Medicare B CONNECTION
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FIRST COAST SERVICE OPTIONS, INC.
A Newsletter for MAC Jurisdiction N Providers
January 2019

In this issue

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

Provider type affected

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

What you need to know

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

Background

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

The travel codes allow for payment either on a per mileage basis (P9603) or on a flat rate per trip basis (P9604). Medicare makes payment of the travel allowance only if a specimen collection fee is also payable. The travel allowance is intended to cover the estimated travel costs of collecting a specimen including the laboratory technician's salary and travel expenses. MAC discretion allows the MAC to choose either a mileage basis or a flat rate, and how to set each type of allowance. Because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary for a laboratory technician to travel for specimen collection, many MACs established local policy to pay based on a flat rate basis only.

Under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), Medicare prorates the travel payment component based on the number of specimens collected on that trip for both

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The *Medicare B Connection* is published monthly by First Coast Service Options Inc.'s Provider Outreach & Education division to provide timely and useful information to Medicare Part B providers.

Publication staff:

Marielba Cancel
Terri Drury
Maria Murdoch
Mark Willett
Robert Petty

Fax comments about this publication to:

Medicare Publications
904-361-0723

Articles included in the *Medicare B Connection* represent formal notice of coverage policies. Policies have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined within to ensure compliance with Medicare coverage and payment guidelines.

About the Medicare B Connection

The *Medicare B Connection* is a comprehensive publication developed by First Coast Service Options Inc. (First Coast) for Part B providers in Florida, Puerto Rico, and the U.S. Virgin Islands and is distributed on a monthly basis.

Important notifications that require communication in between publications will be posted to the First Coast Medicare provider education website at *https://medicare.fcso.com*. In some cases, additional unscheduled special issues may be posted.

Who receives the *Connection*

Anyone may view, print, or download the *Connection* from our provider education website(s). Providers who cannot obtain the *Connection* from the internet are required to register with us to receive a complimentary hardcopy.

Distribution of the *Connection* in hardcopy is limited to providers who have billed at least one Part B claim to First Coast Medicare during the twelve months prior to the release of each issue. Providers meeting these criteria are eligible to receive a complimentary copy of that issue, if a technical barrier exists that prevents them from obtaining it from the internet and they have returned a completed registration form to us.

Registration forms must be submitted annually or when you experience a change in circumstances that impacts your electronic access.

For additional copies, providers may purchase a separate annual subscription (see order form in the back of this issue). All issues published since 1997 may be downloaded from the internet, free of charge.

We use the same mailing address for all correspondence, and cannot designate that the *Connection* be sent to a specific person/department within a provider's office. To ensure continued receipt of all Medicare correspondence, providers must keep their addresses current with the Medicare provider enrollment department. Please remember that address changes must be done using the appropriate CMS-855.

Publication format

The *Connection* is arranged into distinct sections.

- The **Claims** section provides claim submission requirements and tips.
- The **Coverage/Reimbursement** section discusses specific CPT® and HCPCS procedure codes. It is arranged by categories (not specialties). For example, "Mental Health" would present coverage information of interest to psychiatrists, clinical psychologists and clinical social workers, rather than listing articles separately under individual provider specialties. Also presented in this section are changes to the Medicare physician fee schedule, and other pricing issues.

- The section pertaining to **Electronic Data Interchange** (EDI) submission also includes information pertaining to the Health Insurance Portability and Accountability Act (HIPAA).
- The **Local Coverage Determination** section features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives.
- The **General Information** section includes fraud and abuse, and national provider identifier topics, plus additional topics not included elsewhere.
- In addition to the above, other sections include:
- **Educational Resources**, and
- **Contact information** for Florida, Puerto Rico, and the U.S. Virgin Islands.

The *Medicare B Connection* represents formal notice of coverage policies

Articles included in each edition represent formal notice that specific coverage policies either have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines.

Never miss an appeals deadline again

When it comes to submitting a claims appeal request, *timing is everything*. Don't worry – you won't need a desk calendar to count the days to your submission deadline. Try our *"time limit" calculators on our Appeals of claim decisions page*. Each calculator will *automatically calculate* when you must submit your request based upon the date of either the initial claim determination or the preceding appeal level.

Medicare Part B advance beneficiary notices

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for treatment and diagnosis of the patient.

For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare's possible denial of payment if the provider does not want to accept financial responsibility for the service or item. Advance beneficiary notices (ABNs) advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment.

Patient liability notice

The Centers for Medicare & Medicaid Services' (CMS) has developed the Advance Beneficiary Notice of Noncoverage (ABN) (Form CMS-R-131), formerly the "Advance Beneficiary Notice." Section 50 of the *Medicare Claims Processing Manual* provides instructions regarding the notice that these providers issue to beneficiaries in advance of initiating, reducing, or terminating what they believe to be noncovered items or services. The ABN must meet all of the standards found in Chapter 30. Beginning March 1, 2009, the ABN-G and ABN-L was no longer valid; and notifiers must use the revised Advance Beneficiary Notice of Noncoverage (CMS-R-131). Section 50 of the *Medicare Claims Processing Manual* is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf#page=44*.

Reproducible copies of Form CMS-R-131 ABNs (in English and Spanish) and other BNI information may be found at *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html*.

ABN modifiers

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting modifier GA (waiver of liability statement on file) or GZ (item or service expected to be denied as not reasonable and necessary) with the service or item.

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Modifier GZ may be used in cases where a signed ABN is not obtained from the patient; however, when modifier GZ is billed, the provider assumes financial responsibility if the service or item is denied.

Note: Line items submitted with the modifier GZ will be automatically denied and will not be subject to complex medical review.

GA modifier and appeals

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting the modifier GA (waiver of liability statement on file).

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Nonassigned claims containing the modifier GA in which the patient has been found liable must have the patient's written consent for an appeal. Refer to the applicable contact section located at the end of this publication for the address in which to send written appeals requests.

Inpatient rehabilitation facility (IRF) medical review changes

***Note**: This article was revised on December 20, 2018, to remove the Admission order requirement from the portion of the article under "Required documentation elements for an IRF claim include, but are not limited to." Please note that the regulation, CMS-1688-F, removed the admission order documentation requirement from the IRF payment regulation(s) in an effort to reduce duplicative documentation requirements. CMS will continue enforcement of the hospital conditions of participation. Also, a link to the CMS-1688-F is added in the Additional Information section. All other information remains the same. This information was previously published in the December 2017 Medicare B Connection, pages 16-17.*

Provider type affected

This MLN Matters Article is intended for Inpatient Rehabilitation Facilities (IRFs), physicians, and other practitioners with patients in IRFs who are receiving Part A inpatient services.

Provider action needed

Special Edition article SE17036 reiterates policy related to claims submitted with regard to services provided to Medicare beneficiaries in an IRF. Please make sure your billing and coding staffs review these policies associated with the Medicare IRF benefit.

Background

The Medicare IRF benefit provides intensive rehabilitation therapy in a resource intensive inpatient hospital environment, including Inpatient Rehabilitation Hospitals and Inpatient Rehabilitation Units. The IRF benefit is for a beneficiary who, due to the complexity of their nursing, medical management, and rehabilitation needs, requires and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to rehabilitation care.

In order for IRF services to be covered under the Medicare IRF benefit, submitted documentation must sufficiently demonstrate that a beneficiary's admission to an IRF was reasonable and necessary, according to Medicare guidelines. Key elements of IRF coverage criteria include a reasonable expectation that at the time of the beneficiary's admission to the IRF the beneficiary:

- Requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics) one of which must be physical or occupational therapy
- Generally requires an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF
- Is sufficiently stable and can reasonably be expected to be able to actively participate in, and benefit significantly from, an intensive rehabilitation therapy program. The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient's condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient's functional capacity or adaptation to impairments) as a result of the rehabilitation treatment, and if such improvement can be expected to be made within a prescribed period of time
- Requires physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. (See 42 CFR 412.622, which is available at https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-622.pdf.)
- Requires an intensive and coordinated interdisciplinary approach to providing rehabilitation

Required documentation elements for an IRF claim include, but are not limited to:

- A comprehensive preadmission screening that is:
  - Conducted by a licensed or certified clinician(s) designated by a rehabilitation physician
  - Completed within the 48 hours immediately preceding the IRF admission
  - Provides a detailed and comprehensive review of each patient's condition and medical history
- A post-admission physician evaluation that:
  - Is conducted by a rehabilitation physician
  - Is completed within 24 hours of the patient's admission to the IRF
  - Provides documentation of the patient's status on admission to the IRF, including a comparison with the information noted in the preadmission screening documentation
  - Support the medical necessity of the IRF admission
- An individualized plan of care that:
  - Is developed by a rehabilitation physician with input from the interdisciplinary team
  - Is based on the findings of the post-admission

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physician evaluation
  - Is completed within the first 4 days of the IRF admission
  - Supports the determination that the IRF admission is reasonable and necessary
- An inpatient rehabilitation facility patient assessment instrument (IRF-PAI)

Particular attention should be paid to documenting the patient's need for intensive rehabilitation therapy services requiring care in an IRF. Documentation in the patient's medical record must be accurate and avoid vague or subjective descriptions of the patient's care needs that would not be sufficient to indicate the need for intensive rehabilitation services.

Recently, the Centers for Medicare & Medicaid Services (CMS) advised its medical review contractors that when the current industry standard of providing in general at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics) per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period is not met, the claim should undergo further review. This further review will require the use of clinical review judgment to determine medical necessity of the intensive rehabilitation therapy program based on the individual facts and circumstances of the case, and not on the basis of any threshold of therapy time.

Also, CMS advised its medical review contractors that the standard of care for IRF patients is individualized (i.e., one-on-one) therapy. Group and concurrent therapy can be used on a limited basis within the current industry standard of generally 3 hours of therapy per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period. In those instances in which group therapy better meets the patient's needs on a limited basis, the situation/rationale that justifies group therapy should be specified in the patient's medical record at the IRF.

For more information on billing and payment criteria related to IRFs, please refer to the following documentation:

- Chapter 3, Section 140.1.1 of the *Medicare Claims Processing Manual* (Pub. 100-04), titled, *Criteria That Must Be Met By Inpatient Rehabilitation Facilities*, which can be downloaded at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*
- Chapter 1, Section 110 of the *Medicare Benefit Policy Manual* (IRF Services), available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf*
- 42 CFR 412.622, which is available at *https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-622.pdf*

Additional information

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

The IRF regulation CMS-1688-F is available at *https://www.federalregister.gov/documents/2018/08/06/2018-16517/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal*.

Document history

Date of change	Description
December 20, 2018	The article was revised to remove the Admission order requirement from the portion of the article under "Required documentation elements for an IRF claim include, but are not limited to." Please note that the regulation, CMS-1688-F, removed the admission order documentation requirement from the IRF payment regulation(s) in an effort to reduce duplicative documentation requirements. CMS will continue enforcement of the hospital conditions of participation. Also, a link to the CMS-1688-F is added in the Additional Information section. All other information remains the same.
December 11, 2017	Initial article released.

MLN Matters® Number: SE17036 *Revised*
Article Release Date: December 20, 2018
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation Date: N/A

SNF advance beneficiary notice of non-coverage

Note: *This article was revised on January 11, 2019, to reflect the revised CR 10567 issued on January 11. The CR revisions had no impact on the content of the article. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same. This information was previously published in the April 2018 Medicare B Connection, pages 17-18*.

Provider type affected

This *MLN Matters*® article is intended for skilled nursing facilities (SNFs) billing Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

This article informs you about change request (CR) 10567, which advises you that the Centers for Medicare & Medicaid Services (CMS) has revised the skilled nursing facility notice of non-coverage (SNF ABN), Form CMS-10055. With this revision, CMS is discontinuing the five SNF denial letters (namely, the Intermediary Determination of Noncoverage, the UR Committee Determination of Admission, the UR Committee Determination on Continued Stay, the SNF Determination on Admission and the SNF Determination on Continued Stay), and the Notice of Exclusion from Medicare Benefits (NEMB-SNF), Form CMS-20014. Please ensure that your billing staffs are aware of these changes.

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

Background

The authorization for these requirements are Section 1879 of the Social Security Act and 42 Code of Federal Regulations (CFR) 411.404(b) and (c), which specify written notice requirements. These requirements are fulfilled by the SNF ABN.

In order for SNFs to transfer liability to an original Medicare beneficiary for items or services paid under Medicare Part A (SNF prospective payment system (PPS)), the SNF must issue a SNF ABN for:

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

Attached to CR 10567 is a revised Chapter 30 of the *Medicare Claims Processing Manual*. This revised manual chapter provides details on SNF ABN standards and also provides information about:

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

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

SNFs will continue to use the advance beneficiary notice of non-coverage (ABN, Form CMS-R-131) for items or services that Medicare may be deny under Medicare Part B.

Please note that SNFs may start to implement this new notice any time up to the implementation date of CR 10567. Upon the CR 10567 implementation April 30, 2018, the use of the new notice is mandatory.

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

Additional information

The official instruction, CR 10567, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4198CP.pdf*.

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

Document history

Date of change	Description
January 11, 2019	We revised the article to reflect the revised CR 10567 issued on January 11. The CR revisions had no impact on the content of the article. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
March 30, 2018	Initial article released.

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

Clinical Laboratory

CMS releases the April update to new waived tests

Provider type affected

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

Provider action needed

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

Background

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that CMS only pays for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, Medicare edits laboratory claims at the CLIA certificate level. However, the tests mentioned on the first page of the list attached to CR11080 (CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

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

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

- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Panel Dip M300
- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Panel Dip M2000:
- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M300
- 80305QW, May 25, 2018, American Screening Corporation, Inc., Precision DX Quick Cup M2000
- 86618QW, August 30, 2018, Quidel Sofia 2 {Fingerstick whole blood}
- 80305QW, October 2, 2018, McKesson Medical-Surgical, Mckesson Drugs of abuse PPX Test Cup
- 80305QW, October 4, 2018, Jant Pharmacal Corp. Accutest VALUPAK Drug Screen Cup
- 80305QW, October 9, 2018, McKesson Medical-Surgical Inc. McKesson Multi Panel Drugs of abuse Test Cup
- 83036QW, October 23, 2018, Alere Technologies AS, AS100 Analyzer

- 83036QW, October 23, 2018, Alere Technologies AS, Afinion 2 Analyzer
- 80305QW, November 2, 2018, American Screening LLC, Precision Plus Quick Cup Tests 80305QW, November 2, 2018, American Screening LLC, Precision DX Quick Cup Tests
- 87804QW, November 21, 2018, Polymedco Inc., Poly stat Flu A&B {for use with nasal and nasophayngeal swabs}
- 87634QW, November 23, 2018, Mesa Biotech Accula (Accula RSV Test)

Additional information

The official instruction, CR 11080, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4195CP.pdf*.

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

Document history

Date of change	Description
January 11, 2019	Initial article released.

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

General Coverage

New local coverage determinations process

***Note**: This article was revised on January 11, 2019, to reflect the revised CR 10901 issued on January 11. In the article, we added language to show that MACs have the discretion to host multi-jurisdictional CACs. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same. All other information remains the same. This information was previously published in the October 2018 Medicare B Connection, pages 1, 7-9.*

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

Background

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

Most stakeholders acknowledged that the local coverage process is an important means to provide decisions related to the items and services that benefit Medicare's beneficiaries and to ensure beneficiary access to life saving and medically necessary products and procedures. However, there is concern about the lack of local coverage process transparency, including notifying stakeholders of proposed revisions to, and drafting of, new LCDs.

Additional stakeholder concerns include: ineffective MAC processes for soliciting from, and providing to, stakeholders feedback on information provided during open public meetings, a lack of non-physician representation on Contractor Advisory Committees (CACs), and concerns that CAC meetings are not open to the public.

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

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

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

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

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

NEW LCD process

The key parts of the new LCD process are summarized as follows:

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

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

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

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

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

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

3. Clinical Guidelines, Consensus Documents and Consultation

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

4. Publication of the Proposed LCD

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

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

- Revised LCD being issued for compelling reasons.
- Revised LCD that makes a non-substantive correction - For example, typographical or grammatical errors that do not substantially change the LCD.
- Revised LCD that makes a non-discretionary coverage update - Contractors shall update LCDs to reflect changes in NCDs or when a conflict with national policy occurs, coverage provisions in interpretive manuals, and payment systems.
- Revise LCD to effectuate an administrative law judge's decision to nullify an existing LCD due to an LCD challenge.

5. Contractor advisory committee (CAC)

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

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

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

6. Open Meeting

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

7. Publication of the Final Determination

After the close of the comment period and the required meetings and consultation, the final LCD and the response to comment (RTC) article will be published on the MCD.

8. Response to Public Comments

MACs will respond to all comments received during the comment period of the proposed LCD by using the RTC article associated with the LCD. The RTC Article is

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published on the start date of the notice period. The RTC Article will remain publicly available indefinitely on the MCD or the MCD Archive.

9. Notice period

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

Full details of this new process are contained in the updated manual which is an attachment to CR 10901.

LCD reconsideration process

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

1. MACs shall consider all LCD reconsideration requests from:
   - Beneficiaries residing or receiving care in a contractor's jurisdiction
   - Providers doing business in a contractor's jurisdiction
   - Any interested party doing business in a contractor's jurisdiction
2. MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall **not** be accepted for other documents including:
   - National coverage determinations (NCDs);
   - Coverage provisions in interpretive manuals;
   - Proposed LCDs;
   - Template LCDs, unless or until they are adopted and in effect by the contractor;
   - Retired LCDs;
   - Individual claim determinations
   - Bulletins, articles, training materials; and
   - Any instance in which no LCD exists, i.e., requests for development of an LCD.
3. Process Requirements - The requestor shall submit a valid LCD reconsideration request to the appropriate MAC, following instructions on the MAC's Web site. Within 60 calendar days of the day the request is received, the MAC shall determine whether the request is valid or invalid. If the request is invalid, the MAC will respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the MAC will open the LCD and follow the LCD process as outlined in the above for new LCDs or include the LCD on the MAC's waiting list. The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait-listing, of the reconsideration request.

Other important changes

Other key changes to the manual include the following:

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

Additional information

The official instruction, CR 10901, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R854PI.pdf*. The complete manual revision is included in CR 10901.

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

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

Document history

Date of change	Description
January 11, 2019	We revised the article to reflect the revised CR 10901 issued on January 11. In the article, we added language to show that MACs have the discretion to host multi-jurisdictional CACs. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
October 3, 2018	Initial article released.

MLN Matters® Number: MM10901 *Revised*
Related CR Release Date: January 11, 2019
Related CR Transmittal Number: R854PI
Related Change Request (CR) Number: 10901
Effective Date: October 3, 2018
Implementation Date: January 8, 2019

Ambulatory Surgical Center

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

Provider type affected

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

Provider action needed

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

Background

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

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

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

New Device Pass-Through Categories

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

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

Device Offset from Payment:

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

Table 1. – New Device Pass-Through Code Effective January 1, 2019

HCPCS code	Short descriptor	Long descriptor	ASC PI
C1823	Gen, neuro, trans sen/ stim	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	J7

New Separately Payable Procedure Codes Effective January 1, 2019

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

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Table 2. – New Separately Payable Procedure Codes

Effective January 1, 2019

HCPCS code	Short descriptor	Long descriptor	ASC PI
C9752	Intraosseous des lumb/ sacrum	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum	J8
C9754	Perc AV fistula, any site	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	J8
C9755	RF magnetic-guided AV fistula	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/ or ultrasound, with radiologic supervision and interpretation, when performed	J8

HCPCS code	Short descriptor	Long descriptor	ASC PI
93451	Right heart cath	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed	G2
93452	Left hrt cath w/ ventrclgrphy	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
93453	R&I hrt cath w/ ventriclgrphy	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
C9752	Intraosseous des lumb/ sacrum	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum	G2

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HCPCS code	Short descriptor	Long descriptor	ASC PI
C9754	Perc AV fistula, any site	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	G2
C9755	RF magnetic-guided AV fistula	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	G2
93451	Right heart cath	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed	G2
93452	Left hrt cath w/ ventrclgrphy	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
93453	R&I hrt cath w/ ventriclgrphy	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
93454	Coronary artery angio s&i	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;	G2
93455	Coronary art/grft angio s&i	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography	G2
93456	R hrt coronary artery angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization	G2

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HCPCS code	Short descriptor	Long descriptor	ASC PI
93457	R hrt art/ grft angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization	G2
93458	L hrt artery/ ventricle angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	G2
93459	L hrt art/ grft angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	G2
93454	Coronary artery angio s&i	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;	G2
93455	Coronary art/grft angio s&i	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography	G2
93456	R hrt coronary artery angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization	G2
93457	R hrt art/ grft angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization	G2

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HCPCS code	Short descriptor	Long descriptor	ASC PI
93458	L hrt artery/ ventricle angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	G2
93459	L hrt art/ grft angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	G2

HCPCS code	Short descriptor	Long descriptor	ASC PI
93460	R&I hrt art/ ventricle angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	G2

HCPCS code	Short descriptor	Long descriptor	ASC PI
93461	R&I hrt art/ ventricle angio	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	G2

Device Intensive Procedures

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

MAC Use Only Effective January 1, 2019

HCPCS C1890 and both its short and long descriptors are included in table 3. Additional information and requirements will be issued in a future CR release.

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Table 3. Device Intensive Procedures that are Performed without a Device Effective January 1, 2019

HCPCS code	Short descriptor	Long descriptor	ASC PI
C1890	No device w/dev-intensive px	No implantable/insertable device used with device-intensive procedures	J7

Drugs, Biologicals, and Radiopharmaceuticals

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

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

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

CY 2019 HCPCS Code	CY2019 Short Descriptor	CY 2019 Long Descriptor	CY 2019 SI
C9035	Injection, aristada initio	Injection, aripiprazole lauroxil (aristada initio), 1 mg	K2
C9036	Injection, patisiran	Injection, patisiran, 0.1 mg	K2
C9037	Injection, risperidone	Injection, risperidone (perseris), 0.5 mg	K2
C9038	Inj mogamulizumab-kpkc	Injection, mogamulizumab-kpkc, 1 mg	K2
C9039	Injection, plazomicin	Injection, plazomicin, 5 mg	K2
C9407	Iodine i-131 iobenguane, dx	Iodine i-131 iobenguane, diagnostic, 1 millicurie	K2
J0584	Injection, burosumab-twza 1m	Injection, burosumab-twza 1 mg	K2
J0841	Inj crotalidae im f(ab')2 eq	Injection, crotalidae immune f(ab')2 (equine), 120 mg	K2
J1746	Inj., ibalizumab-uiyk, 10 mg	Injection, ibalizumab-uiyk, 10 mg	K2
J2186	Inj., meropenem, vaborbactam	Injection, meropenem and vaborbactam, 10mg/10mg (20mg)	K2
J3397	Inj., vestronidase alfa-vjbk	Injection, vestronidase alfa-vjbk, 1 mg	K2
J7177	Inj., fibryga, 1 mg	Injection, human fibrinogen concentrate (fibryga), 1 mg	K2
J7329	Inj, trivisc 1 mg	Hyaluronan or derivative, trivisc, for intra-articular injection, 1 mg	K2
J9044	Inj, bortezomib, nos, 0.1 mg	Injection, bortezomib, not otherwise specified, 0.1 mg	K2
Q4195	Puraply 1 sq cm	Puraply, per square centimeter	K2
Q4196	Puraply am 1 sq cm	Puraply am, per square centimeter	K2
Q5111	Injection, udenyca 0.5 mg	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	K2

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

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

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

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

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9463	Injection, aprepitant, 1 mg	J0185	Injection, aprepitant, 1 mg
C9466	Injection, benralizumab, 1 mg	J0517	Injection, benralizumab, 1 mg
C9014	Injection, cerliponase alfa, 1 mg	J0567	Injection, cerliponase alfa, 1 mg
C9015	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units
C9034	Injection, dexamethasone 9%, intraocular, 1 mcg	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram
C9493	Injection, edaravone, 1 mg	J1301	Injection, edaravone, 1 mg

CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9033	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
C9029	Injection, guselkumab, 1 mg	J1628	Injection, guselkumab, 1 mg
C9497	Loxapine, inhalation powder, 10 mg	J2062	Loxapine for inhalation, 1 mg
C9464	Injection, rolapitant, 0.5 mg	J2797	Injection, rolapitant, 0.5 mg
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
C9016	Injection, triptorelin, extended-release, 3.75 mg	J3316	Injection, triptorelin, extended-release, 3.75 mg

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CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2019 HCPCS Code	CY 2019 Long Descriptor
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Q9995	Injection, emicizumab-kxwh, 0.5 mg	J7170	Injection, emicizumab-kxwh, 0.5 mg
C9468	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu
C9465	Hyaluronan or derivative, durolane, for intra-articular injection, per dose	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg
C9030	Injection, copanlisib, 1 mg	J9057	Injection, copanlisib, 1 mg
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine
C9492	Injection, durvalumab, 10 mg	J9173	Injection, durvalumab, 10 mg
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	J9229	Injection, inotuzumab ozogamicin, 0.1 mg
C9467	Injection, rituximab and hyaluronidase, 10 mg	J9311	Injection, rituximab 10 mg and hyaluronidase
J9310	Injection, rituximab, 100 mg	J9312	Injection, rituximab, 10 mg

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

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

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

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

e. Biosimilar Payment Policy

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

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

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

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based payment applies.

g. Drugs and Biologicals with a Change in Status Indicator

HCPCS code Q2049, has a change in status indicator from "Y5" to "K2", effective January 1, 2019, since we have pricing information for this drug code.

h. New Biosimilar HCPCS Code Effective October 1, 2018

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

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

HCPCS Code	Short Descriptor	Long Descriptor	ASC PI	Effective Date
Q5110	Nivestym	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	K2	10/01/2018

Skin Substitute Procedure Edits

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

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

CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/ Low Assignment	CY 2019 High/Low Assignment
C9363	Integra meshed bil wound mat	N1	High	High

CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4100	Skin substitute, nos	N1	Low	Low
Q4101	Apligraf	N1	High	High
Q4102	Oasis wound matrix	N1	Low	Low
Q4103	Oasis burn matrix	N1	High	High*
Q4104	Integra bmwd	N1	High	High
Q4105	Integra drt or omnigraft	N1	High	High*
Q4106	Dermagraft	N1	High	High
Q4107	Graftjacket	N1	High	High
Q4108	Integra matrix	N1	High	High
Q4110	Primatrix	N1	High	High*
Q4111	Gammagraft	N1	Low	Low

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CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4115	Alloskin	N1	Low	Low
Q4124	Oasis tri-layer wound matrix	N1	Low	Low
Q4126	Memoderm/ derma/ tranz/ integup	N1	High	High*
Q4127	Talymed	N1	High	High

CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4128	Flexhd/ allopatchhd/ matrixhd	N1	High	High
Q4132	Grafix core, grafixpl core	N1	High	High
Q4133	Grafix stravix prime pl sqcm	N1	High	High
Q4134	Hmatrix	N1	Low	Low
Q4135	Mediskin	N1	Low	Low
Q4136	Ezderm	N1	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	N1	High	High
Q4138	Biodfence dryflex, 1cm	N1	High	High

CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4140	Biodfence 1cm	N1	High	High
Q4141	Alloskin ac, 1cm	N1	High	High*
Q4143	Repriza, 1cm	N1	High	High
Q4146	Tensix, 1cm	N1	High	High
Q4147	Architect ecm px fx 1 sq cm	N1	High	High*
Q4148	Neox neox rt or clarix cord	N1	High	High
Q4150	Allowrap ds or dry 1 sq cm	N1	High	High
Q4151	Amnioband, guardian 1 sq cm	N1	High	High
Q4152	Dermapure 1 square cm	N1	High	High
Q4153	Dermavest, plurivest sq cm	N1	High	High
Q4154	Biovance 1 square cm	N1	High	High
Q4156	Neox 100 or clarix 100	N1	High	High

CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4157	Revitalon 1 square cm	N1	High	High*

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CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4158	Kerecis omega3, per sq cm	N1	High	High*
Q4159	Affinity1 square cm	N1	High	High
Q4160	Nushield 1 square cm	N1	High	High
Q4161	Bio-connekt per square cm	N1	High	High
Q4163	Woundex, bioskin, per sq cm	N1	High	High
Q4164	Helicoll, per square cm	N1	High	High*
Q4165	Keramatrix, per square cm	N1	Low	Low
Q4166	Cytal, per square centimeter	N1	Low	Low
Q4167	Truskin, per sq centimeter	N1	Low	Low
Q4169	Artacent wound, per sq cm	N1	High	High*
Q4170	Cygnus, per sq cm	N1	Low	Low
Q4173	Palingen or palingen xplus	N1	High	High
Q4175	Miroderm	N1	High	High
Q4176	Neopatch, per sq centimeter	N1	Low	Low
Q4178	Floweramniopatch, per sq cm	N1	High	High
Q4179	Flowerderm, per sq cm	N1	Low	Low
Q4180	Revita, per sq cm	N1	High	High
Q4181	Amnio wound, per square cm	N1	High	High*
Q4182	Transcyte, per sq centimeter	N1	Low	Low
Q4183	Surgigraft, 1 sq cm	N1	Low	Low
Q4184	Cellesta, 1 sq cm	N1	Low	Low
Q4186	Epifix 1 sq cm	N1	High	High
Q4187	Epicord 1 sq cm	N1	High	High
Q4188	Amnioarmor 1 sq cm	N1	Low	Low
Q4190	Artacent ac 1 sq cm	N1	Low	Low
Q4191	Restorigin 1 sq cm	N1	Low	Low
Q4193	Coll-e-derm 1 sq cm	N1	Low	Low
Q4194	Novachor 1 sq cm	N1	Low	Low
Q4195+	Puraply 1 sq cm	K2	High	High
Q4196+	Puraply am 1 sq cm	K2	High	High

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CY 2019 HCPCS Code	CY 2019 Short Descriptor	ASC PI	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4197	Puraply xt 1 sq cm	N1	High	High
Q4198	Genesis amnio membrane 1sqcm	N1	Low	Low
Q4200	Skin te 1 sq cm	N1	Low	Low
Q4201	Matrion 1 sq cm	N1	Low	Low
Q4203	Derma-gide, 1 sq cm	N1	Low	Low
Q4204	Xwrap 1 sq cm	N1	Low	Low

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

+ OPPS Pass-through payment status in CY 2019.

CY 2019 ASC Wage Index

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

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

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

Coverage Determinations

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

Additional information

The official instruction, CR11108, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4191CP.pdf*.

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

Document history

Date of change	Description
January 16, 2019	This article was revised to correct Table 2. The ASC PI for C9752, C9754 and C9755 should have been J8 (not G2).
December 31, 2018	Initial article released.

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

Durable Medical Equipment

2019 DMEPOS HCPCS code jurisdiction list

Provider types affected

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

Provider action needed

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

What you need to know

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

Additional information

The official instruction, CR 11085, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4200CP.pdf*.

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

Document history

Date of change	Description
January 11, 2019	Initial article released.

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

New physician specialty code for undersea and hyperbaric medicine

***Note**: This article was revised on December 20, 2018, to reflect the revised CR10666 issued on December 19. The CR was revised to clarify certain MAC reporting requirements for the D2 specialty, the taxonomy requirements for the D4 specialty, and to reflect the D1 specialty code as a supplier specialty and not a physician specialty. In this article, only the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same. This information was previously published in the July 2018 Medicare B Connection, page 14.*

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.

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

The official instructions, CR 10666, issued to your MAC are available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R309FM.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4184CP.pdf*.

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

Document history

Date of change	Description
December 20, 2018	The article was revised to reflect the revised CR10666 issued on December 19. The CR was revised to clarify certain MAC reporting requirements for the D2 specialty, the taxonomy requirements for the D4 specialty, and to reflect the D1 specialty code as a supplier specialty and not a physician specialty. In this article, only the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same.
July 13, 2018	Initial article released.

MLN Matters® Number: MM10666 *Revised*
Related CR Release Date: December 19, 2018
Related CR Transmittal Number: R4084CP, R309FM
Related Change Request (CR) Number: 10666
Effective Date: January 1, 2019
Implementation Date: January 7, 2019

How unsolicited/voluntary refunds are handled

Medicare contractors receive unsolicited/voluntary refunds (i.e., monies received not related to an open account receivable). Part A contractors generally receive unsolicited/voluntary refunds in the form of an adjustment bill, but may receive some unsolicited/voluntary refunds as checks. Part B contractors generally received checks. Substantial funds are returned to the trust funds each year through such unsolicited/voluntary refunds.

The Centers for Medicare & Medicaid Services reminds providers that:

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.

Source: *CMS Pub. 100-06, Chapter 5, Section 410.10*

2019 Medicare Part B Participating Physician and Supplier Directory available after January 30

The *Medicare Part B Participating Physician and Supplier Directory* (MEDPARD) contains names, addresses, telephone numbers, and specialties of physicians and suppliers who have agreed to participate in accepting assignment on all Medicare Part B claims for covered items and services.

The MEDPARD listing will be available no later than January 30 on the First Coast Medicare provider website at *https://medicare.fcso.com/MEDPARD/*.

Source: Pub 100-04, Transmittal 4165, CR 10942

FEES

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Medicare and non-Medicare patients, either at the time the laboratory submits the claim or when the flat rate is set by the MAC.

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

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

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

Additional information

The official instruction, CR11146, issued to your MAC regarding this change, is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4199CP.pdf*.

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

Document history

Date of change	Description
January 11, 2019	Initial article released.

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

This section of *Medicare B Connection* features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives. These initiatives are designed to ensure the appropriateness of medical care and to make sure that the Medicare administrative contractor (MAC) jurisdiction N (JN) Part A LCDs and review guidelines are consistent with accepted standards of medical practice.

Refer to our LCDs/Medical Coverage web page at *https://medicare.fcso.com/Landing/139800.asp* for full-text LCDs, including final LCDs, draft LCDs available for comment, LCD statuses, and LCD comment/response summaries.

Effective and notice dates

Effective dates are provided in each LCD, and are based on the date services are furnished unless otherwise noted in the LCD. Medicare contractors are required to offer a 45-day notice period for LCDs; the date the LCD is posted to the website is considered the notice date.

Electronic notification

To receive quick, automatic notification when new and revised LCDs are posted to the website, subscribe to the First Coast eNews mailing list. Simply go to *https://medicare.fcso.com/Header/137525.asp*, enter your email address and select the subscription option that best meets your needs.

More information

For more information, or, if you do not have internet access, to obtain a hardcopy of a specific LCD, contact Medical Policy at:

Medical Policy and Procedures
PO Box 2078
Jacksonville, FL 32231-0048

Looking for LCDs?

Would you like to find local coverage determinations (LCD) in 10 seconds or less? First Coast's LCD lookup, available at *https://medicare.fcso.com/coverage_find_lcds_and_ncds/lcd_search.asp*, helps you find the coverage information you need quickly and easily. Just enter a procedure code, keyword, or the LCD's "L number," click the corresponding button, and the application will automatically display links to any LCDs applicable to the parameters you specified. Best of all, depending upon the speed of your internet connection, the LCD search process can be completed in less than 10 seconds.

Advance beneficiary notice

Modifier GZ must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they **have not had** an advance beneficiary notification (ABN) signed by the beneficiary.

Note: Line items submitted with the modifier GZ will be automatically denied and will not be subject to complex medical review.

Modifier GA must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they **do have** on file an ABN signed by the beneficiary.

All claims not meeting medical necessity of a local coverage determination must append the billed service with modifier GA or GZ.

2019 Medicare physician fee schedule payment rates and participation program

The annual physician and supplier participation period begins January 1 of each year, and runs through December 31. The annual participation enrollment is scheduled to begin mid-November of each year. (**Note**: The dates listed for release of the participation enrollment/fee disclosure material are subject to publication of the annual final rule.)

The 2019 Medicare physician fee schedule (MPFS) payment rates will be posted to First Coast Service Options' Medicare Provider website after publication of the MPFS final rule in the *Federal Register*. This publication usually occurs in mid-November.

Source: Publication 100-04, Chapter 1, Section 30.3.12.1 (B2)

New LCD

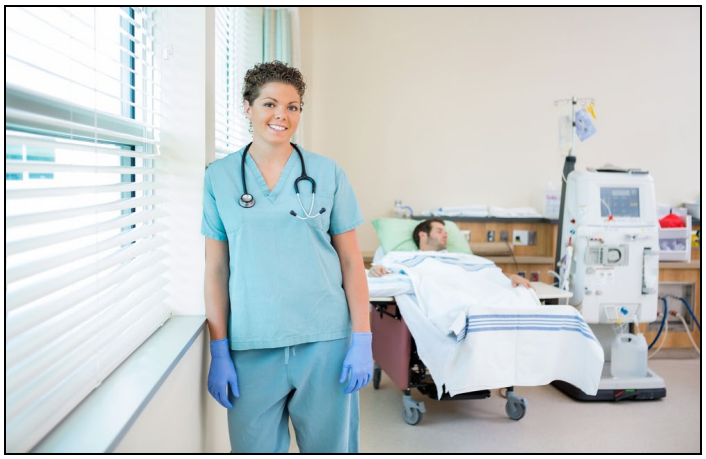
Frequency of hemodialysis – new Part A and Part B LCD

LCD ID number: L37564 (Florida/Puerto Rico/ U.S. Virgin Islands)

The local coverage determination (LCD) for frequency of hemodialysis was developed to continue to provide coverage for additional dialysis treatments beyond the standard thrice weekly payment as it is outlined on the Medicare Benefit. The list of diagnosis codes supporting additional treatments has been expanded. Also, additional clarifying language related to documentation requirements to support the additional services and the use of Modifiers and clear limitations have been established. Furthermore, in creating this new LCD, the current LCD for frequency of hemodialysis services (L33970) and the companion "Coding Guidelines" will be retired when this new LCD and coding & billing article becomes effective.

Effective date

This new LCD is effective for services rendered **on or after February 25, 2019.** LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.



A coding article for an LCD (when present) may be found by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: To review active, future and retired LCDs, please *click here*.

Revisions to LCDs

Routine foot care – revision to the Part B LCD

LCD ID number: L33941 (Florida/Puerto Rico/ U.S. Virgin Islands)

Based on review of the local coverage determination (LCD) for routine foot care, it was determined that some of the italicized language in the "Coverage Indications, Limitations, and/or Medical Necessity" section of the LCD does not represent direct quotations from some of the Centers for Medicare & Medicaid Services (CMS) sources listed in the LCD; therefore, this LCD is being revised to assure consistency with the CMS sources.

Effective date

This LCD revision is effective for services rendered **on or after January 15, 2019.** LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A coding article for an LCD (when present) may be found by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: To review active, future and retired LCDs, please *click here*.

Syphilis test – revision to the Part A and Part B LCD

LCD ID number: L33754 (Florida/Puerto Rico/ U.S. Virgin Islands)

Based on review of the local coverage determination (LCD) for syphilis test, typographical errors were corrected. In addition, the "Sources of Information and Basis for Decision" section of the LCD was revised to remove outdated sources.

Effective date

The LCD revision related to the typographical errors is effective for claims processed **on or after January 15, 2019**.

The LCD revision related to the sources of information is effective for services rendered **on or after January 15, 2019.** LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A coding article for an LCD (when present) may be found by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: To review active, future and retired LCDs, please *click here*.

Vertebroplasty, vertebral augmentation; percutaneous – revision to the Part A and Part B LCD

LCD ID number: L34976 (Florida/Puerto Rico/ U.S. Virgin Islands)

Based on review of the local coverage determination (LCD) for vertebroplasty, vertebral augmentation; percutaneous, language was removed in the "Limitations of Coverage" section of the LCD.

In addition, based on change request (CR) 10901, the "Documentation Requirements" section of the LCD was revised to update the section number for Pub. 100-08, Chapter 13 from 13.5.1 to 13.5.4.

Effective date

The LCD revision related to the "Limitations of Coverage" section of the LCD is effective for claims processed **on or after January 22, 2019.**

The LCD revision related to CR 10901 is effective for claims processed **on or after January 8, 2019**, for services rendered **on or after September 26, 2018**. LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A coding article for an LCD (when present) may be found by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: To review active, future and retired LCDs, please *click here*.

Additional information

Independent diagnostic testing facility (IDTF) – revision to the Part B LCD "Coding Guideline" attachment

LCD ID number: L33910 (Florida/Puerto Rico/ U.S. Virgin Islands)

Based on change request (CR) 11043, the local coverage determination (LCD) "coding guideline" attachment for independent diagnostic testing facility (IDTF) was revised. The descriptor for physician supervision of diagnostic procedures indicator "03" was revised to include the following: "(Diagnostic imaging procedures performed by a Registered Radiologist Assistant (RRA) who is certified and registered by The American Registry of Radiologic Technologists (ARRT) or a Radiology Practitioner Assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA), and is authorized to furnish the procedure under state law, may be performed under direct supervision)".

Effective date

This revision to the LCD "Coding Guideline" attachment is effective for services rendered **on or after January 1, 2019.** LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A coding article for an LCD (when present) may be found by selecting "Related Local Coverage Documents" in the "Section Navigation" drop-down menu at the top of the LCD page.

Note: To review active, future and retired LCDs, please *click here*.

Upcoming provider outreach and educational events

Topic: Medicare quarterly updates (Part B)

Date: Wednesday, March 20
Time: 11:00 a.m.-12:30 p.m.
Type of Event: Webcast

https://medicare.fcso.com/Events/0425417.asp

Note: Unless otherwise indicated, designated times for educational events are stated as ET, and the focus is to Florida, Puerto Rico, and the U.S. Virgin Islands.

Two easy ways to register

Online – Visit our provider training website at *https://gm1.geolearning.com/geonext/fcso/opensite.geo*, log on to your account and select the course you wish to register. Class materials are available under "My Courses" no later than one day before the event**.**

First-time User? Set up an account by completing *Request User Account Form* online. Providers who do not have yet a national provider identifier may enter "99999" in the NPI field. You will receive logon information within 72 hours of your request.

Fax – Providers without internet access may request a fax registration form through our Registration Hotline at 1-904-791-8103. Class materials will be faxed to you the day of the event.

Please Note:

- Pre-registration is required for all teleconferences, webcasts and in-person educational seminars.
- Dates and times are subject to change prior to opening of event registration.

Registrant's Name: _____

Registrant's Title: _____

Provider's Name: _____

Telephone Number: _____ Fax Number: _____

Email Address: _____

Provider Address: _____

City, State, ZIP Code: _____

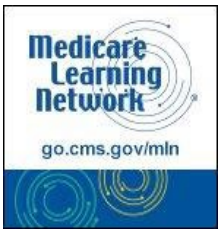
Keep checking our website, *https://medicare.fcso.com/*, for details and newly scheduled educational events (teleconferences, webcasts, etc.) or call the First Coast Provider Education Registration Hotline at 1-904-791-8103 to learn more about the about our newest training opportunities for providers.

Never miss a training opportunity

If you or your colleagues were unable to attend one of our past Medicare educational webcasts, you still have the opportunity to learn about the topics covered during the training session. Visit the First Coast Medicare training website, download the recording of the event, and listen to the webcast when you have the time.

Take advantage of 24-hour access to free online training

In addition to live training events, we also offer you the advantage of self-paced, free online courses that will allow you and your staff to train when and where it is most convenient for you. In addition, our comprehensive course catalog allows you to find the Medicare training that fits your specific needs, and several of our online courses offer CEUs. Learn more on the First Coast Medicare training website and explore our catalog of online courses.



CMS MLN Connects®

The Centers for Medicare & Medicaid Services (CMS) *MLN Connects®* is an official *Medicare Learning Network®* (*MLN*) – branded product that contains a week's worth of news for Medicare fee-for-service (FFS) providers. CMS sends these messages weekly to national health industry provider associations, who then disseminates the *MLN Connects®* to its membership as appropriate.

MLN Connects® for January 3, 2019

MLN Connects® for Thursday, January 3, 2019

View this edition as a PDF

News & Announcements

- Medicare Shared Savings Program: Final Rule Creates Pathways to Success
- Physician Compare Preview Period Extended to January 7
- Hospice Provider Preview Reports: Review Your Data by January 9
- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- Laboratory Date of Service Exception Policy: Enforcement Discretion Exercised until July 1
- Quality Payment Program: 2019 Resources
- eCQM Resource: The Collaborative Measure Development Workspace
- Medicare Enrollment Application Fee for CY 2019
- Delivery of Initial Prescriptions of Immunosuppressive Drugs
- Antipsychotic Drug Use in Nursing Homes: Trend Update
- Get Your Patients Off to a Healthy Start in 2019

Provider Compliance

- Coding for Specimen Validity Testing Billed in Combination with Urine Drug Testing — Reminder

Claims, Pricers & Codes

- Medicare Diabetes Prevention Program: Valid Claims

Upcoming Events

- ESRD Quality Incentive Program: CY 2019 ESRD PPS Final Rule Call — January 15
- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call —January 22
- Home Health Patient-Driven Groupings Model Call — February 12

Medicare Learning Network Publications & Multimedia

- Claim Status Category and Codes Update MLN Matters Article — New
- Ensuring Only the Active Billing Hospice Can Submit a Revocation MLN Matters Article — New
- Guidance for MACs Processing BFCC QIO 2MN SSR Determinations MLN Matters Article — New
- I/OCE Version 20.0: January 2019 MLN Matters Article — New
- FISS/DDE: New Search Features MLN Matters Article — New
- Quality Payment Program in 2018: Group Participation Web-Based Training — New
- SNF PPS Call: Audio Recording and Transcript — New
- IRF Medical Review Changes MLN Matters Article — Revised
- New Physician Specialty Code for Undersea and Hyperbaric Medicine MLN Matters Article — Revised
- Repetitive, Scheduled Non-emergent Ambulance Prior Authorization Model MLN Matters Article — Revised
- Looking for Educational Materials?

MLN Connects® for January 10, 2019

MLN Connects® for January 10, 2019

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News & Announcements

- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- New Medicare Card: Transition Period Ends December 31
- January is Cervical Health Awareness Month

Provider Compliance

- Proper Use of the KX Modifier for Part B Immunosuppressive Drug Claims — Reminder

Upcoming Events

- ESRD Quality Incentive Program: CY 2019 ESRD PPS Final Rule Call — January 15
- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call —January 22
- New Electronic System for Provider Reimbursement Review Board Appeals Call — February 5
- Home Health Patient-Driven Groupings Model Call — February 12
- New Part D Opioid Overutilization Policies Call — February 14

Medicare Learning Network Publications & Multimedia

- Orders for DMEPOS Items: What Suppliers Need to Know MLN Matters Article — New
- ASC Payment System: January 2019 Update MLN Matters Article — New
- Hospital OPPS: January 2019 Update MLN Matters Article — New
- CLFS and Laboratory Services: CY 2019 Update MLN Matters Article — New
- Immunosuppressive Guidance: Updates MLN Matters Article — New
- Home Health Rural Add-on Payment MLN Matters Article — Revised
- Implantable Defibrillators: NCD 20.4 MLN Matters Article — Revised
- Medicare Billing: Form CMS-1500 and the 837 Professional Web-Based Training Course — Revised

MLN Connects® -- Special Edition for January 16, 2019

New Medicare Card Mailing Complete, 58% of Claims Submitted with MBI

CMS finished mailing new Medicare cards to people with Medicare across all *mailing waves*, including Wave 7 states and territories and also to people with Medicare Parts A&B who live in Canada and Mexico.

Medicare patients are using their new cards in doctor's offices and other health care facilities. For the week ending January 11, 2019, fee-for-service health care providers submitted 58% of claims with new Medicare Beneficiary Identifiers (MBIs), showing that many of you are already successfully submitting claims with MBIs. While you can continue using the former Social Security Number-based Health Insurance Claim Numbers during the transition period, we encourage you to use the new MBIs for all Medicare transactions.

To ensure that you have access to your patients' new numbers, you can individually look up MBIs if you have access to your Medicare Administrative Contractor's secure *provider portal*. Likewise, your patients can access their new Medicare numbers or print official cards within their secure *MyMedicare.gov* accounts.

If your Medicare patients say they did not get a card, instruct them to:

- Look for unopened mail. We mailed new Medicare cards in a plain white envelope from the Department of Health and Human Services.
- Sign into *MyMedicare.gov* to get their new numbers or print official cards. They need to create an account if they do not already have one.
- Call 1-800-MEDICARE (1-800-633-4227), so we can help them get their new cards.
- Continue to use their current cards to get health care services. They can use their old cards until December 31, 2019.

MLN Connects® for January 17, 2019

MLN Connects® for January 17, 2019

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News & Announcements

- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- Hospice Quality Reporting Program: Quality Measure User's Manual
- Qualified Medicare Beneficiary Billing Requirements
- Medicare Diabetes Prevention Program: Become a Medicare Enrolled Supplier
- Glaucoma Awareness Month: Make a Resolution for Healthy Vision

Provider Compliance

- Hospice Election Statements Lack Required Information or Have Other Vulnerabilities — Reminder

Upcoming Events

- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call — January 22
- Comparative Billing Report Webinar on Intensity-Modulated Radiation Therapy Webinar — January 24
- New Electronic System for Provider Reimbursement Review Board Appeals Call — February 5
- Home Health Patient-Driven Groupings Model Call — February 12
- New Part D Opioid Overutilization Policies Call — February 14

Medicare Learning Network Publications & Multimedia

- 2019 DMEPOS HCPCS Code Jurisdiction List MLN Matters Article — New
- DMEPOS CBP: Quarterly Update MLN Matters Article — New
- NCCI PTP Edits: Quarterly Update MLN Matters Article — New
- Medicare Claims Processing Manual MLN Matters Article — New
- Clinical Lab Fee Schedule: Medicare Travel Allowance Fees MLN Matters Article — New
- New Waived Tests MLN Matters Article — New
- ICD-10 and Other Coding Revisions to NCDs MLN Matters Article — Revised
- Local Coverage Determinations MLN Matters Article — Revised
- Skilled Nursing Facility ABN MLN Matters Article — Revised
- Medicare Preventive Services Educational Tool — Revised
- Remittance Advice: An Overview Booklet — Revised

Medicare Learning Network®

The *Medicare Learning Network®* (*MLN*) is the home for education, information, and resources for the health care professional community. The *MLN* provides access to CMS Program information you need, when you need it, so you can focus more on providing care to your patients. Find out what the *MLN* has to offer you and your staff at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html*.

Phone numbers

Customer service
866-454-9007
877-660-1759 (speech and hearing impaired)

Education event registration hotline
904-791-8103 (NOT toll-free)

Electronic data interchange (EDI)
888-670-0940

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866-454-9007
877-660-1759 (TTY)

Fax number (for general inquiries)
904-361-0696

Interactive voice response (IVR) system
877-847-4992

Provider enrollment
866-454-9007
877-660-1759 (TTY)

The SPOT help desk
855-416-4199
email: *FCSOSPOTHelp@FCSO.com*

Addresses

Claims
Medicare Part B Claims
P.O. Box 2525
Jacksonville, FL 32231-0019

Redeterminations
Medicare Part B Redetermination
P.O. Box 2360
Jacksonville, FL 32231-0018

Redetermination of overpayments
Overpayment Redetermination, Review Request
P.O Box 45248
Jacksonville, FL 32232-5248

Reconsiderations
C2C Innovative Solutions, Inc.
Part B QIC South Operations
ATTN: Administration Manager
PO Box 45300
Jacksonville, FL 32232-5300

General inquiries
General inquiry request
P.O. Box 2360
Jacksonville, FL 32231-0018

Email**:** *EDOC-CS-FLINQB@fcso.com>>*
Online form: *https://medicare.fcso.com/Feedback/161670.asp*

Provider enrollment
Provider Enrollment
P.O. Box 3409
Mechanicsburg, PA 17055-1849

Special or overnight deliveries
Provider Enrollment
2020 Technology Parkway Suite 100
Mechanicsburg, PA 17055-1849

Medical policy
Medical Policy and Procedure
P.O. Box 2078
Jacksonville, FL 32231-0048
Email: *medical.policy@fcso.com*

Medicare secondary payer
Medicare Part B Secondary Payer Dept.
P.O. Box 44078
Jacksonville, FL 32231-4078

Electronic data interchange (EDI)
Medicare EDI
P.O. Box 44071
Jacksonville, FL 32231-4071

Overpayments
Medicare Part B Debt Recovery
P.O. Box 44141
Jacksonville, FL 32231-4141

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Medicare Education and Outreach
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Jacksonville, FL 32232-5157

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Jacksonville, FL 32232-5087

Freedom of Information Act requests
FOIA Florida
P.O. Box 45268
Jacksonville, FL 32232-5268

Overnight mail and/or special courier service
First Coast Service Options Inc.
532 Riverside Avenue
Jacksonville, FL 32202-4914

Websites

Provider
First Coast Service Options Inc. (First Coast), your CMS-contracted Medicare administrative contractor
https://medicare.fcso.com

Find your *other contractors* (e.g. DME, HHA, etc)

Centers for Medicare & Medicaid Services
https://www.cms.gov

E-learning Center
https://gm1.geolearning.com/geonext/fcso/opensite.geo

Beneficiaries
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https://www.medicare.gov

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877-660-1759 (TTY)

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888-845-8614
877-660-1759 (TTY)

The SPOT help desk

855-416-4199
Email: *FCSOSPOTHelp@FCSO.com*

Addresses

Claims

Medicare Part B Claims
P.O. Box 45098
Jacksonville, FL 32232-5098

Redeterminations

Medicare Part B Redetermination
P.O. Box 45024
Jacksonville, FL 32232-5024

Redetermination of overpayments

First Coast Service Options Inc.
P.O Box 45091
Jacksonville, FL 32232-5091

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Part B QIC South Operations
ATTN: Administration Manager
PO Box 45300
Jacksonville, FL 32232-5300

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CMS-855 Applications
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Mechanicsburg, PA 17055-1849

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Jacksonville, FL 32231-0048
Email: *medical.policy@fcso.com*

Medicare secondary payer

Medicare Part B Secondary Payer Dept.
P.O. Box 44078
Jacksonville, FL 32231-4078

Electronic data interchange (EDI)

Medicare EDI, 4C
P.O. Box 44071
Jacksonville, FL 32231-4071

Overpayments

Medicare Part B Debt Recovery
P.O. Box 45013
Jacksonville, FL 32232-5013

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Medicare Education and Outreach
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Jacksonville, FL 32232-5157

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Fraud and abuse complaints
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Jacksonville, FL 32232-5087

Freedom of Information Act requests

FOIA USVI
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1-877-715-1921
1-888-216-8261 (speech and hearing impaired)

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904-791-8103 (NOT toll-free)
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Medicare Part B Claims
P.O. Box 45036
Jacksonville, FL 32232-5036

Redeterminations
Medicare Part B Redetermination
P.O. Box 45056
Jacksonville, FL 32232-5056

Redetermination of overpayments
First Coast Service Options Inc.
P.O Box 45015
Jacksonville, FL 32232-5015

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ATTN: Administration Manager
PO Box 45300
Jacksonville, FL 32232-5300

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Jacksonville, FL 32232-5098

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Jacksonville, FL 32231-5040

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