF PPS and Quality Reporting Updates Final Rule.

2) Section 1886(s)(2)(A)(i) of the Act requires the application of the “productivity adjustment” described in Section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (that is, the RY that coincides with a FY), and each subsequent RY. For the FY beginning in 2018 (that is, FY 2019), the reduction is 0.8 percent. CMS implemented that provision in the FY 2019 IPF PPS and Quality Reporting Updates Final Rule.

Therefore, CMS updates the IPF PPS base rate for FY 2019 by applying the adjusted market basket update of 1.35 percent (which includes the 2012-based IPF market basket update of 2.9 percent, the 0.75 percentage point reduction to the market basket update required by the Affordable Care Act, and a required productivity adjustment reduction of 0.8 percent), and the wage index budget neutrality factor of 1.0013 to the FY 2018 Federal per-diem base rate of $771.35, yielding a FY 2019 Federal per-diem base rate of $782.78.

Similarly, applying the adjusted market basket update of 1.35 percent and the wage index budget neutrality factor of 1.0013 to the FY 2018 Electroconvulsive Therapy (ECT) payment per treatment of $332.08 yields an ECT payment per treatment of $337.00 for FY 2019.

IPF Quality Reporting Program (IPFQR)

Section 1886(s)(4) of the Act requires the establishment of a quality data-reporting program for the IPF PPS beginning in FY 2014. CMS finalized initial requirements for quality reporting for IPFs in the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates, Final Rule (August 31, 2012) (77 FR 53258, 53644 through 53360).

Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 and each subsequent FY, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during the FY by 2 percentage points for any IPF that does not comply with the quality data submission requirements with respect to an applicable year. Therefore, a 2-percentage-point reduction is applied when calculating the Federal per-diem base rate and the ECT payment per treatment:

- For IPFs that failed to submit quality reporting data under the IPFQR program, for FY 2019, CMS applied a -0.65 percent payment rate update (a negative update that reflects the IPF market basket increase for FY 2019 of 2.9 percent, less the productivity adjustment of 0.8 percentage point, reduced by the Affordable Care Act required 0.75 percent point, and further reduced by 2 percentage points in accordance with section
1886(s)(4)(A)(ii) of the Act) and the wage index budget neutrality factor of 1.0013 to the FY 2018 Federal per diem base rate of $771.35, yielding a FY 2019 Federal per diem base rate of $767.33.

- Similarly, for FY 2019, CMS applied a -0.65 percent payment rate update to the FY 2018 ECT payment per treatment of $332.08, yielding a FY 2019 ECT payment per treatment of $330.35.

**PRICER Updates: IPF PPS FY 2019 (October 1, 2018 - September 30, 2019)**

- The Federal per-diem base rate is $782.78 for IPFs that complied with quality data submission requirements.
- The Federal per-diem base rate is $767.33, when applying the 2-percentage-point reduction, for IPFs that failed to comply with quality data submission requirements.
- The fixed dollar loss threshold amount is $12,865.
- The IPF PPS wage index is based on the FY 2018 pre-floor, pre-reclassified acute care hospital wage index.
- The labor-related share is 74.8 percent.
- The non-labor-related share is 25.2 percent.
- The ECT payment per treatment is $337.00 for IPFs that complied with quality data submission requirements.
- The ECT payment per treatment is $330.35 when applying the 2-percentage-point reduction for IPFs that failed to comply with quality data submission requirements.

**Provider-Specific File (PSF) Updates**

The FY 2019 IPF PPS wage index uses the most recent Office of Management and Budget (OMB) statistical area delineations to identify a facility’s urban or rural status for the purpose of determining if a rural adjustment will apply to the facility. There were no changes made to the OMB designations in the FY 2019 IPF PPS wage index. For FY 2019, no IPFs should have any special pay indicators or receive any wage index value other than those given in the FY 2019 IPF PPS wage index.

**The National Urban and Rural Cost to Charge Ratios for the IPF PPS FY 2019**

CMS is applying the national Cost-to-Charge Ratios to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. For new facilities, CMS is using these national ratios until the facility’s actual CCR can be computed using the first tentatively settled or final settled cost report, which will then be used for the subsequent cost report period.
- The IPFs whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for whom the fiscal intermediary obtains inaccurate or incomplete data with which to calculate either an operating or capital CCR or both.
The CCRs are:

- National Median CCRs
  - Rural - 0.5890
  - Urban - 0.4365
- National Ceiling CCRs
  - Rural - 2.0068
  - Urban - 1.6862

The Cost of Living Adjustments (COLAs) factor for IPF PPS Fiscal Year 2019 for Alaska and Hawaii is 1.25, except for the County of Hawaii, for which the factor is 1.21.

**ICD-10 CM/PCS Updates**

For FY 2019, the IPF PPS adjustment factors are unchanged from those used in FY 2018. However, CMS updated the ICD-10-CM/PCS code set, effective October 1, 2018. These updates affect the ICD-10-CM/PCS codes that underlie the IPF PPS MS-DRGs and the IPF PPS comorbidity categories. The updated FY 2019 MS-DRG code lists are available on the IPPS website at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html), and the updated FY 2019 IPF PPS comorbidity categories are available at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html).

There were no changes from FY 2018 to FY 2019 to the IPF Code First list or the IPF ECT procedure code list.

**FY 2019 IPF PPS Wage Index**

The FY 2019 final IPF PPS wage index is available at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/WageIndex.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/WageIndex.html).

**Rural Adjustment**

For FY 2019, IPFs designated as “rural” continue to receive a 17-percent rural adjustment.

**ADDITIONAL INFORMATION**


If you have questions, your MACs may have more information. Find their website at [http://go.cms.gov/MAC-website-list](http://go.cms.gov/MAC-website-list).
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Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2019

MLN Matters Number: MM10826
Related Change Request (CR) Number: 10826
Related CR Release Date: August 3, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R4101CP
Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for Inpatient Rehabilitation Facilities (IRFs) billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

WHAT YOU NEED TO KNOW

Change Request (CR) 10826 notifies MACs that a new IRF PRICER software package will be released prior to October 1, 2018, that will contain the updated rates that are effective for claims with discharges that fall within October 1, 2018, through September 30, 2019. MACs will install and pay IRF claims with the FY 2019 IRF Prospective Payment System (PPS) PRICER for discharges on or after October 1, 2018. Be sure your billing staffs are aware of these changes.

BACKGROUND

On August 7, 2001, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register a final rule that established the PPS for IRFs, as authorized under Section 1886(j) of the Social Security Act (the Act). In that final rule, CMS set forth per discharge Federal rates for Federal fiscal year (FY) 2002. These IRF PPS payment rates became effective for cost reporting periods beginning on or after January 1, 2002. Annual updates to the IRF PPS rates are required by Section 1886(j)(3)(C) of the Act.

KEY POINTS FOR FY 2019 IRF PPS

The FY 2019 IRF PPS Final Rule sets forth the prospective payment rates applicable for IRFs for FY 2019. The PRICER updates for FY2019 are in the following table.
PRICER Updates for IRF PPS FY 2019 (October 1, 2018 – September 30, 2019)

<table>
<thead>
<tr>
<th>Pricer Update</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Federal Rate</td>
<td>$16,021</td>
</tr>
<tr>
<td>Adjusted Standard Federal Rate</td>
<td>$15,705</td>
</tr>
<tr>
<td>Fixed Loss Amount</td>
<td>$9,402</td>
</tr>
<tr>
<td>Labor-related Share</td>
<td>0.705</td>
</tr>
<tr>
<td>Non-labor Related Share</td>
<td>0.295</td>
</tr>
<tr>
<td>Urban National Average Cost to Charge Ratio (CCR)</td>
<td>0.412</td>
</tr>
<tr>
<td>Rural National Average CCR</td>
<td>0.515</td>
</tr>
<tr>
<td>Low Income Patient (LIP) Adjustment</td>
<td>0.3177</td>
</tr>
<tr>
<td>Teaching Adjustment</td>
<td>1.0163</td>
</tr>
<tr>
<td>Rural Adjustment</td>
<td>1.149</td>
</tr>
</tbody>
</table>

Section 1886(j)(7)(A)(i) of the Act requires application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. The mandated reduction will be applied in FY 2019 for IRFs that failed to comply with the data submission requirements during the data collection period January 1, 2017 through December 31, 2017. Thus, in compliance with 1886(j)(7)(A)(i) of the Act, CMS will apply a 2 percentage point reduction to the applicable FY 2019 market basket increase factor (1.35 percent) in calculating an adjusted FY 2019 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements.

Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

The adjusted FY 2019 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements for the period from January 1, 2017 through December 31, 2017 will be $15,705.
ADDITIONAL INFORMATION


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

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 3, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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July 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM10667
Related Change Request (CR) Number: 10667
Related CR Release Date: May 25, 2018
Effective Date: July 1, 2018
Related CR Transmittal Number: R4061CP
Implementation Date: July 2, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10667 instructs MACs to download and implement the July 2018 and, if released, the revised April, 2018, January 2018, October 2017, and July 2017 ASP drug pricing files for Medicare Part B drugs via the Centers for Medicare & Medicaid Services (CMS) Data Center (CDC). Medicare will use these files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after July 2, 2018, with dates of service July 1, 2018, through September 30, 2018. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The Average Sales Price (ASP) methodology is based on quarterly data submitted by manufacturers to CMS. CMS supplies 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 available in Chapter 4, Section 50 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.

- File: July 2018 ASP and ASP NOC -- Effective Dates of Service: July 1, 2018, through September 30, 2018
- File: April 2018 ASP and ASP NOC -- Effective for Dates of Service of April 1, 2018, through June 30, 2018
- File: January 2018 ASP and ASP NOC -- Effective for Dates of Service of January 1, 2018, through March 31, 2018
- File: October 2017 ASP and ASP NOC -- Effective for Dates of Service of October 1, 2017, through December 31, 2017
- File: July 2017 ASP and ASP NOC -- Effective for Dates of Service of July 1, 2017, through September 30, 2017

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

For any drug or biological not listed in the ASP or NOC drug pricing files that is billed with the KD modifier, MACs will determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2017, associated with the passage of the 21st Century Cures Act which is available at https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf.

### 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/Medicare/Medicare-Contracting/FFSProvCustSvcGen/MAC-Website-List.html.

### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 25, 2018</td>
<td>Initial article released</td>
</tr>
</tbody>
</table>

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

MLN Matters Number: MM10781 Revised  Related Change Request (CR) #: 10781
Related CR Release Date: June 15, 2018  Effective Date: July 1, 2018
Related CR Transmittal Number: R4075CP  Implementation Date: July 2, 2018

Note: This article was revised on June 19, 2018, to reflect an updated Change Request (CR). That update added new Retacrit codes Q5105 and Q5106 and new PLAcodes 0045U - 0061U. Code Q9994 was also added for In-Line Cartridge Containing Digestive Enzyme(s). These codes are effective July 1, 2018. CMS is also changing status indicators for two drug codes, The status indicator for J9216 and Q2049 were also changed from SI "K" to SI "E2" effective July 1, 2018. The CR release date, transmittal number and link to the transmittal also changed. All other information remains the same.

PROVIDERS TYPE AFFECTED

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

PROVIDER ACTION NEEDED

CR10781 describes changes to and billing instructions for various payment policies implemented in the July 2018 OPPS update. Make sure your billing staffs are aware of these changes.

BACKGROUND

This recurring update notification describes changes to billing instructions for various payment policies implemented in the July 2018 OPPS update. The July 2018 I/OCE will reflect the HCPCS, APC, HCPCS modifier, and revenue code additions, changes, and deletions identified in this CR.

Key Changes in CR 10781

Key changes and billing instructions for various payment policies implemented in July 2018 OPPS updates are as follows:
Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Changes Effective April 1, 2018

The American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel established two new MAAA codes, specifically, 0012M and 0013M, effective April 1, 2018. Because the codes were released on March 1, 2018, it was too late to include them in the April 2018 OPPS update. Instead, the codes are being included in the July 2018 update with an effective date of April 1, 2018. Table 1 lists the long descriptor and status indicator (SI) for CPT codes 0012M and 0013M.

Table 1 — Multianalyte Assays with Algorithmic Analyses (MAAA) CPT Coding Changes Effective April 1, 2018

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>OPPS Status Indicator (SI)</th>
<th>OPPS Ambulatory Payment Classification (APC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0012M</td>
<td>Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0013M</td>
<td>Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma</td>
<td>A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Proprietary Laboratory Analyses (PLA) CPT Coding Changes Effective April 1, 2018

The AMA CPT Editorial Panel established 10 new PLA CPT codes, specifically, CPT codes 0035U through 0044U effective April 1, 2018. Because the codes were released on February 22, 2018, it was too late to include them in the January 2018 OPPS update. Instead, they are being included in the July 2018 update with an effective date of April 1, 2018.

Table 2 lists the long descriptors and status indicators for CPT codes 0035U through 0044U. For more information on OPPS status indicators “A” and “Q4”, refer to OPPS Addendum D1 of the Calendar Year (CY) 2018 OPPS/Ambulatory Surgical Center (ASC) final rule. CPT codes 0035U through 0044U have been added to the July 2018 I/OCE, with an effective date of April 1, 2018. These codes, along with their short descriptors and status indicators, are also listed in the July 2018 OPPS Addendum B.
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0035U</td>
<td>Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0036U</td>
<td>Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0037U</td>
<td>Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0038U</td>
<td>Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0039U</td>
<td>Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0040U</td>
<td>BCR/ABL1 (t (9;22)) (e.g., chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0041U</td>
<td>Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0042U</td>
<td>Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0043U</td>
<td>Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0044U</td>
<td>Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG</td>
<td>Q4</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Proprietary Laboratory Analysis (PLA) CPT Coding Changes Effective July 1, 2018

Effective July 1, 2018, the AMA CPT Editorial Panel established 17 new PLA codes, specifically, CPT codes 0045U through 0061U. Table 3, lists the long descriptors and status indicators for these codes. For more information on OPPS status indicators “A” and “Q4”, refer to OPPS Addendum D1 of the Calendar Year (CY) 2018 OPPS/Ambulatory Surgical Center (ASC) final rule. These codes, along with their short descriptors and status indicators, are also listed in the July 2018 OPPS Addendum B.

Table 3 — PLA CPT Coding Changes Effective July 1, 2018

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0045U</td>
<td>Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0046U</td>
<td>FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0047U</td>
<td>Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0048U</td>
<td>Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0049U</td>
<td>NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0050U</td>
<td>Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0051U</td>
<td>Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>CPT Code</td>
<td>Long Descriptor</td>
<td>OPPS SI</td>
<td>OPPS APC</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td>0052U</td>
<td>Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0053U</td>
<td>Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0054U</td>
<td>Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0055U</td>
<td>Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0056U</td>
<td>Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0057U</td>
<td>Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank</td>
<td>A</td>
<td>N/A</td>
</tr>
<tr>
<td>0058U</td>
<td>Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0059U</td>
<td>Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative</td>
<td>Q4</td>
<td>N/A</td>
</tr>
<tr>
<td>0060U</td>
<td>Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood</td>
<td>A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis

### Category III CPT Codes Effective July 1, 2018

The AMA releases Category III CPT codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January.

For the July 2018 update, CMS is implementing four Category III CPT codes that the AMA released in January 2018 for implementation on July 1, 2018. The status indicators and APC assignments for these codes are shown in Table 4. Payment rates for these services can be found in Addendum B of the July 2018 OPPS Update.

**Table 4 — Category III CPT Codes Effective July 1, 2018**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0505T</td>
<td>Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural road mapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion</td>
<td>J1</td>
<td>5193</td>
</tr>
<tr>
<td>0506T</td>
<td>Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report</td>
<td>Q1</td>
<td>5733</td>
</tr>
<tr>
<td>0507T</td>
<td>Near-infrared dual imaging (i.e., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report</td>
<td>Q1</td>
<td>5733</td>
</tr>
<tr>
<td>0508T</td>
<td>Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia</td>
<td>S</td>
<td>5522</td>
</tr>
</tbody>
</table>
Bilateral Indicator for HCPCS Code C9749

In the April 2018 OPPS update CR (Transmittal 4005, CR 10515 dated March 20, 2018), CMS announced the establishment of HCPCS Code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s), effective April 1, 2018. CMS is also clarifying that this code describes an inherently bilateral procedure, and that for unilateral procedures, hospital outpatient departments need to report either modifier 73 or 74. Modifiers 73 and 74 are only used to indicate discontinued procedures for which anesthesia is planned or provided.

Packaging of CPT code 01402 when reported with Total Knee Arthroplasty (CPT code 27447)

CPT code 01402 describes anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty. For CY 2018, the status indicator assigned to this code is “C”, which indicates that this is an inpatient procedure that is not paid for under the OPPS.

For the July 2018 update, when CPT code 01402 is reported with CPT code 27447, Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty), this code is paid under the OPPS and payment for this service is packaged into the payment for CPT code 27447. If the code is not reported with CPT code 27447, the code is treated as an inpatient procedure that is not paid for under the OPPS. This change is retroactive to January 1, 2018.

Drugs, Biologicals, and Radiopharmaceuticals

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

For CY 2018, payment for nonpass-through drugs, biologicals and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP - 22.5 percent, if acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical.

In CY 2018, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Updated payment rates, effective July 1, 2018, and drug price restatements can be found in the July 2018 update of the OPPS Addendum A and Addendum B.

B. Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2018

Six drugs and biologicals have been granted OPPS pass-through status, effective July 1, 2018. These items, along with their descriptors and APC assignments, are identified in Table 5.
### Table 5 — Drugs and Biologicals with OPPS Pass-Through Status
*Effective July 1, 2018*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>OPPS Status Indicator</th>
<th>OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9030</td>
<td>Injection, copanlisib, 1 mg</td>
<td>G</td>
<td>9030</td>
</tr>
<tr>
<td>C9031</td>
<td>Lutetium Lu 177, dotatate, therapeutic, 1 mCi</td>
<td>G</td>
<td>9067</td>
</tr>
<tr>
<td>C9032</td>
<td>Injection, voretigene neparvovec-rzyl, 1 billion vector genome</td>
<td>G</td>
<td>9070</td>
</tr>
<tr>
<td>Q9991</td>
<td>Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg</td>
<td>G</td>
<td>9073</td>
</tr>
<tr>
<td>Q9992</td>
<td>Injection, buprenorphine extended-release (Sublocade), greater than 100 mg</td>
<td>G</td>
<td>9239</td>
</tr>
<tr>
<td>Q9995</td>
<td>Injection, emicizumab-kxwh, 0.5 mg</td>
<td>G</td>
<td>9257</td>
</tr>
</tbody>
</table>

### C. 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 CMS website on the first date of the quarter at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html).

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

### D. Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Effective July 1, 2018, HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) will replace HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg). The status indicator will remain G, “Pass-Through Drugs and Biologicals”. Table 6 describes the HCPCS code change and effective date.
Table 6 — Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>OPPS APC</th>
<th>Effective Date</th>
<th>Termination Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9469</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
<td>G</td>
<td>9469</td>
<td>04/01/2018</td>
<td>06/30/2018</td>
</tr>
<tr>
<td>Q9993</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
<td>G</td>
<td>9469</td>
<td>07/01/2018</td>
<td></td>
</tr>
</tbody>
</table>

Note: HCPCS code Q9994 (In-line cartridge containing digestive enzyme(s) for enteral feeding, each) will also be added and is listed in the upcoming July 2018 I/OCE CR, effective July 1, 2018.

E. Change to Status Indicator for CPT Code 90739

Hepatitis B vaccine associated with CPT code 90739 (Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use) was approved by the Food and Drug Administration (FDA) on November 09, 2017. Therefore, CMS is changing the status indicator for 90739 from SI=E1 (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type) to SI=F (Not paid under OPPS. Paid at reasonable cost.), effective April 1, 2018, in the July 2018 I/OCE update. Table 7 describes the status indicator change and effective date.

Table 7 — Change to Status Indicator for CPT Code 90739

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>90739</td>
<td>Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use</td>
<td>E1</td>
<td>January 1, 2013 – March 31, 2018</td>
</tr>
<tr>
<td>90739</td>
<td>Hepatitis b vaccine (hepb), adult dosage, 2 dose schedule, for intramuscular use</td>
<td>F</td>
<td>April 1, 2018</td>
</tr>
</tbody>
</table>
F. Drugs and Biologicals with a change in Status Indicator

Two drugs, specifically, HCPCS codes J9216 and Q2049, listed in Table 8 have a change in status indicator from “K” to “E2” effective July 1, 2018, to indicate that CMS has no pricing information for both drug codes.

Table 8 — Drugs and Biologicals with a Change in Status Indicator

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Old SI</th>
<th>New SI</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9216</td>
<td>Injection, interferon, gamma 1-b, 3 million units</td>
<td>K</td>
<td>E2</td>
<td>07/01/2018</td>
</tr>
<tr>
<td>Q2049</td>
<td>Injection, doxorubicin hydrochloride, liposomal, imported lipodox, 10 mg</td>
<td>K</td>
<td>E2</td>
<td>07/01/2018</td>
</tr>
</tbody>
</table>

G. New Biosimilar Biological Products Effective July 1, 2018

Two new HCPCS codes will be created for reporting Retacrit, (epoetin alfa-epbx) as a biosimilar to Epogen/Procrit (epoetin alfa) for the treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection. Retacrit is also approved for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery. Both codes are assigned to status indicator “K”. These codes are listed in Table 9 and are effective for services furnished on or after July 1, 2018. Payment for each of these codes may be found in the July 2018 update of the OPPS Addendum B at [http://www.cms.gov/HospitalOutpatientPPS/](http://www.cms.gov/HospitalOutpatientPPS/).
Table 9 — New HCPCS Drug Codes for Retacrit Effective July 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>OPPS SI</th>
<th>OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5105</td>
<td>Inj Retacrit esrd on dialysis</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units</td>
<td>K</td>
<td>9096</td>
</tr>
<tr>
<td>Q5106</td>
<td>Inj Retacrit non-esrd use</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units</td>
<td>K</td>
<td>9097</td>
</tr>
</tbody>
</table>

Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group

One skin substitute product, HCPCS code Q4178, has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. The product is listed in Table 10.

Table 10 — Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective July 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>OPPS SI</th>
<th>Low/High Cost Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4178</td>
<td>Floweramniopatch, per sq cm</td>
<td>N</td>
<td>High</td>
</tr>
</tbody>
</table>

Allow HCPCS Code Q4116 (Alloderm, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

HCPCS code Q4116 (Alloderm, per square centimeter) may be billed with either revenue code 0278 (Other implants) or revenue code 0636 (Drugs requiring detailed coding). HCPCS code Q4116 is used both as an applied skin substitute and as an implanted biologic used in breast reconstruction, and these procedures are reported with two different revenue codes. This request is described in Table 11.
Table 11 — Allow HCPCS Code Q4116 (Alloderm, per square centimeter) to Be Billed with Either Revenue Code 0278 (Other implants) or Revenue Code 0636 (Drugs requiring detailed coding)

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>OPP SI</th>
<th>Allowed Revenue Codes for Billing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4116</td>
<td>Alloderm, per square centimeter</td>
<td>N</td>
<td>0278, 0636</td>
</tr>
</tbody>
</table>

Coverage Determinations

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

ADDITIONAL INFORMATION


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

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 19, 2018</td>
<td>This article was revised to reflect an updated Change Request (CR). That update added new Retacrit codes Q5105 and Q5106 and new PLAcodes 0045U - 0061U. Code Q9994 was also added for In-Line Cartridge Containing Digestive Enzyme(s). These codes are effective July 1, 2018. CMS is also changing status indicators for two drug codes, The status indicator for J9216 and Q2049 were also changed from SI &quot;K&quot; to SI &quot;E2&quot; effective July 1, 2018. The CR release date, transmittal number and link to the transmittal also changed.</td>
</tr>
<tr>
<td>June 5, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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July Quarterly Update for 2018 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

MLN Matters Number: MM10707
Related CR Release Date: June 8, 2018
Related CR Transmittal Number: R4072CP
Related Change Request (CR) Number: 10707

Effective Date: January 1, 2018 for fees for code Q0477, June 1, 2018 for CMS-1687-IFC-related rural and blended fees, July 1, 2018 for all other changes
Implementation Date: July 2, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10707 provides the July 2018 Medicare DMEPOS fee schedule quarterly update listing fee schedule amounts for non-rural and rural areas. Additionally, the Parenteral and Enteral Nutrition (PEN) fee schedule file includes state fee schedule amounts for enteral nutrition items and national fee schedule amounts for parental nutrition items. Also, the files for this update include the July 2018 DMEPOS Rural ZIP code file containing the Third Quarter 2018 Rural ZIP code changes.

BACKGROUND

Sections 1834(a), (h), and (i) of the Social Security Act (the Act) require payment for DME, prosthetic devices, orthotics, prosthetics, and surgical dressings be completed on a fee schedule basis. Further, payment on a fee schedule basis is a regulatory requirement at 42 Code of Federal Regulations (CFR) §414.102, for parenteral and enteral nutrition, splints, casts and Intraocular Lenses (IOLs) inserted in a physician's office.

Additionally, Section 1834(a)(1)(F)(ii) of the Act mandates adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from Competitive Bidding Programs (CBPs) for DME. Section 1842(s) (3)(B) of the Act provides authority for adjusting the fee schedule amount for enteral nutrients, equipment and supplies (enteral nutrition) based on information from CBPs.
The methodologies for adjusting DMEPOS fee schedule amounts under this authority are established at 42 CFR §414.210(g). The DMEPOS and PEN fee schedule files contain Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the adjustments, as well as codes that are not subject to the fee schedule CBP adjustments.


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.

Key changes in this update are as follows:

**Interim Final Rule with Comment Period (CMS-1687-IFC)**

The interim final rule with comment period (CMS-1687-IFC) entitled “Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas” was published in the Federal Register on Friday, May 11, 2018. The IFC amends the regulations to increase the fee schedule amounts for items furnished from June 1, 2018 through December 31, 2018, in rural areas and non-contiguous areas (Alaska, Hawaii, and United States territories) not subject to the CBP. This change requires new 2018 rural and non-contiguous fee schedules be calculated for HCPCS codes for certain DME and PEN adjusted using competitive bidding information effective June 1, 2018. The new rural and non-contiguous fee schedule amounts are based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted fee schedule amounts updated by the covered item updates specified in sections 1834(a)(14) and 1842(s)(B) of the Act. For areas other than rural or non-continuous areas, the fee schedules for DME and PEN codes with adjusted fee schedule amounts will continue to be based on 100 percent of the adjusted fee schedule amounts from June 1, 2018 through December 31, 2018.

Because the revised rural and non-contiguous fee schedule amounts are based in part on unadjusted fee schedule amounts, the fees for certain items included in the 2008 Original Round One CBP, denoted with the HCPCS pricing modifier, are added back to the fee schedule file only for items furnished in rural and non-contiguous areas. Background information and a list of the applicable KE HCPCS codes was issued in Transmittal 1630, CR 6270, dated November 7, 2008. (See the related MLN Matters article MM6270 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6270.pdf.) Beginning June 1, 2018 through December 31, 2018, the rural and non-contiguous KE fee
schedule amounts will be based on a blend of 50 percent of the adjusted fee schedule amount and 50 percent of the unadjusted KE fee schedule amount updated by the covered item updates specified in sections 1834(a)(14) and 1842(s)(B) of the Act. The non-rural fees for these KE codes will be populated with zeros on the fee schedule file since KE is not a valid option for areas without blended fees.

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

Also, because the IFC results in a change to the 2018 fee schedule amounts for the various classes of oxygen and oxygen equipment, the annual oxygen budget neutrality adjustment for 2018 is recomputed and the adjustments to the stationary oxygen equipment, mandated by regulations at section 414.226(c)(6), will be applied to the fees on the June 1, 2018 file.

DMEPOS and PEN fee schedule files containing the revised rural and non-contiguous 50/50 blend fees were transmitted in May to the Part B and DME MACs for the June 1, 2018 implementation. However, the DMEPOS Institutional Claim (FI) fee schedule file was not updated with the revised rural and non-contiguous 50/50 blend in June. The July 2018 DMEPOS fee schedule FI file will incorporate the 50/50 blend rural and non-contiguous fees with a June 1, 2018 effective date. As part of the July 2018 DMEPOS fee schedule file update, HHHMACs shall adjust any impacted 50/50 blend claims processed for dates of service between June 1, 2018 and June 30, 2018 that are brought to their attention by the supplier.

MACs will not search for and adjust claims for HCPCS codes with revised 50/50 blend fees appearing on the July 2018 DMEPOS FI file with effective dates of June 1, 2018 for dates of service June 1, 2018 through June 30, 2018. However, they will adjust these claims when you bring them to their attention for dates of service June 1, 2018 through June 30, 2018.

Other Changes

As part of this update, the fee schedules for HCPCS code Q0477 (Power Module Patient Cable for Use with Electric or Electric/Pneumatic Ventricular Assist Device, Replacement Only) are revised and effective for dates of service on or after January 1, 2018. If you resubmit impacted claims, MACs will adjust previously processed claims for code Q0477 with dates of service on or after January 1, 2018.
The fee schedules Public Use Files (PUFs) will be available for State Medicaid Agencies, managed care organizations, and other interested parties shortly after the release of the data files at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html).

### ADDITIONAL INFORMATION


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

### DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 11, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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October 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

MLN Matters Number: MM10899
Related Change Request (CR) Number: 10899
Related CR Release Date: August 3, 2018
Effective Date: October 1, 2018
Related CR Transmittal Number: R4107CP
Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10899 provides the quarterly update for Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to the prior quarterly pricing files. CR 10899 instructs MACs to download and implement the October 2018 and, if released, the revised July 2018, April 2018, January 2018, and October 2017 ASP drug pricing files for Medicare Part B drugs. Medicare shall use the October 2018 ASP and Not Otherwise Classified (NOC) drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2018 with dates of service October 1, 2018, through December 31, 2018. Make sure your billing staffs are aware of these updates.

BACKGROUND

The ASP methodology is based on quarterly data that manufacturers submit to the Centers for Medicare & Medicaid Services (CMS). CMS supplies MACs with the ASP and NOC drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions available in Chapter 4, Section 50 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf.
• File: October 2018 ASP and ASP NOC – effective dates of service: October 1, 2018, through December 31, 2018;
• File: July 2018 ASP and ASP NOC – effective dates of service: July 1, 2018, through September 30, 2018;
• File: April 2018 ASP and ASP NOC – effective dates of April 1, 2018, through June 30, 2018;
• File: January 2018 ASP and ASP NOC – effective dates of service: January 1, 2018, through March 31, 2018; and

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

For any drug or biological not listed in the ASP or NOC drug pricing files that is billed with the KD modifier, MACs will determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of Durable Medical Equipment on or after January 1, 2017, associated with the passage of the 21st Century Cures Act which is available at https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf.

MACs will not search and adjust claims that have already been processed unless you bring such claims to your MAC’s attention

ADDITIONAL INFORMATION


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

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Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update

MLN Matters Number: MM10825 Related Change Request (CR) Number: 10825
Related CR Release Date: July 6, 2018 Effective Date: October 1, 2018
Related CR Transmittal Number: R4084CP Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for Skilled Nursing Facilities (SNFs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries paid under the Skilled Nursing Facility (SNF) Prospective Payment System (PPS).

PROVIDER ACTION NEEDED

Change Request (CR) 10825 informs MACs about updates to the payment rates under the PPS for SNFs, for Fiscal Year (FY) 2019, as required by statute. Make sure your billing staffs are aware of these changes. Also, be sure your billing staff are aware of the annual updates.

BACKGROUND

Annual updates to the PPS rates are required by Section 1888(e) of the Social Security Act, as amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), the Medicare, Medicaid, and State Children’s Health Insurance Plan (SCHIP) Benefits Improvement and Protection Act of 2000 (BIPA), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), relating to Medicare payments and consolidated billing for SNFs.

Each July, the Centers for Medicare & Medicaid Services (CMS) publishes the SNF payment rates for the upcoming FY (that is, October 1, 2018, through September 30, 2019) in the Federal Register, available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/List-of-SNF-Federal-Regulations.html. The update methodology is similar to that used in the previous year, which includes a forecast error adjustment whenever the difference between the forecasted and actual change in the SNF market basket exceeds a 0.5-percentage point. The statute mandates an update to the Federal rates using the latest SNF full market basket adjusted for productivity. However, for FY 2019, the SNF payment increase factor is 2.4 percent, as required by Section 53111 of the Bipartisan Budget Act of 2018. The payment rates will be effective October 1, 2018.
ADDITIONAL INFORMATION


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

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October Quarterly Update for 2018 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

MLN Matters Number: MM10881 Related Change Request (CR) Number: 10881
Related CR Release Date: August 10, 2018 Effective Date: October 1, 2018
Related CR Transmittal Number: R4108CP Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10881 informs DME MACs about the changes to the DMEPOS fee schedule which is updated on a quarterly basis, when necessary, to implement fee schedule amounts for new codes and correct any fee schedule amounts for existing codes. Make sure that your billing staffs are aware of these changes.

BACKGROUND

The DMEPOS fee schedules are updated on a quarterly basis, when necessary, in order to implement fee schedule amounts for new and existing codes, as applicable, and apply changes in payment policies. The update process for the DMEPOS fee schedule is located in the Medicare Claims Processing Manual, Chapter 23, Section 60.

Payment on a fee schedule basis is required for Durable Medical Equipment (DME), prosthetic devices, orthotics, prosthetics and surgical dressings by Section 1834(a), (h), and (i) of the Social Security Act (the Act). Additionally, payment on a fee schedule basis is a regulatory requirement at 42 Code of Federal Regulations (CFR) 414.102 for Parenteral and Enteral Nutrition (PEN), splints, casts and Intraocular Lenses (IOLs) inserted in a physician's office.

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

The methodologies for adjusting DMEPOS fee schedule amounts under this authority are established at 42 CFR, Section 414.210(g). The DMEPOS and PEN fee schedule files contain Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the adjustments, as well as codes that are not subject to the fee schedule CBP adjustments.

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.

October quarterly updates are only required for the DMEPOS Rural Zip code file containing the Quarter 4 2018 Rural ZIP code changes. An October update to the 2018 DMEPOS and PEN fee schedule files is not required.

The October 2018 DMEPOS Rural Zip file (PUF) will be available for State Medicaid Agencies, managed care organizations, and other interested parties shortly after the release of the data files at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.

ADDITIONAL INFORMATION


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Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM10875  Related Change Request (CR) Number: 10875
Related CR Release Date: July 20, 2018  Effective Date: October 1, 2018
Related CR Transmittal Number: R4090CP  Implementation Date: October 1, 2018

PROVIDER TYPE 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) 10875 provides instructions for the quarterly update to the Clinical Laboratory Fee Schedule (CLFS). These updates apply to Chapter 16, Section 20 of the Medicare Claims Processing Manual. Please make sure your billing staffs are aware of these updates.

BACKGROUND

Effective January 1, 2018, CLFS rates will be based on weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. For more details, the PAMA regulations are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

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

Access to Data File

Internet access to the quarterly CLFS data file will be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicare State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, will use the Internet to retrieve the quarterly CLFS. It will be available in Excel, text, and comma delimited formats.

Pricing Information

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

New Codes

The following new codes will be contractor-priced, until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in July 2018. The following "U" codes will have Healthcare Common Procedure Coding System (HCPCS) Pricing Indicator Code – 22: Price established by A/B MACs Part B (for example, gap-fills, A/B MACs Part B established panels) instead of Pricing Indicator – 21: Price Subject to National Limitation Amount. (Code, Long Descriptor, Short Descriptor, Effective Date, Type of Service (TOS).

These new codes are effective July 1, 2018

- 0045U TOS 5; Short Descriptor—ONC BRST DUX CARC IS 12 GENE; Long Descriptor—Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
- 0046U TOS 5; Short Descriptor—FLT3 GENE ITD VARIANTS QUAN; Long Descriptor—FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
- 0047U TOS 5; Short Descriptor—ONC PRST8 MRNA 17 GENE ALG; Long Descriptor—Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
- 0048U TOS 5; Short Descriptor—ONC SLD ORG NEO DNA 468 GENE; Long Descriptor—Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
- 0049U TOS 5; Short Descriptor—NPM1 GENE ANALYSIS QUAN; Long Descriptor—NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative
- 0050U TOS 5; Short Descriptor—TRGT GEN SEQ DNA 194 GENES; Long Descriptor—Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
- 0051U TOS 5; Short Descriptor—RX MNTR LC-MS/MS UR 31 PNL; Long Descriptor—Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
- 0052U TOS 5; Short Descriptor—LPOPRTN BLD W/5 MAJ CLASSES; Long Descriptor—Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation
- 0053U TOS 5; Short Descriptor—ONC PRST8 CA FISH ALYS 4 GEN; Long Descriptor—Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9,
CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade

- 0054U TOS 5; Short Descriptor—RX MNTR 14+ DRUGS & SBSTS; Long Descriptor—Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service

- 0055U TOS 5; Short Descriptor—CARD HRT TRNSPL 96 DNA SEQ; Long Descriptor—Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma

- 0056U TOS 5; Short Descriptor—HEM AML DNA GENE REARGMT; Long Descriptor—Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)

- 0057U TOS 5; Short Descriptor—ONC SLD ORG NEO MRNA 51 GENE; Long Descriptor—Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank

- 0058U TOS 5; Short Descriptor—ONC MERKEL CLL CARC SRM QUAN; Long Descriptor—Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative

- 0059U TOS 5; Short Descriptor—ONC MERKEL CLL CARC SRM +/-; Long Descriptor—Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative

- 0060U TOS 5; Short Descriptor—TWN ZYG GEN SEQ ALYS CHRMS2; Long Descriptor—Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood

- 0061U TOS 5; Short Descriptor—TC MEAS 5 BMRK SF DI M-S ALYS; Long Descriptor—Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging

This following existing code are revised, effective July 1, 2018:

- 0006U TOS 5; Short Descriptor—DETC IA MEDS 120+ ANALYTES; Long Descriptor—Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified per date of service

This following existing code is approved as an Advanced Diagnostic Laboratory Test (ADLT)
and was added to the CLFS effective July 1, 2018:

- 0037U TOS 5; Short Descriptor—Trgt gen seq dna 324 genes; Long Descriptor—Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

**Note:** MACs will not search their files to either retract payment or retroactively pay claims. However, MACs should adjust claims if they are brought to their attention.

### ADDITIONAL INFORMATION


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

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Quarterly Update to 2018 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement

MLN Matters Number: MM10852  Related Change Request (CR) Number: 10852
Related CR Release Date: July 20, 2018  Effective Date: January 1, 2016
Related CR Transmittal Number: R4093CP  Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

This MLN Matters® Article is intended for providers who submit claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) for services provided in a Skilled Nursing Facility (SNF) to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10852 provides updates to the lists of Healthcare Common Procedure Coding System (HCPCS) codes that are subject to the Consolidated Billing (CB) provision of the SNF Prospective Payment System (PPS). Changes to Current Procedural Terminology (CPT)/HCPCS codes and Medicare Physician Fee Schedule designations are to revise Common Working File (CWF) edits to allow MACs to make appropriate payments in accordance with policy for SNF CB in the “Medicare Claims Processing Manual”, Chapter 6, Section 20.6. Make sure your billing staffs are aware of these changes.

BACKGROUND

CR10852 alerts providers that the Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of HCPCS codes that are excluded from the CB provision of the SNF PPS. Services excluded from SNF PPS and CB may be paid to providers, other than SNFs, for beneficiaries, even when in a SNF stay. Services not appearing on the exclusion lists submitted on claims to MACs, including DME MACs, will not be paid by Medicare to any providers other than a SNF.

For non-therapy services, SNF CB applies only when the services are furnished to a SNF resident during a covered Part A stay; however, SNF CB applies to physical and occupational therapies and speech-language pathology services whenever they are furnished to a SNF resident, regardless of whether Part A covers the stay. In order to assure proper payment in all settings, Medicare systems must edit for services provided to SNF beneficiaries both included and excluded from SNF CB.
The updated lists for institutional and professional billing are available at [http://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html](http://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html). Certain codes are included as services that are not subject to SNF CB. You may submit these codes globally (no modifier), professional component only (modifier 26), or technical component only (modifier TC).

Certain codes are included as services that are not subject to SNF CB. These codes can be submitted globally (no modifier), professional component only (modifier 26), or technical component only (modifier TC). When the codes listed below are submitted globally or just for the technical component, the claims submitted to the MACs (Part B) are being rejected by the CWF. That is to say, they are not allowed to pay separately outside of the consolidated payment that is made to the SNF. When submitted with the 26 modifier for just the professional component, the claims have been allowed to pay. The codes are:

- Codes that should have been added effective January 1, 2016 - 77770, 77771, 77772
- Codes that should have been added effective January 1, 2017 - G0491, G0500, J9034, J9301, Q0083, Q0084, Q0085, 36598, 77385, 77386, 77770, 77771, 77772, 79005, 79101, 79445, 96446, 99151, 99152, 99155, 99156, and 99157
- Codes that should have been added effective January 1, 2018 - 00731, 00732, 00811, 00812, 00813, and 77772

The above errors are occurring because CMS did not add the codes to the appropriate coding lists with the 2016, 2017, and 2018 SNF CB Annual Updates. Therefore, for claims with dates of service on or after January 1, 2016, the MACs (Part B) will re-open and reprocess impacted claims, if you bring those claims to the attention of your MAC. MACs (Part B) will notify providers that if they have already received payment for these services from the SNF, they need to return that payment to the SNF in order to receive payment from Medicare. Providers may not be paid twice for the same service and such a request could be construed as a fraudulent claim.

The following HCPCS will be added to Major Category 1 (Exclusion of Services Beyond the Scope of a SNF) exclusions retroactive to July 1, 2018:

- Q5105 Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units
- Q5106 Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units

For claims processed on or after October 1, 2018, HCPCS codes Q5105 and Q5106 will be added to Physician Services for SNF Consolidated Billing with an effective date of July 1, 2018.

Note: MACs will re-open and re-process the claims brought to their attention, for claims with dates of service on or after July 1, 2018, that have previously been denied/rejected prior to the implementation of CR 10852.
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Quarterly Update to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

MLN Matters Number: MM10818 Revised Related Change Request (CR) Number: CR 10818
Related CR Release Date: June 15, 2018 Effective Date: July 1, 2018
Related CR Transmittal Number: R4073CP Implementation Date: July 2, 2018

Note: This article was revised on June 19, 2018, to add information on the revenue codes to be used for reporting code Q5105 on the 72x type of bill for ESRD beneficiaries. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10818 provides instructions for new codes added to the Healthcare Common Procedure Coding System (HCPCS) file for anemia management that will be included in the list of items and services subject to the ESRD PPS Consolidated Billing (CB) requirements. Make sure your billing staff is aware of the changes.

BACKGROUND

Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) required the implementation of an End Stage Renal Disease Prospective Payment System (ESRD PPS), effective January 1, 2011.

The ESRD PPS:

- Includes consolidated billing requirements for limited Part B services included in the ESRD facility’s bundled payment
- Provides ESRD facilities a single payment that covers all of the resources used to furnish an outpatient dialysis treatment
- Provides outlier payments, if applicable, for high cost patients due to unusual variations in the type or amount of medically necessary care.
The Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of items and services subject to Part B CB, and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

CR10818 provides instructions for a new code (Q5105 - Injection, epoetin alfa, biosimilar, (Retacrit) 100 units (for esrd on dialysis)) added to the Healthcare Common Procedure Coding System (HCPCS) file for anemia management; and which will be included in the list of items and services subject to the ESRD PPS CB requirements, effective July 1, 2018. This code will be reportable with revenue code 0634 or 0635 on the 72X type of bill for ESRD beneficiaries.

Anemia management is a functional category under the ESRD PPS, and the drugs and biologicals that fall within this category are always considered to be used for the treatment of ESRD. Further, in accordance with 42 CFR 413.237(a)(1), HCPCS Q5105 is considered to be an eligible outlier service and will be included in the outlier calculation. If the pricing data is not available on the ASP drug file, then MACs will manually price the drug using 1847A pricing methodologies. ESRD facilities will not receive separate payment for Q5105, with or without the AY modifier (Item or service furnished to an ESRD patient that is not for the treatment of ESRD), and the claims will process the line item as covered with no separate payment under the ESRD PPS.

In addition, there is a new HCPCS code - Q5106 (Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units). This code will be reportable with revenue code 0636 on the 72X type of bill for individuals with Acute Kidney Injury (AKI). Q5106 is paid for through the AKI payment rate and therefore separate payment is not allowable on the 72X type of bill.

The updated list of renal dialysis services that are subject to the ESRD PPS CB requirements is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Also, CR10818 has an attachment that is a list of drugs always considered ESRD.

**ADDITIONAL INFORMATION**


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

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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>June 19, 2018</td>
<td>This article was revised to add information on the revenue codes to be used for reporting code Q5105 on the 72x type of bill for ESRD beneficiaries. All other information remains the same.</td>
</tr>
<tr>
<td>June 15, 2018</td>
<td>Initial article released.</td>
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Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2018 Update

MLN Matters Number: MM10644  Related Change Request (CR) Number: 10644
Related CR Release Date: May 18, 2018  Effective Date: January 1, 2018
Related CR Transmittal Number: R4053CP  Implementation Date: July 2, 2018

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) 10644 amends payment files issued to MACs based upon 2018 Medicare Physician Fee Schedule (MPFS) Final Rule. Make sure your billings staffs are aware of these changes.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) issued payment files to the MACs based upon the 2018 Medicare Physician Fee Schedule (MPFS) Final Rule, published in the Federal Register on November 15, 2017, to be effective for services furnished between January 1, 2018 and December 31, 2018.

CR 10644 presents a summary of the changes for the July update to the 2018 MPFSDB. Unless otherwise stated, these changes are effective for dates of service on and after January 1, 2018. The following tables show those changes.
<table>
<thead>
<tr>
<th>CPT/HCPCS &amp; MOD</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0511</td>
<td>Change PC/TC indicator to “0”</td>
</tr>
<tr>
<td>G0512</td>
<td>Change PC/TC indicator to “0”</td>
</tr>
<tr>
<td>G0460*</td>
<td>Change Status = A, Work RVU = 2.25, Non-Facility PE RVU = 2.89, Facility PE RVU = .94, Malpractice RVU = .34, Mult Proc = 2, Bilat Surg = 0, Asst Surg = 1, Co-Surg = 0, Team Surge = 0, Global Days = 000</td>
</tr>
<tr>
<td>71045 TC</td>
<td>Facility and Non-Facility PE RVU changed to 0.42</td>
</tr>
<tr>
<td>71045</td>
<td>Facility and Non-Facility PE RVU changed to 0.35</td>
</tr>
</tbody>
</table>

* The work RVU of G0460 was valued at the work RVU of one billing of Current Procedural Terminology (CPT) code 11042 (1.01) plus two billings of CPT code 11045 (0.50), along with a single billing of CPT codes 99195 (0.00) and 38213 (0.24) to cover the lab portion of the work. The direct PE inputs were crosswalked from CPT code 11042 along with the inclusion of additional clinical labor, supplies, and equipment based on CMS determination of what would be typical and medically necessary for the procedure.

The following “Q” codes are effective for services performed on or after July 1, 2018 (see MM10624 for additional information).

<table>
<thead>
<tr>
<th>Code</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Q9991</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply</td>
</tr>
<tr>
<td>Q9992</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply</td>
</tr>
<tr>
<td>Q9993</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply</td>
</tr>
<tr>
<td>Q9995</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply</td>
</tr>
</tbody>
</table>
The following new CPT Category III codes have been added for dates of service July 1, 2018, and after:

<table>
<thead>
<tr>
<th>Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0505T</td>
<td>Ev fempop artl revsc</td>
<td>Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion</td>
</tr>
<tr>
<td>0506T</td>
<td>Mac pgmt opt dns meas hfp</td>
<td>Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report</td>
</tr>
<tr>
<td>0507T</td>
<td>Near ifr 2img mibmn glnd i&amp;r</td>
<td>Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report</td>
</tr>
<tr>
<td>0508T</td>
<td>Pls echo us b1 dns meas tib</td>
<td>Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia</td>
</tr>
</tbody>
</table>
Note: MACs will not search their files to retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims brought to their attention.

<table>
<thead>
<tr>
<th>HCPCS/Mod</th>
<th>0505T</th>
<th>0506T</th>
<th>0506T -26</th>
<th>0506T -TC</th>
<th>0507T</th>
<th>0507T -26</th>
<th>0507T -TC</th>
<th>0508T</th>
<th>0508T -26</th>
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<td>C</td>
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<td>Muti</td>
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<td>7</td>
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<td>7</td>
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<td>Bilat</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asst Surg</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Co-Surg</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Team Surg</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
<td>0</td>
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<tr>
<td>PC/TC</td>
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<tr>
<td>Global</td>
<td>YYY</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
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<td>Diag Supv</td>
<td>09</td>
<td>09</td>
<td>09</td>
<td>01</td>
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<td>09</td>
<td>01</td>
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<td>09</td>
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</tbody>
</table>

Note: Pre, intra and post-operative percentages for CPT codes 0505T-0508T are all "0.00."

**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/Medicare/Medicare-Contracting/FFSProvCustSvcGen/MAC-Website-List.html.
**DOCUMENT HISTORY**

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<td>May 21, 2018</td>
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Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2018 Update

MLN Matters Number: MM10898  Related Change Request (CR) Number: 10898
Related CR Release Date: August 10, 2018  Effective Date: January 1, 2018
Related CR Transmittal Number: R4109CP  Implementation Date: October 1, 2018

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10898 amends payment files issued to MACs based upon the 2018 Medicare Physician Fee Schedule (MPFS) Final Rule. Make sure your billings staffs are aware of these changes.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) issued payment files to the MACs based upon the 2018 MPFS Final Rule, published in the Federal Register on November 15, 2017, to be effective for services furnished from January 1, 2018, through December 31, 2018.

CR 10898 presents a summary of the changes for the October update to the 2018 MPFS. Section 1848(c)(4) of the Social Security Act authorizes the Secretary to establish ancillary policies necessary to implement relative value units (RVU) for physicians’ services. Unless otherwise stated, these changes are effective for dates of service on and after January 1, 2018.

The HCPCS codes listed below have been added to the Medicare Physician Fee Schedule Database (MPFSDB) effective for dates of service on and after October 1, 2018.

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<th>ACTION</th>
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<td>G9978</td>
<td>Non-Facility &amp; Facility PE RVU = 0.23. All other MPFS indicators &amp; RVUs = 99201</td>
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<tr>
<td>G9979</td>
<td>Non-Facility &amp; Facility PE RVU = 0.42. All other MPFS indicators &amp; RVUs = 99202</td>
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### HCPCS ACTION

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>G9980</td>
<td>Non-Facility &amp; Facility PE RVU = 0.60. All other MPFS indicators &amp; RVUs = 99203</td>
</tr>
<tr>
<td>G9981</td>
<td>Non-Facility &amp; Facility PE RVU = 1.01. All other MPFS indicators &amp; RVUs = 99204</td>
</tr>
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<td>G9982</td>
<td>Non-Facility &amp; Facility PE RVU = 1.32. All other MPFS indicators &amp; RVUs = 99205</td>
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<tr>
<td>G9983</td>
<td>Non-Facility &amp; Facility PE RVU = 0.20. All other MPFS indicators &amp; RVUs = 99212</td>
</tr>
<tr>
<td>G9984</td>
<td>Non-Facility &amp; Facility PE RVU = 0.41. All other MPFS indicators &amp; RVUs = 99213</td>
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<td>G9985</td>
<td>Non-Facility &amp; Facility PE RVU = 0.62. All other MPFS indicators &amp; RVUs = 99214</td>
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<td>G9986</td>
<td>Non-Facility &amp; Facility PE RVU = 0.88. All other MPFS indicators &amp; RVUs = 99215</td>
</tr>
<tr>
<td>G9987</td>
<td>Non-Facility &amp; Facility PE RVU = 1.06. All other MPFS indicators &amp; RVUs = G9187</td>
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</table>

The following “Q” codes are effective on or after July 1, 2018 (see CR 10626 for additional information on HCPCS code Q9994 and CR 10624 on HCPCS codes Q5105 and Q5106). HCPCS code Q5108 is effective July 12, 2018. See CR 10834 for more information on HCPCS Q5108:

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>Q9994</td>
<td>Procedure Status = X; there are no RVUs, payment policy indicators do not apply.</td>
</tr>
<tr>
<td>Q5105</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply.</td>
</tr>
<tr>
<td>Q5106</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply.</td>
</tr>
<tr>
<td>Q5108</td>
<td>Procedure Status = E; there are no RVUs, payment policy indicators do not apply.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
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<th>J5 MAC (IA, KS, MO, NE, AND NATIONAL)</th>
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<td><strong>Kansas</strong></td>
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<td>WPS GHA</td>
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<tr>
<td>General Correspondence</td>
<td>General Correspondence</td>
</tr>
<tr>
<td>P.O. Box 7665</td>
<td>P.O. Box 7576</td>
</tr>
<tr>
<td>Madison, WI 53707-7665</td>
<td>Madison, WI 53707-7576</td>
</tr>
<tr>
<td>(866) 518-3285</td>
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<tr>
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<tr>
<td>Madison, WI 53708-8890</td>
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<td>(866) 518-3285</td>
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