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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, G0481, G0482, G0483, G0484, G0485, G0486, G0487, G0488, G0489

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, G0481, G0482, G0483, G0484, G0485, G0486, G0487, G0488, G0489

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.
**Document History**

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<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 28, 2018</td>
<td>The article was revised 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.</td>
</tr>
<tr>
<td>April 27, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
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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:  
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.

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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>August 14, 2018</td>
<td>Initial article released.</td>
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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.

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<td>July 13, 2013</td>
<td>Initial article released.</td>
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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/codelists/healthcare/claim-status-category-codes/ and http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/. Included in the code lists are specific details, including the date when a code was added, changed, or deleted.
All code changes approved during the 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


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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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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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: Implementation Date: January 7, 2019
R4087CP, R306FM

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**


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

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New Q Code for In-Line Cartridge Containing Digestive Enzyme(s)

MLN Matters Number: MM10626
Related Change Request (CR) Number: 10626
Related CR Release Date: June 1, 2018
Effective Date: July 1, 2018
Related CR Transmittal Number: R4063CP
Implementation Date: July 2, 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) 10626 instructs MACS to add Healthcare Common Procedure Coding System (HCPCS) code Q9994 to the Level II HCPCS code set effective July 1, 2018. Make sure your billing staffs are aware of these changes.

BACKGROUND
The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of the Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA) to identify medical services and procedures furnished by physicians and other health care professionals. The Level II HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes.

Policy Change
Q9994 is added to the Level II HCPCS code set effective July 1, 2018:

- Long Description: In-line cartridge containing digestive enzyme(s) for enteral feeding, each
- Short Description: Enzyme cartridge enteral nut

The billing jurisdiction for this code will be DME MAC.
ADDITIONAL INFORMATION


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

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New Waived Tests

MLN Matters Number: MM10819  Related Change Request (CR) Number: 10819
Related CR Release Date: July 20, 2018  Effective Date: October 1, 2018
Related CR Transmittal Number: R4091CP  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) 10819 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its contractors of the new tests so that the contractors can accurately process claims. There are 17 newly added waived complexity tests. Make sure your billing staffs are aware of these changes.

BACKGROUND

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

CR10819 describes the latest tests approved by the FDA as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the new tests in the table below must have the modifier QW to be recognized as a waived test. However, the following tests do not require a QW modifier to be recognized as a waived test:
CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are shown in the following table:
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Effective Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>87502QW</td>
<td>March 23, 2018</td>
<td>Alere i System (Alere i Influenza A &amp; B 2)</td>
</tr>
<tr>
<td>85018QW</td>
<td>April 11, 2018</td>
<td>EKF-diagnostic GmbH, DiaSpect Tm System</td>
</tr>
<tr>
<td>80305QW</td>
<td>May 8, 2018</td>
<td>ForaCare Inc. TD-4140 Smart Dongle Blood Glucose β-Ketone Monitoring System</td>
</tr>
<tr>
<td>80305QW</td>
<td>May 8, 2018, May 11, 2018</td>
<td>Rapid Self Test, Inc. RST Drug of Abuse Multi-Test Cup</td>
</tr>
<tr>
<td>80305QW</td>
<td>May 11, 2018</td>
<td>Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Cup Tests</td>
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<tr>
<td>80305QW</td>
<td>May 11, 2018</td>
<td>Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Cup with OPI2000 Tests</td>
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<tr>
<td>80305QW</td>
<td>May 11, 2018</td>
<td>Rhema Scientific, Inc. Rhema Scientific Multi-Panel Drug Screen Dip Card Tests</td>
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<tr>
<td>82274QW, G0328QW</td>
<td>May 18, 2018</td>
<td>Cen-Med Enterprises, Elite Plus Silver Immunochemical Rapid Fecal Occult Blood Test</td>
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<tr>
<td>80305QW</td>
<td>May 24, 2018</td>
<td>Premier Biotech Inc. Premier Bio-Cup</td>
</tr>
<tr>
<td>80305QW</td>
<td>May 24, 2018</td>
<td>Premier Biotech Inc. Premier Bio-Dip</td>
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<tr>
<td>80305QW</td>
<td>May 25, 2018</td>
<td>BTNX Inc. Rapid Response One Step DOA Cup MOR 300 (Urine)</td>
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<tr>
<td>80305QW</td>
<td>May 25, 2018</td>
<td>BTNX Inc. Rapid Response One Step DOA Cup MOR 2000 (Urine)</td>
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<tr>
<td>80305QW</td>
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<td>BTNX Inc. Rapid Response Single/Multi DOA Panel MOR 300 (Urine)</td>
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</table>

In the April 2017 transmittal, CR9687 (see MM9687), the attachment accompanying the transmittal was re-organized to include a generic test system name and a statement to refer to the FDA waived analytes Internet site for those Healthcare Common Procedure Coding System (HCPCS) codes with more than 20 test systems listed. Beginning with
CR 10819, the attachment will not mention a specific test system for those HCPCS codes with more than 10 test systems. The additional codes mentioned in the attachment to CR 10819 will only be mentioned in a generic manner are 85018QW, 85610QW, and 87804QW.

**Note:** MACs will not search their files to either retract payment or retroactively pay claims. However, they will 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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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 xr 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 (MPFSDB) Status Indicator: E
- **Q9992**
  - Short Description: Buprenorphine xr 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**


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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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<td>April 20, 2018</td>
<td>Initial article released.</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


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

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Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 24.3, Effective October 1, 2018

MLN Matters Number: MM10827 Related Change Request (CR) Number: 10827
Related CR Release Date: June 29, 2018 Effective Date: October 1, 2018
Related CR Transmittal Number: R4080CP 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

Change Request (CR) 10827 updates the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) edits, which relate to Chapter 23, Section 20.9 of the Medicare Claims Processing Manual (Pub. 100-04). Please make sure your billing staffs are aware of these updates.

BACKGROUND

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

Version 24.2 will include all previous versions and updates from January 1, 1996, to the present. In the past, NCCI was organized in two tables: Column 1/Column 2 Correct Coding Edits and Mutually Exclusive Code (MEC) Edits. In order to simplify the use of NCCI edit files (two tables), on April 1, 2012, CMS consolidated these two edit files into the Column One/Column Two Correct Coding edit file. Separate consolidations have occurred for the two practitioner NCCI edit files and the two NCCI edit files used for the Outpatient Code Editor (OCE).

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

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

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

ADDITIONAL INFORMATION


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

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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

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

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Update to Medicare 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#se42.3.424_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**


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

The article has been updated and reformatted to support Article Guidance on Non-Oncological Conditions. 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 2.5 mg 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 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 lutsystmeic (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.

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tr>
<td>July 20, 2018</td>
<td>Initial article released.</td>
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</table>

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**Coverage - Policies**

## INFORMATION ON WEBSITE

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

[https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources](https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources)

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

WPS GHA  
Attn: Freedom of Information Act (FOIA)  
P.O. Box 7877  
Madison, WI 53708-8788  

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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

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy/Article Title</th>
<th>CMS MCD #</th>
<th>WPS #</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>J5/J8</td>
<td>MoIDX: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC)</td>
<td>L37671</td>
<td>MoIDX-041</td>
<td>10/17/2018</td>
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### August 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

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WPS GHA
Summer 2018 Communiqué

**Contract Policy Title CMS MCD # WPS # Effective Date**

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<tr>
<td>J5/J8</td>
<td>High Intensity Focused Ultrasound (HIFU) in the Treatment of Recurrent Prostate Cancer</td>
<td>A56019</td>
<td>NA</td>
<td>08/15/2018</td>
</tr>
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<td>J5/J8</td>
<td>MolDX: AlloSure Donor-Derived Cell-Free DNA Test</td>
<td>L37665</td>
<td>MolDX-037</td>
<td>08/16/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: EndoPredict® Breast Cancer Gene Expression Test</td>
<td>L37663</td>
<td>MolDX-036</td>
<td>08/16/2018</td>
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<tr>
<td>J5/J8</td>
<td>MolDX: FDA Approved CLL Companion Diagnostic Test Coding and Billing Guidelines</td>
<td>A56020</td>
<td>NA</td>
<td>08/15/2018</td>
</tr>
<tr>
<td>J5/J8</td>
<td>MolDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer</td>
<td>L37667</td>
<td>MolDX-038</td>
<td>08/16/2018</td>
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</table>

**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: [https://www.wpsgha.com/wps/portal/mac/site/policies/news-and-updates](https://www.wpsgha.com/wps/portal/mac/site/policies/news-and-updates)

**August 2018**

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<tr>
<td>J5/J8</td>
<td>Billing and Coding for Rezum® Procedure</td>
<td>A55353</td>
<td>NA</td>
<td>08/01/2018</td>
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</table>

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

**REVISED POLICIES/ARTICLES**

The following are revised policies/articles. Be sure to note the effective date of the revised 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): [http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx)

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</tr>
<tr>
<td>J5/J8</td>
<td>Category III Codes</td>
<td>L35490</td>
<td>PHYS-084</td>
<td>09/01/2018</td>
</tr>
<tr>
<td></td>
<td>Under Utilization Guidelines, deleted the following sentence &quot;Services described by CPT codes 0075T and 0076T are allowed when provided in accordance with NCD 20.7, Percutaneous Transluminal Angioplasty.&quot;</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>The following information has been added to this LCD:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Coverage Indications, Limitations and/or Medical Necessity</strong></td>
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<tr>
<td></td>
<td>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.</td>
<td></td>
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<tr>
<td></td>
<td><strong>Step 2: Added and/or Deficient Mismatch Repair (MMR) by Immunohistochemistry (IHC)</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
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<tr>
<td></td>
<td><strong>IHC and/or MSI Testing</strong></td>
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<td></td>
<td>Added:</td>
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<tr>
<td></td>
<td>• 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.</td>
<td></td>
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<tr>
<td></td>
<td><strong>MMR Germline Gene Mutation Testing Exception</strong></td>
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<tr>
<td></td>
<td>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).</td>
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<tr>
<td></td>
<td>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.</td>
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<tr>
<td></td>
<td>Corrected the step numbers in the paragraph below: <strong>Step 5B: MSH2 Testing</strong></td>
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<tr>
<td></td>
<td>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.</td>
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</tr>
</tbody>
</table>
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.

J5/J8  
**Special Stains and Immunohistochemistry (IHC) Indications for Gastric Pathology**

A55739  NA  09/01/2018

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**

J5/J8  
**Erythropoiesis Stimulating Agents (ESAs) and Billing and Coding Guidelines**

L34633  INJ-023  07/01/2018

- 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

**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.

**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 & 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: "Use SV101-7 to describe non-specific procedure codes." (Do not use the 2400 NTE segment to describe non-specific procedure codes with 5010.) The SV101-7 data element allows for 80 bytes (i.e., characters, including spaces) of information.

In order for WPS GHA to correctly reimburse NOC drugs and biologicals, providers must indicate the following in the 2400/SV101-7 data element, or Item 19 of the CMS 1500 form:

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

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

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

Pricing for NOC J-codes is determined by the information provided on the Average
<table>
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<tbody>
<tr>
<td>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.</td>
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</tr>
<tr>
<td>J5/J8</td>
<td>High Intensity Focused Ultrasound (HIFU) in the Treatment of Recurrent Prostate Cancer</td>
<td>A56019</td>
<td>NA</td>
<td>08/15/2018</td>
</tr>
<tr>
<td>For clarification added the following statement to the narrative section of the Article Guidance: It should primarily serve as a billing and coding guideline.</td>
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<tr>
<td>Added the National Comprehensive Cancer Network (NCCN) to the Sources of Information section.</td>
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<td>J5/J8</td>
<td>MolDX: Molecular Diagnostic Tests (MDT)</td>
<td>L36807</td>
<td>MolDX-004</td>
<td>08/01/2018</td>
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<td>Onc mrna 5 gen rsk urthl ca</td>
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<tr>
<td>0013M</td>
<td>Onc mrna 5 gen recr urthl ca</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0035U</td>
<td>Neuro csf prion prtn qual</td>
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<tr>
<td>0036U</td>
<td>Xome tum &amp; nml spec seq alys</td>
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<tr>
<td>0037U</td>
<td>Trgt gen seq dna 324 genes</td>
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<tr>
<td>0038U</td>
<td>Vitamin d srn microsamp quan</td>
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<tr>
<td>0039U</td>
<td>Dna antb 2strand hi avidity</td>
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<td>0040U</td>
<td>Bcr/abl1 gene major bp quan</td>
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<tr>
<td>0041U</td>
<td>B brgdferi antb 5 prtn igm</td>
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<tr>
<td>0042U</td>
<td>B brgdferi antb 12 prtn igg</td>
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<td>0043U</td>
<td>Tbrf b grp antb 4 prtn igm</td>
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<td>0044U</td>
<td>Tbrf b grp antb 4 prtn igg</td>
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<td>Removed CPT codes:</td>
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<tr>
<td>87999</td>
<td>Microbiology procedure</td>
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<tr>
<td>88199</td>
<td>Cytopathology procedure</td>
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<td>88299</td>
<td>Cytogenetic study</td>
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<td>88399</td>
<td>Surgical pathology procedure</td>
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<tr>
<td>89398</td>
<td>Unlisted reprod med lab proc</td>
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<tr>
<td>Moved 0024U-0034U codes from the Group 1 paragraph into the Group 1 Codes section.</td>
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<td>Replaced McKesson Diagnostic Exchange with DEXTM Diagnostics Exchange. To obtain a unique identifier for a test and to submit information for a technical</td>
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<td>A55846</td>
<td>NA</td>
<td>08/01/2018</td>
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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

| J5/J8    | Non-Invasive Cerebrovascular Studies | L35753    | CV-045 | 08/01/2018    |

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
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy/Article Title</th>
<th>CMS MCD #</th>
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<th>Effective Date</th>
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<tbody>
<tr>
<td>J5/J8</td>
<td>Category III Codes</td>
<td>L35490</td>
<td>PHYS-084</td>
<td>07/01/2018</td>
</tr>
</tbody>
</table>

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.

Created a Group 5 table of Codes for CPT codes.
### Group 5 Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame replacement when performed.</td>
</tr>
</tbody>
</table>

### 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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G25.0</td>
<td>Essential tremor</td>
</tr>
</tbody>
</table>

### 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
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy/Article Title</th>
<th>CMS MCD #</th>
<th>WPS #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
</tbody>
</table>

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.

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 an 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. Deep venous thrombosis prophylaxis is recommended during Epoetin alfa-epbx
### Contract Policy/Article Title

<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy/Article Title</th>
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</thead>
<tbody>
<tr>
<td>(biosimilar) therapy.</td>
<td></td>
</tr>
</tbody>
</table>

#### CPT/HCPCS Codes
- Group 1 Paragraph and Group 1 Codes
- Added J3590.

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

#### ICD-10 Codes that Support Medical Necessity
- Group 1 Paragraph, A. End Stage Renal Disease (ESRD)
  - Added J3590.
- Group 2 Paragraph, Chronic Kidney Disease NOT on dialysis
  - Added J3590
- Group 4 Paragraph, C. Indications other than Renal Disease, 1. Anemia related to therapy with Zidovudine (AZT)
  - Added J3590 and
- Group 11 Paragraph, 5. Prophylactic pre-operative use for reduction of allogeneic blood transfusions prior to elective hip and knee replacement surgery
  - Added J3590.

- Added NOC drug billing: Please refer to the Not Otherwise Classified (NOC) Billing requirements contained within the Billing & Coding Guidelines for claims submitted with J3590 unclassified biologics, effective 05/15/2018.

#### Billing and Coding Guidelines for Erythropoiesis Stimulating Agents (ESAs) updated:
- Not Otherwise Classified (NOC) Billing:
  - Use J3590 for Epoetin alfa-epbx (biosimilar) FDA approval/effective date 05/15/2018.

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

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

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

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

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.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>J5/J8</td>
<td>MoIDX: CDH1 Genetic Testing Coding and Billing Guidelines</td>
<td>A55622</td>
<td>NA</td>
<td>07/01/2018</td>
</tr>
</tbody>
</table>
|          | **Policy/Article Details:**
|          | Information on the incidence of Hereditary Diffuse Gastric Cancer has been removed from the introductory paragraph. It now reads as:
|          | 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. |
| J5/J8    | MoIDX: Myriad’s BRACAnalysis CDx® Coding and Billing Guidelines | A55224 | NA    | 07/01/2018     |
|          | **Policy/Article Details:**
|          | Coverage has been added for metastatic breast cancer.
|          | 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.
|          | 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:

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td>ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants, who are or may become eligible for treatment with Lynparza® (olaparib).”</td>
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<tr>
<td></td>
<td>The following diagnosis codes have been added:</td>
<td></td>
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<tr>
<td></td>
<td>C48.0 - C48.2 Malignant neoplasm of retroperitoneum</td>
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<tr>
<td></td>
<td>Malignant neoplasm of specified parts of peritoneum</td>
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<tr>
<td></td>
<td>Malignant neoplasm of peritoneum, unspecified</td>
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<td></td>
<td>C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum</td>
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<tr>
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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></td>
<td>C50.019 Malignant neoplasm of nipple and areola, unspecified female breast</td>
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<td></td>
<td>C50.021 Malignant neoplasm of nipple and areola, right male breast</td>
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<td></td>
<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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<tr>
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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></td>
<td>C50.129 Malignant neoplasm of central portion of unspecified male breast</td>
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<tr>
<td></td>
<td>C50.211 Malignant neoplasm of upper-inner quadrant of right female breast</td>
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<td></td>
<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>C50.322 Malignant neoplasm of lower-inner quadrant of left male breast</td>
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<td>C50.519 Malignant neoplasm of lower-outer quadrant of unspecified female breast</td>
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<td>C50.611 Malignant neoplasm of axillary tail of right female breast</td>
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<td>C50.621 Malignant neoplasm of axillary tail of right male breast</td>
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<tr>
<td>C57.00-C57.02</td>
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<tr>
<td>Z85.3</td>
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<td>Z85.43</td>
<td>Personal history of malignant neoplasm of ovary</td>
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<tr>
<td>Z85.44</td>
<td>Personal history of malignant neoplasm of other female genital organs</td>
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</tbody>
</table>

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.

J5/J8 Treatment of Varicose Veins of the L34536 GSURG- 10/01/2015
<table>
<thead>
<tr>
<th>Contract</th>
<th>Policy/Article Title</th>
<th>CMS MCD #</th>
<th>WPS #</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Extremities</td>
<td></td>
<td>041</td>
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</tbody>
</table>

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.
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/.

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<td>May 18, 2018</td>
<td>Initial article released.</td>
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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.
**DOCUMENT HISTORY**

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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 B) - A Collaborative Effort Between WPS GHA and NGS
09/11/2018 - Holyoke, MA - 12:30 PM - 4:00 PM ET
10/23/2018 - Glen Ellyn, IL - 12:30 PM - 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 B providers (billing on a 1500) 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 B)
10/09/2018 - Springfield, MO - 12:30 PM - 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 would like to invite all Part B providers (billing on a 1500) 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

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 LEARN I NG NET WORK (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

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upcoming calls, registration information, and links to previous call materials, visit

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

The Quarterly Provider Update can be accessed on the CMS website at:

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:
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.

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.

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July 2018 Update of the Ambulatory Surgical Center (ASC) Payment System

MLN Matters Number: MM10788 Revised
Related Change Request (CR) Number: 10788
Related CR Release Date: June 26, 2018
Effective Date: July 1, 2018
Related CR Transmittal Number: R4076CP
Implementation Date: July 2, 2018

Note: This article was revised on June 28, 2018, to reflect an updated Change Request. To reflect those changes this article modified Section 2.b and the related Table 1. It also added Section 2e and 2f with corresponding Table 3. The CR Release Date, transmittal number and link to the transmittal also changed. All other information remains the same.

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10788 informs MACs about updates to the ASC payment system for July 2018. Be sure your billing staffs are aware of these changes.

BACKGROUND

Change Request (CR) 10788 describes changes to and billing instructions for various payment policies implemented in the July 2018 ASC payment system update. As appropriate, this notification also includes updates to the Healthcare Common Procedure Coding System (HCPCS). Included in CR10788 are Calendar Year (CY) 2018 payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG) files. The CR also includes a July 2018 ASC payment rates for covered surgical and ancillary services (ASCFS) update file. CR10788 is not issuing a No ASC Code Pair file. The key changes are as follows:

1. Bilateral Indicator for HCPCS Code C9749

In the April 2018 Outpatient Prospective Payment System (OPPS) update (Transmittal 4005, CR10515, dated March 20, 2018), the Centers for Medicare & Medicaid Services (CMS) announced the establishment of HCPCS code C9749 (Repair of nasal vestibular lateral wall...
stenosis with implant(s)), effective April 1, 2018. CMS is clarifying that this code describes an inherently bilateral procedure, and that for unilateral procedures; ASCs 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.

2. Drugs, Biologicals, and Radiopharmaceuticals

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

   For CY 2018, payment for non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals continues to be made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical. In addition, in CY 2018, a single payment of ASP + 6 percent continues to be made for pass-through drugs, biologicals, and therapeutic radiopharmaceuticals to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.

   Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later-quarter ASP submissions become available. Updated payment rates effective July 1, 2018, and drug price restatements are available in the July 2018 update of ASC Addendum BB, which is at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

   b. July 2018 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2018

   Seven new HCPCS codes have been created for reporting drugs and biologicals in the ASC payment system effective July 1, 2018, where there have not previously been specific codes available. These new codes are listed in Table 1.

   Table 1 — July 2018 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
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<tbody>
<tr>
<td>C9030</td>
<td>Injection, copanlisib, 1 mg</td>
<td>Inj copanlisib</td>
<td>K2</td>
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<tr>
<td>C9032</td>
<td>Injection, voretigene neparvovec-rzyl, 1 billion vector genome</td>
<td>Voretigene neparvovec-rzyl</td>
<td>K2</td>
</tr>
<tr>
<td>Q5105</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units</td>
<td>Inj Retacrit esrd on dialysis</td>
<td>K2</td>
</tr>
<tr>
<td>Q5106</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units</td>
<td>Inj Retacrit non-esrd use</td>
<td>K2</td>
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### c. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

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

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

### d. Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2018

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 ASC Payment Indicator will remain K2, “Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate.” These codes are listed in Table 2.

**Table 2 — Other Changes to CY 2018 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2018**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
<th>Effective Date</th>
<th>Termination Date</th>
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<tbody>
<tr>
<td>C9469</td>
<td>Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg</td>
<td>Inj triamcinolone acetonide</td>
<td>K2</td>
<td>04/01/2018</td>
<td>06/30/2018</td>
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e. 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. The codes, descriptors, and ASC payment indicators are separately listed in Table 3, and are effective for services furnished on or after July 1, 2018. Payment for each of these codes can be found in Addendum BB of the July 2018 ASC addenda that are posted on the CMS website.

Table 3 - New Biosimilar Biological Products Effective July 1, 2018

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
<th>Effective Date</th>
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<tr>
<td>Q5105</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units</td>
<td>Inj Retacrit esrd on dialysi</td>
<td>K2</td>
<td>07/01/2018</td>
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<tr>
<td>Q5106</td>
<td>Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units</td>
<td>Inj Retacrit non-esrd use</td>
<td>K2</td>
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f. Drugs and Biologicals with a Change in Status Indicator

Two drugs, specifically, HCPCS codes J9216 and Q2049, have a change in status indicator from “K2” to not separately payable, effective July 1, 2018, since we do not have pricing information for either drug code.

3. Category III CPT Code Effective July 1, 2018

The AMA releases Category III CPT codes twice per year:

- In January, for implementation beginning the following July
- In July, for implementation beginning the following January
For the July 2018 update, CMS is implementing one Category III CPT code that the AMA released in January 2018 for implementation on January 1, 2018. The ASC payment indicator for this code is shown in Table 4. The payment rate for this service is in Addendum BB of the July 2018 ASC addenda at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html).

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

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>Short Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0508T</td>
<td>Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia</td>
<td>Pls echo us b1 dns meas tib</td>
<td>Z2</td>
</tr>
</tbody>
</table>

4. **Reassignment of Skin Substitute Product from the Low-Cost Group to the High-Cost Group**

The payment for skin substitute products that do not qualify for hospital OPPS pass-through status is packaged into the OPPS payment for the associated skin substitute application procedure. This policy is also implemented in the ASC payment system. The skin substitute products are divided into two groups: 1) High-cost skin substitute products and 2) Low-cost skin substitute products for packaging purposes.

The skin substitute product listed in Table 5 has been reassigned from the low-cost skin substitute group to the high-cost skin substitute group based on updated pricing information.

**Note:** This skin substitute product is packaged and should not be separately billed by ASCs.

**Table 5 — Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective July 1, 2018**

<table>
<thead>
<tr>
<th>CY 2018 HCPCS Code</th>
<th>CY 2018 Short Descriptor</th>
<th>CY 2018 ASC PI</th>
<th>Low/High Cost</th>
<th>Skin Substitute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4178</td>
<td>Floweramniopatch, per sq cm</td>
<td>N1</td>
<td>High</td>
<td></td>
</tr>
</tbody>
</table>

ASCs should not separately bill for packaged skin substitutes (ASC PI=N1). High-cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low-cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by HCPCS codes C5271-C5278. All OPPS pass-through skin substitute products (ASC PI=K2) should be billed in combination with one of the skin application procedures described by CPT codes 15271-15278.
5. Coverage Determinations

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

ADDITIONAL INFORMATION


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

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<td>June 28, 2018</td>
<td>This article was revised to reflect an updated Change Request. To show those changes this article modified Section 2.b and the related Table 1. It also added Section 2e and 2f with corresponding Table 3. The CR Release Date, transmittal number and link to the transmittal also changed.</td>
</tr>
<tr>
<td>June 1, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

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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.

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 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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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 SFDI 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.

DOCUMENT HISTORY

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<tr>
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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. 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.
ADDITIONAL INFORMATION


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

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Quarterly Update to the 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</td>
<td>Facility and Non-Facility PE RVU changed to 0.42</td>
</tr>
<tr>
<td>71045 TC</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>
</tr>
</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>
<th>0508T -TC</th>
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<td>Muti</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>
</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>
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<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>
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<tr>
<td>Team Surg</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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<td>PC/TC</td>
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<tr>
<td>Global</td>
<td>YYYY</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
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<tr>
<td>Diag Supv</td>
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<td>09</td>
<td>09</td>
<td>01</td>
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<td>09</td>
<td>01</td>
<td>09</td>
<td>09</td>
<td>01</td>
</tr>
</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](https://www.cms.gov/Medicare/Medicare-Contracting/FFSProvCustSvcGen/MAC-Website-List.html).
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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.

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>ACTION</th>
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<tbody>
<tr>
<td>G9978</td>
<td>Non-Facility &amp; Facility PE RVU = 0.23. All other MPFS indicators &amp; RVUs = 99201</td>
</tr>
<tr>
<td>G9979</td>
<td>Non-Facility &amp; Facility PE RVU = 0.42. All other MPFS indicators &amp; RVUs = 99202</td>
</tr>
<tr>
<td>HCPCS</td>
<td>ACTION</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
</tr>
<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>
<tr>
<td>G9982</td>
<td>Non-Facility &amp; Facility PE RVU = 1.32. All other MPFS indicators &amp; RVUs = 99205</td>
</tr>
<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>
</tr>
<tr>
<td>G9985</td>
<td>Non-Facility &amp; Facility PE RVU = 0.62. All other MPFS indicators &amp; RVUs = 99214</td>
</tr>
<tr>
<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>
</tr>
</tbody>
</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>
<th>Action</th>
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</thead>
<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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