Medicare B CONNECTION

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FIRST COAST SERVICE OPTIONS, INC.

A Newsletter for MAC Jurisdiction N Providers

April 2015

In this issue

'Doc Fix' fixed – President signs the Medicare Access and CHIP Reauthorization Act of 2015 into law

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 was signed into law April 16, averting a potential negative 21 percent update in the Medicare physician fee schedule and adding a. 0.5 percent update starting July 1, 2015.

The Act also restores exceptions to the therapy cap, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals that expired on April 1.

Section 202 of MACRA revises Medicare provisions affecting the outpatient therapy caps:

- The outpatient therapy cap exception process will remain in effect for claims with dates of service through December 31, 2017.
- Hospital outpatient claims for therapy services with dates of service through December 31, 2017, continue to apply to the therapy caps.
- Editing remains in effect to suspend claims for therapy services that exceed the $3,700 threshold for claims with dates of service through December 31, 2017.

MACRA extends through December 31, 2017, a three percent increase in the ambulance fee schedule for rural transports and a two percent increase for urban transports.

The Centers for Medicare & Medicaid Services will release a separate instruction to address mandated changes to the subsequent review of these claims.

Contents

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.

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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.

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Subscribe to First Coast Service Options *eNews*, to learn the latest Medicare news and critical program changes affecting the provider community. Join as many lists as you wish, in English or Spanish, and customize your subscription to fit your specific needs, line of business, specialty, or topics of interest. So, *subscribe to eNews, and stay informed.*

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 *http://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.

Your Feedback Matters

To ensure that our website meets the needs of our provider community, we carefully analyze your feedback and implement changes to better meet your needs. Discover the results of your feedback on our "*Website enhancements*" page. You'll find the latest enhancements to our provider websites and find out how you can share your thoughts and ideas with First Coast's Web team.

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 *http://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 *http://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 (wavier 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.

July update to the correct coding initiative edits

Provider types affected

This *MLN Matters*® article is intended for physicians, other providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

Change request (CR) 9108 informs MACs about the release of the latest package of national correct coding initiative (NCCI) edits, version 21.2, which will be effective July 1, 2015. Make sure that your billing staffs are aware of these changes.

Background

The Centers for Medicare & Medicaid Services (CMS) developed the NCCI edits to promote national correct coding methodologies and to control improper coding that leads to inappropriate payment in Part B claims. The coding policies developed are based on coding conventions defined in the American Medical Association's *Current Procedural Terminology Manual*, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practice, and review of current coding practice.

The latest package of NCCI edits, version 21.2, effective July 1, 2015, will be available via the CMS Data Center (CDC). A test file will be available on or about May 2, 2015, and a final file will be available on or about May 17, 2015.

Version 21.2 will include all previous versions and updates from January 1, 1996, to the present. In the past, NCCI was organized in two tables: column one/column two correct coding edits and mutually exclusive code (MEC) edits. In order to simplify the use of NCCI edit files (two tables), on April 1, 2012, CMS consolidated these two edit files into the column one/column two correct coding edit file. Separate consolidations have occurred for the two-practitioner NCCI edit files and the two NCCI edit files used for OCE. It will only be necessary to search the column one/column two correct coding edit file for active or previously deleted edits. CMS no longer publishes a mutually exclusive edit file on its website for either practitioner or outpatient hospital services, since all active and **deleted edits will appear in the single column one/column two correct coding edit file on each website.**

The edits previously contained in the mutually exclusive edit file are NOT being deleted but are being moved to the column one/column two correct coding edit file.

Additional information

The official instruction, CR 9108 issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3222CP.pdf*.

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

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

MLN Matters® Number: MM9108
Related Change Request (CR) #: CR 9108
Related CR Release Date: March 27, 2015
Effective Date: July 1, 2015
Related CR Transmittal #: R3222CP
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Try our E/M interactive worksheet

First Coast Service Options (First Coast) Inc. is proud of its exclusive E/M interactive worksheet, available at *http://medicare.fcso.com/EM/165590.asp*. This resource was developed to assist providers with identifying the appropriate code to bill for evaluation and management (E/M) services performed during a specific patient visit. This interactive resource is ideal for use as a checklist by physicians or as a quality assurance tool by auditors, billing specialists, and coders. After you've tried the E/M interactive worksheet, send us your thoughts of this resource through our website feedback form, available at *http://medicare.fcso.com/Feedback/160958.asp*.

Ambulatory Surgical Center

April 2015 update of the ambulatory surgical center payment system

***Note**: This article was revised April 2 and April 17, 2015, respectively, to revised to delete the word "only" from items 1.a. and 1.b. under "Key points of CR 9100" and to add another bullet under "Claim Adjustment" to cover claims for dates of service April 1-June 30, 2014. In addition, the CR transmittal number, release date, and the Web address for accessing the CR are revised. All other information remains the same. This information was previously published in the March 2015 Medicare B Connection, Pages 8-10.*

Provider types affected

This *MLN Matters*® article is intended for physicians and ambulatory surgical centers (ASCs) submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

CR 9100 describes changes to and billing instructions for various payment policies implemented in the April 2015 ASC payment system update and includes updates to the Healthcare Common Procedure Coding System (HCPCS). Make sure your billing staffs are aware of these changes.

Key points of CR 9100

1. New device pass-through category and device offset from payment

Additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the outpatient prospective payment system (OPPS). 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 two, but not more than three years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that additional categories be created for transitional pass-through payment of new medical devices not described by current or expired categories of devices. This policy was implemented in the 2008 revised ASC payment system.

CMS is establishing one new HCPCS device pass-through category as of April 1, 2015, for the OPPS and the ASC payment systems. The table, below, provides a listing of new coding and payment information concerning the new device category for transitional pass-through payment. HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser) is assigned ASC PI= J7 (OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced).

New device pass-through code HCPCS

HCPCS	Short descriptor	Long descriptor	ASC PI
C2623	Cath, translumin, drug-coat	Catheter, transluminal angioplasty, drug-coated, non-laser	J7

a. Device offset from payment

The C2623 device should always be billed with *CPT*® *37224* (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty), or *CPT*® *37226* (*Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed*).

The Centers for Medicare & Medicare Services (CMS) has determined that a portion of the OPPS payment associated with the cost of HCPCS code C2623 is reflected in the OPPS payment for *CPT*® codes *37224* and *37226*. The ASC code pair file will be used to establish the reduced ASC payment amount for *CPT*® *37224* and *37226*, only when billed with HCPCS code C2623.

b. Billing instructions for *CPT*® *37224* and *37226*

Pass-through category C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), is to be billed, and paid for, as a pass-through device only when provided with *CPT*® *37224* (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty), or *CPT*® *37226* (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) beginning on and after C2623's effective date of April 1, 2015.

2. New services

No new services have been assigned for payment in the ASC payment system effective April 1, 2015.

3. Drugs, biologicals, and radiopharmaceuticals

a. New April 2015 HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals.

For April 2015, six new HCPCS codes, shown in the table below, have been created for reporting drugs and

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biologicals in the ASC setting, where there have not previously been specific codes available.

New April 2015 HCPCS codes effective for certain drugs, biologicals, and radiopharmaceuticals

HCPCS code[1]	Long descriptor	ASC PI
C9445	Injection, c-1 esterase inhibitor (recombinant), Ruconest, 10 units	K2
C9448	Netupitant 300mg and palonosetron 0.5 mg, oral	K2
C9449	Injection, blinatumomab, 1 mcg	K2
C9450[2]	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K2
C9451	Injection, peramivir, 1 mg	K2
C9452	Injection, ceftolozane 50 mg and tazobactam 25 mg	K2

Notes:

1. HCPCS codes listed in the above table are new codes effective April 1, 2015.
2. HCPCS code C9450 is associated with Iluvien® and should not be used to report any other fluocinolone acetonide intravitreal implant (e.g., Retisert®). ASCs should note that the dosage descriptor for Iluvien is 0.01 mg. Because each implant is a fixed dose containing 0.19 mg of fluocinlone acetonide, ASCs should report 19 units of C9450 for each implant.

b. Drugs and biologicals with payments based on average sales price (ASP) effective April 1, 2015

For 2015, payment for non-pass-through drugs, biologicals and therapeutic radiopharmaceuticals is 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. Additionally, in 2015, a single payment of ASP + 6 percent for pass-through drugs, biologicals and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.

Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Updated payment rates effective April 1, 2015, are available the April 2015 ASC Addendum BB, which is at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html*.

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

a. Revised ASC payment indicator for code J0365

Effective April 1, 2015, the ASC payment indicator for HCPCS code J0365 (Injection, aprotonin, 10,000 kiu) will change from K2 to Y5. This code is listed in the following table, along with the effective date for the revised status indicator.

Drugs and biologicals with revised ASC payment indicators

HCPCS code	Long descriptor	ASC PI	Effective date
J0365	Injection, aprotonin, 10,000 kiu	Y5	4/1/2015

b. Other changes to 2015 HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals

Effective April 1, 2015, HCPCS code Q9975 (Factor VIII FC Fusion Recomb) will replace HCPCS code C9136 Factor viii (Eloctate). The payment indicator for Q9975 will remain K2. Code C9136 has a termination date of March 31, 2015.

The following table describes the HCPCS code change and effective date.

New HCPCS codes for certain drugs and biologicals effective April 1, 2015

HCPCS code	Short descriptor	Long descriptor	ASC PI	Add date
Q9975	Factor VIII FC Fusion Recomb	Injection, factor viii, fc fusion protein, (recombinant), per i.u.	K2	4/1/15

5. Billing guidance for corneal allograft tissue

ASCs can bill for corneal allograft tissue used for coverage (*CPT® 66180*) or revision (CPT® *66185*) of a glaucoma aqueous shunt with HCPCS code V2785. Contractors pay for corneal tissue acquisition reported with HCPCS code V2785 based on acquisition/invoice cost.

6. 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

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product, procedure, or service may be paid if covered by the program. Your MAC determines whether a drug, device, procedure, or other service meets all program requirements for coverage; for example, that it is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment.

7. Claim adjustment

Your MAC will adjust, as appropriate, claims that you bring to their attention that:

1. Have dates of service January 1-March 31, 2015, and were originally processed prior to the installation of the revised January 2015 ASC DRUG file.
2. Have dates of service April 1-June 30, 2014, and were originally processed prior to the installation of the revised April 2014 ASC DRUG file.
3. Have dates of service July 1-September 30, 2014, and were originally processed prior to the installation of the revised July 2014 ASC DRUG file.
4. Have dates of service October 1-December 30, 2014, and were originally processed prior to the installation of the revised October 2014 ASC DRUG file.

Additional information

The official instruction, CR 9100, issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3234CP.pdf*.

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

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Cardiac Services

National coverage determination (NCD) for single chamber and dual chamber permanent cardiac pacemakers

***Note**: This article is being republished correcting the breakout box regarding the acceptance of the KX modifier as an attestation. This information was previously published in the March edition of the Medicare B Connection, Pages 10-13*

Provider types affected

This *MLN Matters*® article is intended for physicians, providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for single chamber and dual chamber permanent cardiac pacemaker services provided to Medicare beneficiaries.

Provider action needed

Change request (CR) 9078 informs MACs that the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) and concluded that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Make sure that your billing staffs are aware of these changes.

Background

Permanent cardiac pacemakers refer to a group of self-contained, battery-operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads. Single chamber pacemakers typically target either the right atrium or right ventricle. Dual chamber pacemakers stimulate both the right atrium and the right ventricle.

On August 13, 2013, CMS issued an NCD, in which CMS concluded that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible, symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example, syncope, seizures, congestive heart failure, dizziness, or confusion).

The following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction.
2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.

The following indications are non-covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

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1. Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia.
2. Asymptomatic first degree atrioventricular block. *(exception)
3. Asymptomatic sinus bradycardia.
4. Asymptomatic sino-atrial block or asymptomatic sinus arrest. *(exception)
5. Ineffective atrial contractions (for example, chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia. *(exception)
6. Asymptomatic second degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart).
7. Syncope of undetermined cause. *(exception)
8. Bradycardia during sleep.
9. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block. *(exception)
10. Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy.
11. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia. *(exception)
12. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged.

MACs will determine coverage under Section 1862(a)(1)(A) of the Social Security Act for any other indications for the implantation and use of single chamber or dual chamber cardiac pacemakers that are not specifically addressed in this NCD. NOTES: MACs shall accept the inclusion of the KX modifier on the claim line(s) as an attestation by the practitioner and/or provider of the service that documentation is on file verifying the patient has non-reversible symptomatic bradycardia (symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example, syncope, seizures, congestive heart failure, dizziness, or confusion)).

Note: The final decision memorandum addresses Medicare policy specific to implanted permanent cardiac pacemakers, single chamber or dual chamber, for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Medicare coverage of removal/replacement of implanted permanent cardiac pacemakers, single chamber or dual chamber, for the above-noted

indications, were not addressed in the final decision. Therefore, it is expected that MACs will continue to apply the reasonable and necessary standard in determining local coverage within their respective jurisdictions for removal/replacement of implanted permanent cardiac pacemakers, single chamber or dual chamber.

Cardiac pacemaker Healthcare Common Procedure Coding System (HCPCS) and *Current Procedural Terminology* (*CPT*®) codes

Professional claims

Effective for claims with dates of service on or after August 13, 2013, MACs shall pay for implanted permanent cardiac pacemakers, single chamber or dual chamber, for one of the following *CPT*® codes if the claim contains at least one of the designated diagnosis codes in addition to the KX modifier:

- *33206* - Insertion or replacement of permanent pacemaker with transvenous electrode(s) – atrial;
- *33207* - Insertion or replacement of permanent pacemaker with transvenous electrode(s) – ventricular; or
- *33208* - Insertion or replacement of permanent pacemaker with transvenous electrode(s) – atrial and ventricular.

Institutional claims

Effective for claims with dates of service on or after August 13, 2013, MACs shall pay for implanted permanent cardiac pacemakers, single chamber or dual chamber, for the following HCPCS codes if the claim contains at least one of the designated *CPT*® codes, and at least one of the designated diagnosis codes, in addition to the KX modifier:

- C1785 – *Pacemaker, dual chamber, rate-responsive (implantable);*
- C1786 – *Pacemaker, single chamber, rate-responsive (implantable);*
- C2619 – *Pacemaker, dual chamber, nonrate-responsive (implantable);*
- C2620 – *Pacemaker, single chamber, nonrate-*

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responsive (implantable);

- *33206 – Insertion or replacement of permanent pacemaker with transvenous electrode(s) – atrial*
- *33207 – Insertion or replacement of permanent pacemaker with transvenous electrode(s) – ventricular*
- *33208 – Insertion or replacement of permanent pacemaker with transvenous electrode(s) – atrial and ventricular*

MACs have discretion to cover or not cover the following *CPT*® codes:

- *33227 – Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system*; or
- *33228* – Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system.

Cardiac pacemaker ICD-9/ICD-10 diagnosis codes

Professional claims

Claims with dates of service on and after August 13, 2013, for implanted permanent cardiac pacemakers, single chamber or dual chamber, are covered if submitted with one of the following *CPT*® codes: *33206, 33207, or 33208*, and that contain at least one of the following ICD-9/ICD-10 diagnosis codes (upon ICD-10 implementation) listed below in addition to the KX modifier:

- 426.0 Atrioventricular block, complete/ I44.2 Atrioventricular block, complete;
- 426.12 Mobitz (type) II atrioventricular block/ I44.1 Atrioventricular block, second degree;
- 426.13 Other second degree atrioventricular block/ I44.1 Atrioventricular block, second degree;
- 427.81 Sinoatrial node dysfunction/ I49.5 Sick sinus syndrome; or
- 746.86 Congenital heart block/ Q24.6 – Congenital heart block.

The following diagnosis codes can be covered at your MACs discretion if submitted with at least one of the *CPT*® codes and diagnosis codes listed above in addition to the KX modifier:

- 426.10 Atrioventricular block, unspecified/ I44.30 Unspecified atrioventricular block;
- 426.11 First degree atrioventricular block/ I44.0 Atrioventricular block first degree;
- 426.4 Right bundle branch block/ I45.10 Unspecified right bundle-branch block/ I45.19 Other right bundle-branch block;
- 427.0 Paroxysmal supraventricular tachycardia/ I47.1 Supraventricular tachycardia;
- 427.31 Atrial fibrillation/ I48.1 Persistent atrial fibrillation/ I48.91, Unspecified atrial fibrillation;
- 427.32 Atrial flutter/ I48.3 Typical atrial flutter/ I48.4 Atypical atrial flutter or I48.91 Unspecified atrial fibrillation; or
- 780.2 Syncope and collapse/R55 Syncope and collapse (R55 is the ICD-10 dx code but is not payable upon implementation of ICD-10 and is only included here for information purposes).

Institutional claims

For coverage of claims with dates of service on and after August 13, 2013, for implanted permanent cardiac pacemakers, single chamber or dual chamber, using HCPCS codes: C1785, C1786, C2619, C2620, *33206*, *33207*, or *33208*, the claim must contain at least one of the following procedure codes:

- 37.81 Initial insertion of single chamber device, not specified as rate responsive
- 37.82 Initial insertion of single chamber device, rate responsive
- 37.83 Initial insertion of single chamber device

and at least one of the following diagnosis codes in addition to the – KX modifier:

- 426.0 Atrioventricular block, complete;
- 426.12 Mobitz (type) II atrioventricular block;
- 426.13 Other second degree atrioventricular block;
- 427.81 Sinoatrial node dysfunction; or
- 746.86 Congenital heart block.

The following diagnosis codes can be covered, at the MAC's discretion, if submitted with at least one of the diagnosis codes listed above in addition to the –KX modifier:

- 426.10 Atrioventricular block, unspecified/ I44.30 Unspecified atrioventricular block;
- 426.11 First degree atrioventricular block/ I44.0 Atrioventricular block first degree;
- 426.4 Right bundle branch block/ I45.10 Unspecified right bundle-branch block/ I45.19 Other right bundle-branch block;
- 427.0 Paroxysmal supraventricular tachycardia/ I47.1 Supraventricular tachycardia;
- 427.31 Atrial fibrillation/ I48.1 Persistent atrial fibrillation/ I48.91, Unspecified atrial fibrillation;
- 427.32 Atrial flutter/ I48.3 Typical atrial flutter/ I48.4 Atypical atrial flutter or I48.91 Unspecified atrial fibrillation; or
- 780.2 Syncope and collapse/R55 Syncope and collapse (R55 is the ICD-10 dx code but is not payable upon implementation of ICD-10 and is only included here for information purposes).

Professional claims

MACs shall return claims lines for implanted permanent cardiac pacemakers, single chamber or dual chamber,

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containing one of the following *CPT*® codes: *33206*, *33207*, or *33208*, as unprocessable when the -KX modifier is not present. When returning such claims, MACs shall use the following messages:

- **Claim adjustment reason code (CARC) 4** – The procedure code is inconsistent with the modifier used or a required modifier is missing.
- **Remittance advice remarks code (RARC) N517** – Resubmit a new claim with the requested information.

Institutional claims

MACs shall return to providers claims for implanted permanent cardiac pacemakers, single chamber or dual chamber, when any of the following are not present on the claim: At least one HCPCS code: C1785, C1786, C2619, or C2620, at least one *CPT*® code: *33206, 33207, 33208, 33227, 33228*, at least one diagnosis code: 426.0/I44.2, 426.12/I44.1, 426.13/I44.1, 427.81/I49.5, 746.86/Q24.6, at least one procedure code: 37.81/0JH604Z, 0JH634Z, 0JH804Z, 0JH834Z, 37.82/0JH605Z, 0JH635Z, 0JH805Z, 0JH835Z, 38.83/0JH606Z, 0JH636Z, 0JH806Z, 0JH836Z, and the -KX modifier is not present on the claim.

Cardiac pacemaker non-covered ICD-10 diagnosis code

For claims with dates of service on or after implementation of ICD-10, for implanted permanent cardiac pacemakers, single chamber or dual chamber, using one of the following HCPCS and/or *CPT*® codes: *C1785*, *C1786*, *C2619*, *C2620, 33206, 33207*, or *33208*, ICD-10 diagnosis code R55 is not covered even if the claim contains one of the valid diagnosis codes listed above.

MACs will use the following messages when denying claims for implanted permanent cardiac pacemakers, single chamber or dual chamber, containing one of the following HCPCS and/or *CPT*® codes: *C1785, C1786, C2619, C2620, 33206, 33207, or 33208*, and ICD-10 diagnosis code R55 with the following messages:

- **CARC 96**: Non-covered charge(s).
- **RARC N569**: Not covered when performed for the reported diagnosis.
- Group code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed advance beneficiary notice (ABN) is on file.
- Group code PR assigning financial liability to the beneficiary, if a claim is received with occurrence code 32 indicating a signed ABN is on file, or occurrence code 32 is present with modifier GA.

Additional information

The official instruction, CR 9078, was issued to your MAC via two transmittals. The first transmittal updates the *Medicare Claims Processing Manual* and it is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3204CP.pdf*. The second updates the *Medicare National Coverage Determination Manual* and it is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179NCD.pdf*.

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

The KX modifier is accepted as an attestation by the practitioner and/or provider of the service that documentation is on file verifying the patient has non-reversible symptomatic bradycardia.

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Related CR Release Date: February 20, 2015
Effective Date: August 13, 2013
Related CR Transmittal #: R3204CP and R179NCD
Implementation Date: July 6, 2015

Chiropractic Services

Improper chiropractic billing for therapy

Medicare audit reviews have found that a significant portion of chiropractic service claims have been paid inappropriately due to insufficient documentation or lack of medical necessity. These widespread errors contribute to First Coast Service Options' (First Coast) payment error rate, as measured by the Comprehensive Error Rate Testing (CERT) program. First Coast's projected error rate for the November 2014 CERT report is 45 percent for chiropractic services.

Correct claim payment depends on providers complying with Medicare requirements for coverage, coding, and documentation of services. This guide was created to educate providers on the most common errors and how to avoid them to comply with Medicare regulations.

Summary of payment errors

The most common errors noted by Medicare auditors of chiropractic service claims are:

- Insufficient or missing documentation such as missing signatures or missing date of service in the medical record.
- Documentation that does not substantiate that all procedure(s) reported were performed such as:
  - No documentation or insufficient documentation that all spinal levels of manipulation reported has been performed.
  - No documentation that each manipulation reported was performed on a relevant symptomatic spine level.
  - Insufficient or absent documentation that all procedures or services were medically reasonable and necessary.
  - Required elements of the history and examination were absent.
  - Treatment plant was absent or insufficient.
- Lack of medical necessity for treatment furnished as "maintenance" therapy.

Documentation requirements

The record is an integral indicator of the medical necessity for the service provided during an encounter. Providers must ensure that documentation within each encounter reflects the level of service actually provided as well as meets payer requirements for appropriate reimbursement. The documentation may need to include health information such as a change in medications or an update to a chronic health condition impacting an encounter that was reviewed by the provider during the visit. The documentation should also include specific objective findings upon examination indicating the progress (or lack thereof) for the therapeutic interventions /modalities listed in the plan of care.

First Coast has developed a *chiropractic services documentation checklist* to assist providers in ensuring these requirements are met. Be aware, however, that this checklist is for providers' internal use and its completion does not constitute a guarantee of coverage.

Limitation of coverage

Coverage of chiropractic services is specifically limited to treatment by means of manual manipulation (e.g., by use of the hands) of the spine to correct a subluxation. Subluxation is defined as a motion segment in which alignment, movement integrity, and/ or physiological function of the spine are altered, although contact between joint surfaces remains intact. Manual devices (e.g., those that are hand held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. No additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

No other diagnostic or therapeutic service furnished by a chiropractor, or under the chiropractor's order, is covered. If a provider orders, takes, or interprets an X-ray or any other diagnostic test, the X-ray or other diagnostic test can be used for documentation; however there is no Medicare coverage for those services.

Medical necessity for treatment for acute and chronic subluxation

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment. In addition, the manipulative services rendered must have a direct therapeutic relationship to the patient's condition, and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by X-ray or physical examination, as described above.

Most spinal joint problems fall into the following categories:

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- **Acute subluxation**: A patient's condition is considered acute when the patient is being treated for a new injury that is identified by X-ray or physical examination as specified above. The results of chiropractic manipulation are expected to be an improvement in, or an arrest of, progression of the patient's condition.
- **Chronic subluxation**: A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvement, further manipulative treatment is considered maintenance therapy and is not covered.

Maintenance therapy limitations of coverage

Maintenance therapy includes services that seek to prevent disease, promote health, prolong and/or enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot be reasonably expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

Providers must place the acute treatment (AT) modifier on a claim when providing active and/or corrective treatment to treat acute or chronic subluxation. However, the presence of the AT modifier may not indicate that the service is reasonable and necessary.

The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied.

When rendering maintenance therapy, providers should consider providing the advance beneficiary notice of noncoverage (ABN) to the beneficiary. Chiropractors who give beneficiaries an ABN will place the modifier GA (or in rare instances modifier GZ) on the claim. The decision to deliver an ABN must be based on a genuine reason to expect that Medicare will not pay for a particular service on a specific occasion for that beneficiary due to a lack of medical necessity for that service. The beneficiary can then make a reasonable and informed decision about receiving and paying for the service. If the beneficiary decides to receive the service, you must submit a claim to Medicare even though you expect that Medicare will deny the claim and that the beneficiary will pay.

Coding

Providers should use the appropriate *Current Procedural Terminology* (*CPT*®) code that best describes the service performed:

- *98940*: *Chiropractic manipulative Treatment, spinal, one or two regions*
- *98941*: *Spinal three to four regions*
- *98942*: *Spinal, five regions*

Providers should also bill the appropriate modifier with the *CPT*® service when necessary:

- **AT modifier**: Indicates that the provider is rendering active and/or corrective treatment to treat acute or chronic subluxation. Additional information on this modifier is provided below.
- **GA modifier**: Indicates that the provider expects Medicare to deny a service (e.g., maintenance service) as not reasonable and necessary, and they have on file an ABN signed by the beneficiary.
- **GZ modifier**: On rare occasions, this modifier is used to indicate that the provider expects that Medicare will deny an item or service as not reasonable and necessary, and that they do not have an ABN signed by the beneficiary.

Medicare does not expect that **all** claims submitted for payment will include the AT modifier. The provider must document services in the medical record for this modifier in accordance with the Centers for Medicare & Medicaid Services' (CMS') *Medicare Benefit Policy Manual*, *Chapter 15, Section 240*.

CMS manual references

The *Medicare Benefit Policy Manual*, Chapter 15, *Section 30.5* – Chiropractor's Services and *Section 240* – Chiropractic Services

The *Medicare Claims Processing Manual*, *Chapter 12, Section 220* – Chiropractic Services

Other references

Office of Inspector General, May 2009, "*Inappropriate Medicare Payments for Chiropractic Services*"

The *Medicare Learning Network*® (*MLN*) educational product titled, "*Advance Beneficiary Notice of Noncoverage (ABN)*"

Respond to ADR requests on the SPOT

The SPOT allows users to respond promptly to prepay claim additional development response (ADR) requests … *online*. ADRs and any required documentation may be submitted from SPOT to First Coast's e-documentation system.

Drugs and Biologicals

FDA approves first biosimilar product

Provider types affected

This article is intended for health care professionals who submit claims to Medicare administrative contractors (MACs) for Medicare Part B services furnished to Medicare beneficiaries.

What you need to know

The Centers for Medicare & Medicaid Services (CMS) is aware that the Food and Drug Administration (FDA) has approved the first biosimilar product. CMS policies will ensure Medicare beneficiaries will have access to this new product, as it does for other drugs that receive FDA approval. The purpose of this article is to address questions that have arisen regarding biosimilar products.

Questions and answers about biosimilar products

Question: How will a health care professional that administers this product get reimbursed under Medicare Part B?

Answer: Medicare Part B payment for newly approved drugs and biologicals is available once the product is approved by the FDA. CMS will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the average sales price (ASP) payment methodology, and issue additional guidance as necessary. Initially, once the manufacturer's wholesale acquisition cost (WAC) is available, Medicare will pay 106 percent of the WAC for the product until ASP information is available. Once ASP information is available for this biosimilar product, Medicare payment will equal the ASP for the biosimilar product plus six percent of the ASP for the reference product.

Question: How soon will CMS be releasing coding information related to Part B reimbursement?

Answer: CMS anticipates including the approved biosimilar in the next quarterly Healthcare Common Procedure Coding System (HCPCS) tape release in the coming weeks, appearing in the claims processing system on July 1, 2015, effective retroactively to the FDA-approval date.

Question: Will CMS be assigning unique codes to each biosimilar released?

Answer: CMS will create a separate code to distinguish the biosimilar from the reference biological.

CMS is considering policy options for coding of additional biosimilars, and will release further guidance in the future.

Question: Will use of a distinguishing identifier to biological products make it harder to achieve Medicare reimbursement?

Answer: Distinguishing identifiers will have no bearing on coding and payment.

Question: How will CMS address providing access to biosimilars through Medicare Part D?

Answer: Although coverage for filgrastim will generally be provided through Part B, it could also be covered under Part D in certain circumstances (for example, nursing homes or intermediate care facilities for individuals with intellectual disabilities ICF/IID)). CMS will be releasing guidance to plans confirming that biosimilars approved by the FDA will be subject to existing rules for prescription drugs under Part D.

Additional information

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

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Implementation Date: N/A

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Laboratory/Pathology

Changes to the laboratory national coverage determination software for July 2015

Provider types affected

This *MLN Matters*® article is intended for physicians, other providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

What you need to know

Change request (CR) 9124 informs MACs about the changes that will be included in the July 2015 quarterly release of the edit module for clinical diagnostic laboratory services. Make sure that your billing staffs are aware of these changes.

Background

CR 9124 announces the changes that will be included in the July 2015 quarterly release of the edit module for clinical diagnostic laboratory services. The national coverage determinations (NCD) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and the final rule was published on November 23, 2001. Nationally uniform software was developed and incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs were processed uniformly throughout the nation effective April 1, 2003.

These changes are effective for services furnished on or after October 1, 2015, for International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10). (There are no ICD-9 updates in the July update.)

CR 9124 conveys four changes to the edit module, which are:

- Delete ICD-10-CM code I513 from the list of ICD-10-CM codes that are covered by Medicare for the Partial Prothrombin Time (PTT) (190.16) NCD;
- Add ICD-10-CM code S069X3A to the list of ICD-10-CM codes that are covered by Medicare for the Partial Prothrombin Time (PTT) (190.16) NCD;
- Delete ICD-10-CM codes I513 and T560X4A from the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD; and
- Add ICD-10-CM code S069X3A to the list of ICD-10-CM codes that are covered by Medicare for the Prothrombin Time (PT) (190.17) NCD.

Additional information

The official instruction, CR 9124 issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3228CP.pdf*.

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

MLN Matters® Number: MM9124
Related Change Request (CR) #: CR 9124
Related CR Release Date: April 3, 2015
Effective Date: October 1, 2015
Related CR Transmittal #: R3228CP
Implementation Date: July 6, 2015

RARC alerts providers about upcoming transition to ICD-10

By mid-April, providers will begin seeing a new remittance advice remark code (RARC) N742 on their remittance advices (RAs), "Alert: This claim was processed based on one or more ICD-9 codes. The transition to ICD-10 is required by October 1, 2015, for health care providers, health plans, and clearinghouses. More information can be found at *http://www.cms.gov/Medicare/Coding/ICD10/ProviderResources.html*." Medicare administrative contractors will start using the new RARC in April. Since RARCs are an industry standard, the new RARC has been available for other health plans to use since March 1, 2015.

This is another example of the unprecedented level of outreach by CMS to prepare the health care community for ICD-10. CMS has a very mature and rigorous testing program for its Medicare fee-for-service claim processing systems and has completed extensive testing in preparation for ICD-10. CMS is ready for ICD-10 and encourages medical practices and hospitals that bill Medicare to complete their preparations for the October 1, 2015, implementation date.

Medicare Physician Fee Schedule

Update on the status of provisions expiring on April 1

The negative 21 percent payment rate adjustment under current law for the Medicare physician fee schedule is scheduled to take effect on April 1, 2015. The Centers for Medicare & Medicaid Services (CMS) is taking steps to limit the impact on Medicare providers and beneficiaries by holding claims for a short period of time beginning on April 1st. Holding claims for a short period of time allows CMS to implement any subsequent Congressional action while minimizing claims reprocessing and disruption of physician cash flow in the event of legislation addressing the 21 percent payment reduction. Under current law, electronic claims are not paid sooner than 14 calendar days (29 days for paper claims) after the date of receipt. As we stated in our *recent email* to physicians, CMS will provide more information about next steps by April 11, 2015.

In addition to the Medicare physician fee schedule adjustment, other provisions affecting providers will also expire by April 1, including exceptions to the outpatient therapy caps, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals. These provisions include:

Exceptions process for Medicare Part B outpatient therapy caps: These caps are the annual per beneficiary cap amounts for occupational therapy and for physical therapy and speech-language pathology services combined, determined for each calendar year. Based on current law, exceptions to the therapy caps, which are allowed for reasonable and necessary therapy services above the caps, will be considered only for dates of service through March 31, 2015.

Add-on payments for ambulance services: Currently Medicare provides for an increase in the ambulance fee schedule amounts (both base rate and mileage) for covered ground ambulance transports that originate in rural areas by three percent and covered ground ambulance transports that originate in urban areas by two percent. In addition, currently Medicare provides for an increase of 22.6 percent in the base rate of the ambulance fee schedule amount for covered ground ambulance transports that originate in rural areas designated as super rural. These provisions expire as of April 1, 2015.

Payments for low-volume hospitals and Medicare dependent hospitals: The Affordable Care Act and subsequent legislation made temporary changes to the low-volume hospital payment adjustment for hospitals that meet certain discharge and mileage criteria. The Medicare Dependent Hospital program also provides enhanced payment to support small rural hospitals for which Medicare patients make up a significant percentage of inpatient days or discharges. These temporary changes to the low-volume hospital adjustment and the Medicare Dependent Hospital provision expire on April 1, 2015.

Recovery auditor inpatient hospital status reviews: CMS will continue to prohibit recovery auditor inpatient hospital patient status reviews for dates of admission occurring between October 1, 2013, and April 30, 2015. In addition, CMS will continue the Inpatient Probe and Educate process through April 30, 2015.

CMS must take steps to implement the negative update and the expiration of the other provisions noted above. Providers should remember that claims for services furnished on or before March 31, 2015, are not affected by the payment cut and will be processed and paid under normal time frames. We are working to limit any impact to Medicare providers and beneficiaries as much as possible.

Attention health professionals: Information Regarding the Medicare Access and CHIP Reauthorization Act of 2015

On April 14, 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015; the President is expected to sign it shortly. This law eliminates the negative update of 21 percent scheduled to take effect as of April 1, 2015, for the Medicare Physician Fee Schedule. In addition, provisions allowing for exceptions to the therapy cap, add-on payments for ambulance services, payments for low volume hospitals, and payments for Medicare dependent hospitals that expired on April 1 have been extended. CMS will immediately begin work to implement these provisions.

In an effort to minimize financial effects on providers, CMS previously instituted a 10-business day processing hold for all impacted claims with dates of service April 1, 2015, and later. While the Medicare Administrative Contractors (MACs) have been instructed to implement the rates in the legislation, a small volume of claims will be processed at the reduced rate based on the negative update amount. The MACs will automatically reprocess claims paid at the reduced rate with the new payment rate.

No action is necessary from providers who have already submitted claims for the impacted dates of service.

Preventive Services

Preventive and screening services update

***Note**: This article was revised April 8, 2015, to reflect the revised change request (CR) 8874 issued April 3. In the article, the CR release date, transmittal number, and the Web address for accessing CR 8874 are revised. In addition, information regarding deductible and coinsurance applicability to HCPCS 00810 services in the "Anesthesia furnished in conjunction with colonoscopy" section of the article is updated. All other information remains the same. This information was previously published in the January 2015 Medicare B Connection, Pages 28-30.*

Provider types affected

This *MLN Matters*® article is intended for Medicare practitioners providing preventive and screening services to Medicare beneficiaries and billing Medicare administrative contractors (MACs) for those services.

Provider action needed

CR 8874 is an update from the Centers for Medicare & Medicaid Services (CMS) to ensure accurate program payment for three screening services. The coinsurance and deductible for these services are currently waived, but due to coding changes and additions, the payments for 2015 would not be accurate without updated CR 8874 for intensive behavioral group therapy for obesity, digital breast tomosynthesis, and anesthesia associated with screening colonoscopy. Make sure billing staffs are aware of these updates.

Background

The following outlines the CMS updates:

Intensive behavioral therapy for obesity

Intensive behavioral therapy for obesity became a covered preventive service under Medicare, effective November 29, 2011. It is reported with HCPCS code G0447 (Face-to-face behavioral counseling for obesity, 15 minutes). Coverage requirements are in the *Medicare National Coverage Determinations (NCDs) Manual*, Chapter 1, Section 210.

To improve payment accuracy, in 2015 physician fee schedule (PFS) proposed rule, CMS created a new HCPCS code for the reporting and payment of behavioral group counseling for obesity – HCPCS codes G0473 face-to-face behavioral counseling for obesity, group (2-10), 30 minutes).

For coverage requirements of intensive behavioral therapy for obesity, see the NCD for intensive behavioral therapy for obesity.

The same claims editing that applies to G0447 applies to G0473. Therefore, effective for claims with dates of service on or after January 1, 2015, MACs will recognize HCPCS code G0473, but only when billed with one of the ICD-9 codes for body mass index (BMI) 30.0 and over (V85.30,-V85.39, V85.41-V85.45). (Once ICD-10 is effective, the related ICD-10 codes are Z68.30-Z68.39 and Z68.41-Z68.45.) When claims for G0473 are submitted without a required diagnosis code, they will be denied using the following remittance codes:

- **Claim adjustment reason code (CARC) 167**: This (these) diagnosis(es) is (are) not covered. **Note**: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **Remittance advice remarks code (RARC) N386**: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.mcd.search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Effective for claims with dates of service on or after January 1, 2015, beneficiary coinsurance and deductible do not apply to claim lines with HCPCS code G0473.

Note that Medicare pays claims with code G0473 only when submitted by the following provider specialty types as found on the provider's Medicare enrollment record:

- 01 – General practice
- 08 – Family practice
- 11 – Internal medicine
- 16 – Obstetrics/gynecology
- 37 – Pediatric medicine
- 38 – Geriatric medicine
- 50 – Nurse practitioner
- 89 – Certified clinical nurse specialist
- 97 – Physician assistant

Claim lines submitted with G0473, but without an appropriate provider specialty will be denied with the following remittance codes:

- **CARC 8**: The procedure code is inconsistent with the provider type/specialty (taxonomy). **Note**: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **RARC N95**: This provider type/provider specialty may not bill this service.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Further, effective for dates of service on or after January 1, 2015, claim lines with G0473 are only payable for the following places of service (POS) codes:

- 11 – Physician's office
- 22 – Outpatient hospital
- 49 – Independent clinic
- 71 – State or local public health clinic

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Claim lines for G0473 will be denied without an appropriate POS code using the following remittance codes:

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

Remember that Medicare will deny claim lines billed for HCPCS codes G0447 and G0473 if billed more than 22 times in a 12-month period using the following codes:

- **CARC 119**: Benefit maximum for this time period or occurrence has been reached.
- **RARC N362**: The number of days or units of service exceeds our acceptable maximum.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Note: MACs will display the next eligible date for obesity counseling on all MAC provider inquiry screens.

MACs will allow both a claim for the professional service and a claim for a facility fee for G0473 when that code is billed on type of bill (TOB) 13x or on TOB 85x when revenue code 096x, 097x, or 098x is on the TOB 85x. Payment on such claims is based on the following:

- TOB 13x paid based on the OPPS:
- TOB 85x in critical access hospitals based on reasonable cost; except
- TOB 85x Method II hospitals based on 115 percent of the lesser of the fee schedule amount or the submitted charge.

Institutional claims submitted on other than TOB 13x or 85x will be denied using:

- **CARC 171**: Payment is denied when performed by this type of provider on this type of facility. **Note**: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **RARC N428**: Not covered when performed in this place of service.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

Digital breast tomosynthesis

In the 2015 PFS final rule with comment period, CMS established a payment rate for the newly created *CPT*® code *77063* for screening digital breast tomosynthesis mammography. The same policies that are applicable to other screening mammography codes are applicable to *CPT*® code *77063*. In addition, since this is an add-on code it should only be paid when furnished in conjunction with a 2D digital mammography.

Effective January 1, 2015, HCPCS code *77063* (*Screening digital breast tomosynthesis, bilateral (list separately in addition to code for primary procedure*)), must be billed in conjunction with the screening mammography HCPCS code G0202 (Screening mammography, producing direct digital image, bilateral, all views, 2D imaging only. Effective January 1, 2015, beneficiary coinsurance and deductible does not apply to claim lines with *77063* (*Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure*).

Payment for *77063* is made only when billed with an ICD-9 code of V76.11 or V76.12 (and when ICD-10 is effective with ICD-10 code Z12.31). When denying claim lines for *77063* that are submitted without the appropriate diagnosis code, the claim lines are denied using the following messages:

- **CARC 167**: This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **RARC N386**: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at *www.cms.mcd.search.asp*. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- **Group code CO** (if GZ modifier present) or PR (if modifier GA is present).

On institutional claims:

- MACs will pay for tomosynthesis, HCPCS code *77063*, on TOBs 12x, 13x, 22x, 23x based on MPFS, and TOB 85x with revenue code other than 096x, 097x, or 098x based on reasonable cost. TOB 85x claims with revenue code 096x, 097x, or 098x are paid based on MPFS (115 percent of the lesser of the fee schedule amount and submitted charge).
- MACs will pay for tomosynthesis, HCPCS code *77063* with revenue codes 096x, 097x, or 098x when billed on TOB 85x Method II based on 115 percent of the lesser of the fee schedule amount or submitted charge.
- MACs will return to the provider any claim submitted with tomosynthesis, HCPCS code 77063 when the TOB is not 12x,13x, 22x, 23x, or 85x.
- MACs will pay for tomosynthesis, HCPCS code *77063*, on institutional claims TOBs 12x, 13x, 22x, 23x, and 85x when submitted with revenue code 0403 and on

See **PREVENTIVE**, next page

PREVENTIVE

From previous page

professional claims TOB 85x when submitted with revenue code 096x, 097x, or 098x.

- Effective for claims with dates of service on or after January 1, 2015, MACs will RTP claims for HCPCS code *77063* that are not submitted with revenue code 0403, 096x, 097x, or 098x.

Anesthesia furnished in conjunction with colonoscopy

Section 4104 of the Affordable Care Act defined the term "preventive services" to include "colorectal cancer screening tests" and as a result it waives any coinsurance that would otherwise apply under Section 1833(a)(1) of the Act for screening colonoscopies. In addition, the Affordable Care Act amended Section 1833(b)(1) of the Act to waive the Part B deductible for screening colonoscopies. These provisions are effective for services furnished on or after January 1, 2011.

In the 2015 PFS proposed rule, CMS proposed to revise the definition of "colorectal cancer screening tests" to include anesthesia separately furnished in conjunction with screening colonoscopies; and in the 2015 PFS final rule with comment period, CMS finalized this proposal. The definition of "colorectal cancer screening tests" includes anesthesia separately furnished in conjunction with screening colonoscopies in the Medicare regulations at Section 410.37(a)(1)(iii). As a result, beneficiary coinsurance and deductible does not apply to anesthesia services associated with screening colonoscopies.

As a result, effective for claims with dates of service on or after January 1, 2015, anesthesia professionals who furnish a separately payable anesthesia service in conjunction with a screening colonoscopy (HCPCS code *00810* performed in conjunction with G0105 and G0121) shall include the following on the claim for the services that qualify for the waiver of coinsurance and deductible:

- **Modifier 33: Preventive services** – when the primary purpose of the service is the delivery of an evidence based service in accordance with a USPSTF A or B rating in effect and other preventive services identified in preventive services mandates (legislative or regulatory), the service may be identified by adding 33 to the procedure. For separately reported services specifically identified as preventive, the modifier should not be used.

In addition, deductible is not applied to claim lines with HCPCS *00810* services that are billed with the PT modifier for services on or after January 1, 2015. The deductible is also not applied when the PT modifier is appended to at least either one of the *CPT*® codes within the surgical range of *CPT*® codes (*10000-69999*) or HCPCS codes G6018-G6028 on the claim for services that were furnished on the same date of service as the procedure. But, MACs will apply deductible and coinsurance to claim lines for HCPCS 00810 services billed without modifier *33* or modifier PT.

Additional information

The official instruction, CR 8874, issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3232CP.pdf*.

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

MLN Matters® Number: MM8874 *Revised*
Related Change Request (CR) #: CR 8874
Related CR Release Date: April 3, 2015
Effective Date: January 1, 2015
Related CR Transmittal #: R3232CP
Implementation Date: January 5, 2015

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Therapy Services

Requirements clarified for physician certification and recertification of patient eligibility for home health services

Provider types affected

This *MLN Matters*® article is intended for physicians, non-physician practitioners (NPPs), and home health agencies (HHAs) that submit claims to Medicare administrative contractors (MACs), including home health & hospice (HH&H) MACs for services provided to Medicare beneficiaries.

Provider action needed

Change request (CR) 9119 manualizes policies discussed in the 2015 home health prospective payment system (HH PPS) final rule published on November 6, 2014. CR 9119 instructs MACs to be aware of the revisions to the requirements for physician certification and recertification of patient eligibility for Medicare home health services. MACs are also instructed to be aware of the revised timeframe for therapy functional reassessments. Make sure that your billing staffs are aware of these changes.

Background

The Centers for Medicare & Medicaid Services (CMS) finalized clarifications and revisions to policies regarding physician certification and recertification of patient eligibility for Medicare home health services in the 2015 HH PPS final rule which was published on November 6, 2014 (see *http://www.gpo.gov/fdsys/pkg/FR-2014-11-06/pdf/2014-26057.pdf*). In the final rule, CMS also finalized revisions to the timeframe required for therapy functional reassessments.

Face-to-face encounter requirements

The Affordable Care Act requires that the certifying physician or allowed NPP must have a face-to-face encounter with the beneficiary before they certify the beneficiary's eligibility for the home health benefit.

CMS is implementing the following three changes to the face-to-face encounter requirements for episodes beginning on or after January 1, 2015. These changes will reduce administrative burden and provide HHAs with additional flexibilities in developing individual agency procedures for obtaining documentation supporting patient eligibility for Medicare home health care.

- CMS is eliminating the narrative requirement. The certifying physician is still required to certify (attest) that a face-to-face patient encounter occurred and document the date of the encounter as part of the certification of eligibility. For medical review purposes, Medicare requires documentation in the certifying physician's medical records and/or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) to be used as the basis for certification of patient eligibility.
- If a HHA claim is denied, the corresponding physician claim for certifying/re-certifying patient eligibility for Medicare-covered home health services is considered non-covered as well because there is no longer a corresponding claim for Medicare-covered home health services.
- CMS is clarifying that a face-to-face encounter is required for certifications, rather than initial episodes; and that a certification (versus a re-certification) is generally considered to be any time a new start of care assessment is completed to initiate care.

Therapy reassessments

CMS has eliminated the 13th and 19th visit therapy reassessment requirements. Forepisodes beginning on or after January 1, 2015; at least every 30 calendar days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient. This policy change will lessen HHAs' burden of counting visits.

This change will reduce the risk of non-covered visits so that therapists can focus more on providing quality care for their patients, while still promoting therapist involvement and quality treatment for all beneficiaries regardless of the level of therapy provided.

Additional information

The official instruction, CR 9119, consists of two transmittals. The first updates the *Medicare General Information, Enrollment and Entitlement Manual* and it is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R91GI.pdf*. The second transmittal updates the "Medicare Benefit Policy Manual" and it is at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R207BP.pdf*.

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

MLN Matters® Number: MM9119
Related Change Request (CR) #: CR 9119
Related CR Release Date: April 10, 2015
Effective Date: May 11, 2015
Related CR Transmittal #: R91GI and R207BP
Implementation Date: May 11, 2015

General Coverage

Removal of multiple national coverage determinations using an expedited process

***Note**: This article was revised March 28, 2015, to reflect the revised change request (CR) 9095 issued March 27. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same. This information was previously published in the March 2015 Medicare B Connection, Page 21.*

Provider types affected

This *MLN Matters*® article is intended for physicians, providers, and suppliers who submit claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

Effective December 18, 2014, CR 9095 removes Sections 50.6 – Tinnitus masking, 160.4 – Stereotactic Cingulotomy as a Means of Psychosurgery, 160.6 – Carotid Sinus Nerve Stimulator, 160.9 – Electroencephalographic (EEG) Monitoring During Open – Heart Surgery, 190.4 – Electron Microscope, 220.7 – Xenon Scan, and 220.8 – Nuclear Radiology Procedure from the Medicare *National Coverage Determinations Manual* or the *NCD Manual*. Providers and their staffs should be aware that removing an NCD results in coverage determinations being at the discretion of local MACs within their respective jurisdictions.

Background

CR 9095 removes seven NCDs from Publication 100-03, *NCD Manual*, pursuant to the expedited process that was established in an August 7, 2013, *Federal Register* (FR) notice (78 FR 48164). The FR notice is available at *http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf*.

A CMS decision memorandum dated December 18, 2014, contains a summary of the expedited removal process and explicitly removes seven NCDs from the following *NCD Manual* sections:

- 50.6 – Tinnitus masking
- 160.4 – Stereotactic Cingulotomy as a Means of Psychosurgery
- 160.6 – Carotid Sinus Nerve Stimulator
- 160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery
- 190.4 – Electron Microscope
- 220.7 – Xenon Scan
- 220.8 – Nuclear Radiology Procedure

You can review the CMS decision memorandum at *http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=29&mcdtypename=National+Coverage+Determinations+Proposed+for+Removal&MCDIndexType=7&bc=AgAEAAAAAAAA%3d%3d&*.

In the absence of an NCD, MACs should revert to historical standing policy and consider whether any Medicare claims for these services are reasonable and necessary under the Social Security Act (Section 1862(a)(1)(A); see *http://www.ssa.gov/OP_Home/ssact/title18/1862.htm*) consistent with the existing guidance for making such decisions when there is no NCD.

Additional information

The official instruction, CR 9095, issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R181NCD.pdf*.

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

MLN Matters® Number: MM9095 *Revised*
Related Change Request (CR) #: CR 9095
Related CR Release Date: March 27, 2015
Effective Date: December 18, 2014
Related CR Transmittal #: R181NCD
Implementation Date: April 6, 2015

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Where do I find...

Looking for something specific and don't know where to find it? Find out how to perform routine tasks or locate information that visitors frequently visit our site to accomplish or find. Check out the "Where do I find" page.

Increasing tax withholding to 30 percent for the Internal Revenue Service Federal Payment Levy Program

Provider types affected

This *MLN Matters*® article is intended for physicians, providers, and suppliers who submit claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

What you need to know

Change request (CR) 9154 instructs the Healthcare Integrated General Ledger Accounting System (HIGLAS) system maintainer to make necessary programming changes to increase the tax withhold percentage from 15 percent to 30 percent. If you owe back taxes to the IRS and those taxes are eligible to be withheld from payments due you from Medicare, the withhold rate will increase from the current 15 percent to 30 percent on June 19, 2015.

Background

In July 2000, the IRS, in conjunction with the Department of the Treasury, Financial Management Service (FMS), started the FPLP which is authorized by the Internal Revenue Code Section 6331 (h) (see *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title26/pdf/USCODE-2011-title26-subtitleF-chap64-subchapD-partII-sec6331.pdf*), as prescribed by the Taxpayer Relief Act of 1997 Section 1024 (see *http://www.gpo.gov/fdsys/pkg/PLAW-105publ34/html/PLAW-105publ34.htm*).

Through the FPLP, authority is provided to the Centers for Medicare & Medicaid Services (CMS) to collect overdue taxes through a levy on certain federal payments. This includes federal payments made to Medicare providers.

Consistent with this authority, CMS introduced CR 6125 in October of 2008, which reduced federal payments subjected to the levy by the required 15 percent, or the exact amount of the tax owed if it is less than 15 percent of the payment. You can review the *MLN Matters*® article (MM6125) corresponding to CR 6125 at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm6125.pdf*.

In December 2014, the Internal Revenue Code Section 6331 (h) was amended by the Tax Increase Prevention Act of 2014 Section 209 (a) (see *http://www.gpo.gov/fdsys/pkg/BILLS-113hr5771enr/html/BILLS-113hr5771enr.htm*), which mandated an increase of the tax levy to 30 percent.

Note: The tax levy is continuous until the overdue taxes are paid in full, or other arrangements are made to satisfy the debt.

Additional information

The official instruction, CR 9154, issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1486OTN.pdf*.

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

MLN Matters® Number: MM9154
Related Change Request (CR) #: CR 9154
Related CR Release Date: April 10, 2015
Effective Date: June 19, 2015
Related CR Transmittal #: R1486OTN
Implementation Date: June 19, 2015

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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*.

Private contracting: Definition of emergency care services and appeals of opt out determinations

Provider types affected

This *MLN Matters*® article is intended for physicians and practitioners who opt-out of Medicare, and beneficiaries that receive services from opt out physicians and practitioners.

***Note**: The private contracting regulation at 42 CFR 405.450 describes certain opt-out determinations made by Medicare, and the process that physicians, practitioners, and beneficiaries may use to appeal those determinations. The cross references to the processes used to appeal the determinations described in Section 405.450 were updated in the November 13, 2014 Federal Register (Volume 79, Number 219). The definition of emergency care services at 42 CFR 405.400 was also corrected in that November 13, 2014 Federal Register.*

Provider action needed

Stop – impact to you

The cross reference to Section 405.803 in Section 405.450(a) of the private contracting regulations was replaced with a cross reference to *Section 498.3(b)*. The cross reference to Section 405.803 in Section 405.450(b) of the private contracting regulations was replaced with a cross reference to Section 405.924. Corresponding edits to Section 498.3(b) and Section 405.924 were also made to note that the determinations under Section 405.450(a) and (b) of the private contracting regulations are initial determinations. The definition of emergency care services at *Section 405.400* was also revised to cite to the definition of emergency services in Section 424.101.

Caution – what you need to know

Be aware that a physician or practitioner who is dissatisfied with a Medicare determination under Section 405.450(a) may utilize the enrollment appeals process currently available for providers and suppliers in Part 498. Be aware that a determination described in Section 405.450(b) (that payment cannot be made to a beneficiary for services furnished by a physician or practitioner who has opted out) is an initial determination for the purposes of *Section 405.924* and may be challenged through the existing claims appeals procedures in Part 405 subpart I. Be aware that emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and, because of the danger to life or health, require use of the most accessible hospital available and equipped to furnish those services.

Go – what you need to do

Make sure that your billing staffs are aware of this information.

Background

Emergency care services means inpatient or outpatient hospital services that are necessary to prevent death or serious impairment of health and because of the danger to life or health, which require use of the most accessible hospital available that is equipped to furnish those services.

Congress intended that the term “emergency or urgent care services” not be limited to emergency services since they also included “urgent care services.” Urgent care services are defined in *42 CFR 405.400* as services furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

For example, if a beneficiary has an ear infection with significant pain, the Centers for Medicare & Medicaid Services (CMS) would view that as requiring treatment to avoid the adverse consequences of continued pain and perforation of the eardrum. The patient’s condition would not meet the definition of emergency medical condition because immediate care is not needed to avoid placing the health of the individual in serious jeopardy or to avoid serious impairment or dysfunction. However, although it does not meet the definition of emergency care, the beneficiary needs care within a relatively short period of time (which CMS defines as 12 hours) to avoid adverse consequences and the beneficiary may not be able to find another physician or practitioner to provide treatment within 12 hours.

Additional information

The official instruction, CR 9116, issued to your MAC regarding this change is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R206BP.pdf*.

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

MLN Matters® Number: MM9116
Related Change Request (CR) #: CR 9116
Related CR Release Date: April 10, 2015
Effective Date: July 13, 2015
Related CR Transmittal #: R206BP
Implementation Date: July 13, 2015

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 *http://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 *http://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 *http://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.

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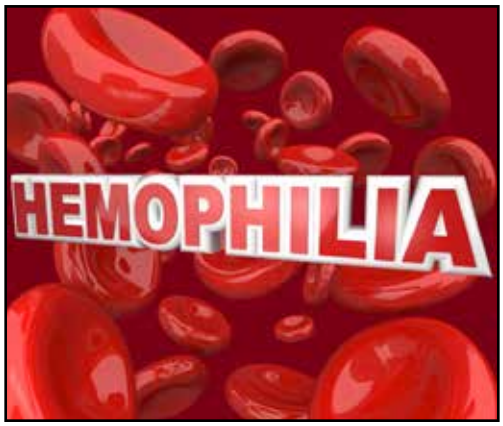
– Linda Zane, President, Physical Therapy Association of Florida

Revisions to LCDs

Hemophilia clotting factors – revision to the Part B LCD

LCD ID number: L29187 (Florida)
LCD ID number: L29345 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for hemophilia clotting factors was revised based on the Food and Drug Administration's (FDA's) approval of Obizur (antihemophilic factor (recombinant), porcine sequence) for the treatment of bleeding episodes in adults with acquired hemophilia A (acquired Factor VIII deficiency). HCPCS codes C9399 and J7199 were added under the "*CPT*®/HCPCS Codes" section of the LCD, and diagnosis code 286.52 was added to the "ICD-9 Codes that Support Medical Necessity" section of the LCD for Obizur. Also, language was added to the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD to include background on acquired hemophilia. The "Sources of Information and Basis for Decision" section of the LCD was also updated. Additionally, HCPCS code J7186 was added under the "*CPT*®/HCPCS Codes" section of the LCD to be consistent with the Part A LCD.



In addition, based on change request (CR) 9100 and CR 9104 (April 2015 quarterly updates), HCPCS code C9136 was deleted and replaced with HCPCS code Q9975.

Effective date

The LCD revision related to the addition of Obizur is effective for claims processed **on or after April 10, 2015**, for services rendered **on or after October 23, 2014**.

The LCD revision for the addition of HCPCS code J7186 is effective for services rendered **on or after June 8, 2015**. This article serves as the 45-day notice period for HCPCS code J7186.

The LCD revision for the deletion of HCPCS codes C9136 and the addition of HCPCS code Q9975 is effective for claims processed **on or after April 6, 2015**, for services rendered **on or after April 1, 2015**.

First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

Coding guidelines for an LCD (when present) may be found by selecting "Attachments" in the "Section Navigation" drop-down menu at the top of the LCD page.

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

Interferon – revision to the Part B LCD

LCD ID number: L29202 (Florida)
LCD ID number: L29354 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for Interferon was revised based on change request (CR) 9104 (April 2015 Quarterly Update). HCPCS code J1826 was added to the LCD for the treatment of multiple sclerosis (ICD-9 code 340).

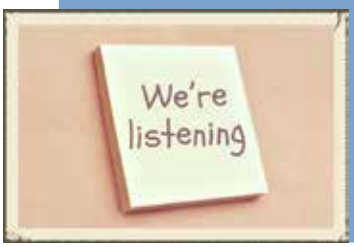
Effective date

This LCD revision is effective for claims processed **on or after April 6, 2015**, for services rendered **on or after January 1, 2015**. First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

Coding guidelines for an LCD (when present) may be found by selecting "Attachments" 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*.

Your Feedback Matters



To ensure that our website meets the needs of our provider community, we carefully analyze your feedback and implement changes to better meet your needs. Discover the results of your feedback on our "*Website enhancements*" page. You'll find the latest enhancements to our provider websites and find out how you can share your thoughts and ideas with First Coast's Web team.

Noncovered services – revision to the Part B LCD (HPV laboratory tests (87623-87625))

LCD ID number: L29288 (Florida)
LCD ID number: L29398 (Puerto Rico/U.S. Virgin Islands)

The local coverage determination (LCD) for noncovered services has been revised to remove *Current Procedural Terminology* (*CPT*®) codes *87623-87625* (HPV testing) from the "Local Noncoverage Decisions/Laboratory Procedures" section of the LCD. Claims submitted for *CPT*® codes *87623-87625* may have been denied in error with the following denial message: "These are non-covered services because this is not deemed a 'medical necessity' by the payer."

This error was corrected on **April 8, 2015**. Claims processed on or after this date were adjudicated correctly.

No action is required by providers.

Providers whose claims were incorrectly denied due to this error do not need to take any action. First Coast Service Options Inc. will perform adjustments to correct the error on all the affected claims. We apologize for any inconvenience this may have caused.

Effective date

The LCD revision is effective for claims processed **on or after April 8, 2015**, for services rendered **on or after January 1, 2015**. First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

Coding guidelines for an LCD (when present) may be found by selecting "Attachments" in the "Section Navigation" drop-down menu at the top of the LCD page.

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

Noncovered services – revision to the Part B LCD

LCD ID number: L29288 (Florida)
LCD ID number: L29398 (Puerto Rico/U.S. Virgin Islands)

Based on change request (CR) 9095 (Removal of Multiple National Coverage Determinations Using Expedited Process), the local coverage determination (LCD) "coding guidelines" attachment for noncovered services has been revised. *Current Procedural Terminology* (*CPT*®) codes *92700* (tinnitus masking), *64999* (sterotactic cingulotomy as a means of psychosurgery), *93799* (carotid sinus nerve stimulator), and *95999* (electroencephalographic (EEG) monitoring during open heart surgery) have been removed from the "procedures" section of the "coding guidelines" attachment.

Effective date

This LCD revision is effective for claims processed **on or after April 6, 2015**, for services rendered **on or after December 18, 2014**.

First Coast Service Options Inc. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

Coding guidelines for an LCD (when present) may be found by selecting "Attachments" 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*.

Take the time to 'chat' with the website team

You now have the opportunity to save your valuable time by asking your website-related questions online – with First Coast's new Live Chat service.

Additional Information

Application of skin substitute grafts for treatment of DFU and VLU of lower extremities-published for an additional 45-day comment period

Draft LCD, application of skin substitute grafts for treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) of lower extremities was initially published for a 45-day comment period in June 2014. The draft is being reposted for an additional 45-day comment period given input from practicing physicians suggested revised language and indication changes that could be considered more restrictive coverage criteria. The current comment period will extend from April 10 through May 25, 2015. Any comments previously submitted to the contractor during the 45-day comment period in June 2014 will be addressed along with any new comments submitted during the current 45-day comment period. Comments should be submitted to the medical policy department at *medical.policy@fcso.com*. After review of all comments, this revised draft policy will be finalized and posted for a 45-day notice period, followed by implementation.

The draft LCD can be viewed by selecting the following link: *http://www.cms.gov/medicare-coverage-database/reports/draft-lcd-status-report.aspx?name=370*1&bc=AQAAAgAAAAAAAA%3d%3d&#ResultAnchor*.

Changes to the investigational device exemption approval process

The Centers for Medicare & Medicaid Services (CMS) change request (CR) 8921, announced changes effective on or after January 1, 2015, to Medicare coverage requirements and review procedures related to the Food and Drug Administration (FDA) approved Category A (Experimental) and Category B (nonexperimental/investigational) IDE studies. Effective for Category A and B IDE studies approved by the FDA on or after January 1, 2015, study sponsors that wish to seek Medicare coverage must submit a request for review and approval to CMS. CMS approval for a Category A IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. A CMS approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial. Refer to the Medicare Benefit Policy Manual, Chapter 14 for detailed instructions on seeking CMS approval.

To ensure proper claims payment, First Coast Service Options, Inc. (First Coast), the Part A and Part B claims administrator for jurisdiction N (JN) will continue to require investigational study sites to submit for the contractor's review, all documentation that is currently required. Please refer to the following article titled "Investigational device exemption (IDE) approval requirements" and request form for a complete list of items the contractor requires for each investigational site. Study sites may submit all of the documentation electronically to *clinicaltrials@fcso.com*. Of note, the contractor no longer requires study sites to send a list of Medicare beneficiaries participating in any approved study for Category B IDE Extension Requests. For IDE studies approved by CMS, the JN MAC will require a copy of the complete FDA approval letter(s) provided to the principal investigator and/or the sponsor or manufacturer of the device, AND a copy of the CMS approval as posted on the CMS website.

Useful links related to devices and clinical trials:

- *Devices and clinical trials – clinical trials background information*
- *Clinical trial coding and cost information form*
- *Post-approval and 510K for carotid artery stenting (CAS) study continuation request*
- *Post-approval and 510K extension studies for CAS approval requirements and request form*
- *Humanitarian use device exemption (HUD/HDE)*
- *Investigational device exemption (IDE) approval requirements and request form*
- *IDE extension requirements and request form*
- *"Medicare Benefit Policy Manual" (Pub. 100-02, Ch. 14), medical devices*
- *Food and Drug Administration (FDA) clinical trial and investigational device exemption Web page*
- *Frequently asked questions (FAQs) about clinical trials and device coverage*
- *Contact MAC JN First Coast Service Options' Medical Policy & Procedures Dept. via email*

Medicare coverage of devices and clinical trials

Medicare covers the use of devices that are "reasonable and necessary for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member". Certain Health & Human Services (HHS) agencies have addressed agreements to facilitate the categorization and approval of devices for marketing related to safety issues under The Food and Drug Administration (FDA) jurisdiction and to facilitate consideration of Medicare coverage related to the reasonable and necessary threshold under the Centers for Medicare & Medicaid Services (CMS) jurisdiction. (**See definitions at the end of this article**.) The CMS delegates responsibilities to its Medicare administrative contractors (MACs) for Medicare claims administration that encompass proper billing and coding by the provider and coverage and payment by the contractor via its systems – FISS (for Part A providers including hospitals) and MCS (Part B providers including physicians). For dates prior to January 1, 2015, Part A and B MAC administers pre-approval of clinical trials limited to certain DEVICE categories in clinical studies as outlined below. Claims for devices described by these categories cannot be considered for coverage until the pre-approval requirements are met and acknowledged in writing by the medical policy and procedures department at First Coast Service Options Inc.

Principle Investigators (PIs) and Medicare providers conducting research studies with traditional Medicare patients should be familiar with several **regulations and guidance documents**:

1. Medicare consideration of coverage of category B devices under the investigational device exemption (IDE) provision. *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*.

There are devices which are refinements of existing technologies or replications of existing technologies made by other manufacturers. Many of these devices are under an FDA-approved IDE as a means of gathering the scientific information (via a clinical study) needed for FDA to establish the safety and effectiveness of that particular device, even though there is evidence that the device type can be safe and effective. On **September 8, 1995, the FDA entered into an agreement with the administrator of the Medicare program**, the Health Care Finance Administration (HCFA- now CMS), to provide information about devices under an IDE to aid in its reimbursement decisions. Under this agreement certain devices could be viewed as "reasonable and necessary" by Medicare and treatments *could be covered if all other applicable Medicare coverage requirements are met*. This was a compromise to address the coverage of devices given that Medicare does not usually cover investigational services/procedures.

Specifically, FDA will place all IDEs it approves in one of two categories:

Category A – experimental (not covered by Medicare)

The IDE involves innovative devices in which "absolute risk" has not been established (i.e., initial questions of safety and effectiveness have not been resolved and thus FDA is unsure whether the device type can be safe and effective)

Category B – investigational; non-experimental (can be covered by Medicare)

The clinical investigations involve device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved). This category includes device types that can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Non-significant risk studies may also be included in this category.

FDA provides the category determination on the IDE approval letter to the sponsor and also forwards this information to CMS. An approved IDE is identified by a six-digit IDE number preceded by a "G" (Gxxxxxx). Investigators/Providers must submit all the required information on the device and clinical study for contractor review and approval prior to submitting Medicare claims. *The Part A and Part B MAC required IDE pre approval process is outlined on the website*.

2. **Medicare clinical trials policies**. *http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html*.

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health & Human Services to "explicitly authorize [Medicare] payment for routine patient care costs... and costs due to medical complications associated with participation in clinical trials." Medicare covers the routine costs of qualifying clinical trials, as such costs are defined in **National Coverage Determination (NCD) 310.1 (routine cost in clinical trials, version 2 effective July 9, 2007)**, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply. The definition of a routine cost excludes the investigational item or service, itself, unless otherwise covered outside of the clinical trial. **Though submitting a Medicare claim for routine cost in a qualifying clinical trial has specific billing requirements, Contractors do not pre review clinical trials except for certain device categories as noted in this article**. Therefore, physicians and allied providers must be compliant with applicable billing, coding, and coverage requirements via the two claim systems (physician and facility claims) in regard to patients in clinical trials. Claims for traditional Medicare beneficiaries in clinical trials should meet the requirements of NCD 310.1 in that the services billed as routine cost must meet the definition of routine cost, and the clinical trial must be a qualifying trial.

Effective January 1, 2005 (change request [CR] 3548, Transmittal 131) Medicare covers the routine cost of clinical trials involving IDE category A devices (the device itself remains non covered) assuming all aspects of the

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contractor's pre approval IDE process are met and only when the device is used in the trial for the diagnosis, monitoring, or treatment on an immediately life-threatening disease or condition (defined as "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment").

3. CMS has asked its contractors to assist in the administration of certain national coverage determinations (NCDs)

NCDs such as Percutaneous Transluminal Angioplasty (PTA) (20.7) located at the following website: *http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=8&bc=BAABAAAAAgAA&* (specific indication - carotid artery stenting [CAS]) with pre-approval of certain IDE studies and certain post approval studies. Also, a CMS NCD can incorporate broader authority such as coverage with evidence development (CED) that may require the contractor to administer information such as approved facility, registry verification, or other data. Located at the following website:

http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Medicare-Coverage-Guidance-Documents-.html. Such requirements are published to the provider community.

Post-approval studies & post-approval extension studies related to CAS procedures

Effective October 12, 2004 (Change Request [CR] 3489, Transmittal 314), Medicare covers percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. As the post-approval studies began to end, CMS extended coverage to post-approval extension studies that receive FDA review of each study protocol (effective February 28, 2006, CR 5088). The process for claims for post-approval studies and post-approval extension studies is similar to the *Category B IDE pre-approval process*, except that under post-approval coverage, providers must use the Pre-Market Approval (PMA) number assigned to the stent system by the FDA given that the FDA cannot issue post marketing numbers. The FDA will issue a letter acknowledging a valid study, and CMS will issue a letter to the sponsor (and both letters should be submitted to the contractor along with the other materials). An approved PMA number is a six-digit number preceded by a "P" (Pxxxxxx).

510K post-approval extension studies related to embolic protection devices during CAS procedures

Effective October 22, 2010 (CR 7249, Transmittal 2113), CMS has determined that all 510K post-approval extension studies must be reviewed by the FDA. The FDA will issue an acknowledgment letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the 510k post-approval extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. The process for claims for 510k post-approval studies is similar to the Category B IDE pre approval process except that the FDA evaluates these studies via the pre-IDE process and each 510k post-approval extension study is identified by a six-digit study identification number preceded by an "I" (Ixxxxxx).

In December 2013, CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local Medicare administrative contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies. An approval for a Category A (experimental) IDE study will allow coverage of routine care items and services (NCD 310.1-Routine Costs in Clinical Trials) furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

Based on CR 8921, CMS announced changes effective on and after January 1, 2015, to Medicare coverage requirements and review procedures related to Category A and B IDE studies. Please refer to the following Medicare manuals:

- *Medicare Benefit Policy Manual*, Chapter 14;
- *Medicare Benefit Policy Manual*, Chapter 16, Section 10; and
- *Medicare Claims Processing Manual*, Chapter 32, Section 68.

IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study sponsors should continue to follow the process established by the MAC for any site additions or protocol changes.

In summary, **Medicare limits pre-approval of clinical trials to DEVICES, specifically to Category A and B IDEs and certain post approval studies related to CAS procedures**. The Part A and the Part B MAC required IDE pre approval process outlined on the website includes the following topics:

- Background on devices and clinical trials (this document)
- Medicare routine cost in clinical trials NCD (#310.10) Located at the following website: *http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&SearchType=Advanced&CoverageSelection=National&NCSelection=NCD&KeyWord=clinical+trials&KeyWordLookUp=Doc&KeyWordSearch*

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- IDE coverage background and approval requirements done prior to any claim submission (Also addresses related requirements for post approval studies. Link to clinical trials on the First Coast website Coding & Cost form & IDE extension request requirements : *http://medicare.fcso.com/Clinical_trials/138007.pdf*
- IDE, post-approval, and 510 K billing guidelines (submission of claims post approval)
- HUD background - see paragraph below. Clinical trials are not reviewed.
- Frequently asked questions on devices and clinical trials (available on the First Coast provider website: *http://medicare.fcso.com/Clinical_trials/195745.asp*
- Of note, a **humanitarian use device (HUD)**, as defined by the Food and Drug Administration (FDA), is a device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals per year in the United States. **Part A and Part B MAC does not review clinical trials for HDE (humanitarian device exemption) given trials are not a requirement of the FDA and Medicare coverage of such devices would be rare and very patient specific**. Such devices may only be used in institutions where a local Institutional Review Board (IRB) has approved the use of the device to treat or diagnose the specific rare disease. Medicare Part A and Part B MAC administer claims under HDE on a case by case basis. See article on website for information that must be made available if practitioner and/or institutional records are requested (pre or post payment) related to claim submission. (As with any claim, payment of claim does not mean coverage hurdle met since not all claims are reviewed prepayment.)

Definitions

HHS

Department of Health and Human Services – refers to cabinet department of the United States government with the goal of protecting the health of all Americans and providing essential human services

FDA

Food and Drug Administration – agency of HHS responsible for protecting and promoting public health through the regulation and supervision of medical device safety (as well as drugs and other products with medical applications).

FDA definitions: *http://www.fda.gov/MedicalDevices/default.htm*.

CMS

Centers for Medicare & Medicaid Services (CMS) – previously known as the Health Care Financing Administration (HCFA), agency of HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and Health Insurance Portability and Accountability Act (HIPAA) standards.

MACs

Medicare administrative contractors – entities contracted with CMS to administer various aspects of the Medicare program and specifically claims payment for medically reasonable and necessary services.

A/B MAC

First Coast Service Options Inc. is the Medicare Part A and B MAC for (Florida, Puerto Rico, and the U.S. Virgin Islands).

FISS

Fiscal intermediary standard system – used to process Medicare claims related to medical care provided by hospitals (Part A and certain Part B benefits) and by certain other providers that submit claims via the UB04 format.

MCS

Multi-carrier system – used to process Medicare claims related to nonhospital-based physician care and to certain other Part B services that submit via the CMS-1500 format.

Medical devices – classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. (Some Class III pre-amendment devices may require a Class III 510(k).) Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special

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controls alone are insufficient to assure the safety and effectiveness of class III devices. Examples of Class I devices include examination gloves hand & held surgical instruments; Class II devices include powered wheelchairs & infusion pumps: and Class III devices include replacement heart valves (PMA needed) & implantable pacemaker pulse generator (PMA generally needed).

Premarket approval (PMA) – 21 CFR (*Code of Federal Regulations*) Part 814 – product requiring PMAs are Class III devices that are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device. A premarket approval means any premarket approval application for a Class III medical device, including all information submitted with or incorporated by reference therein.

Premarket notification (PMN or 510(k)) – a 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device **(21 CFR 807.92(a)(3))** that is not subject to PMA. This type of submission is used for most Class II devices and some Class I devices (and some Class III devices). The majority of these submissions do not involve clinical data.

Investigational device exemption (IDE) – allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification [510(k)] submission to FDA. *Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application*. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. IDE refers to the regulations under 21 CFR 812. *An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under **21 CFR 812** are met*.

Significant risk device (SR device) – an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject.

Investigator – an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed to, or used involving a subject. In the event of an investigation being conducted by a team of individuals, "investigator" refers to the responsible leader of that team.

Sponsor – a person or other entity that initiates but does not actually conduct the investigation. An entity other than an individual (e.g., a corporation or an agency) which uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor, not a sponsor-investigator, and the employees are considered to be investigators. The sponsor of an IDE must be located in the United States (see **21 CFR 812.18**).

Sponsor-investigator – an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the investigational device is administered, dispensed, or used. The term does not, for example, include a corporation or agency. The obligations of a sponsor-investigator include those of an investigator and those of a sponsor.

Prepayment review for polysomnography testing CPT® code 95810 and 95811

First Coast Service Options Inc.(First Coast) recently conducted data analysis due to potential overutilization of *Common Procedural Terminology* (*CPT®*) codes *95810* (*Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameter of sleep attended by a technologist*) and *95811* (*Polysomnography: age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with inhalation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist*). The data indicates a potential overutilization of *CPT® 95810* and *CPT® 95811* based on local coverage eetermination (LCD) L29949 utilization parameters. Recent medical reviews have identified that providers are not following the document requirements as outlined in the LCD (L29949).

For a diagnosis of obstructive sleep apnea (OSA) to be made, the following criteria must be met:

Prior to sleep testing, the patient has a face-to-face clinical evaluation by the treating physician to assess the patient for OSA which must include, at a minimum, the following:

- Sleep history and symptoms including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and
  - Epworth Sleepiness Scale; and
  - Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway system evaluation.

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- The patient has a Medicare-covered sleep test that meets either of the following criteria:
  - The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
  - The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
  - Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke.
- Sleep technicians or technologists attending polysomnography testing or sleep studies affiliated with home sleep study (HST) must have appropriate personnel certification. Examples of certification in polysomnography and sleep technology for technologists are:
  - Registered Polysomnography Technologist (RPSGT)
  - Registered Electroencephalographic Technologist (R. EEG T) – Polysomnography
  - Certified Respiratory Therapist – Sleep Disorders Specialist (RRT-SDS)
  - Registered Respiratory Therapist Sleep Disorder Specialist (RRT-SDS)
  - Credentialing must be provided by nationally recognized credentialing organizations such as:
  - Board of Registered Polysomnographic Technologists (BRPT) that provides (RPSGT) credential; or
  - American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) that providers R. EEG T) – Polysomnography credential; or
  - Performed in a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), or Accreditation Commission for Health Care (ACHC) or Joint Commission; or
  - American Board of Sleep Medicine (ABSM) that providers credentialing in sleep technology; or
  - National Board for Respiratory Care, Inc. (NBRC) that provide specialty examination for respiratory therapists performing sleep disorders testing and therapeutic intervention (CRT-SDS and RRT-SDS).
- All technologists and technicians conducting sleep testing who are not registered by the BRPT, ABRET, ABSM, NBRC or other accepted certification body, must be affiliated with an AASM or ACHC accredited sleep facility or Joint Commission accredited sleep facility (a Joint Commission accredited sleep laboratory). Unregistered technologists and technicians must maintain appropriate training and supervision, and, be supervised by a Registered and licensed technologist, where license is required by state law.

Utilization guidelines as outlined in LCD L29949 Polysomnography and Sleep Testing

More than one home sleep study (HST) per year interval would not be expected. If more than one HST session is performed for suspected OSA, persuasive medical evidence justifying the medical necessity for the additional test will be required. Similarly, more than two polysomnography tests per year interval would not be expected. If more than two polysomnography test sessions are performed for the diagnosis or adjustment of treatment of sleep, pervasive medical evidence justifying the medical necessity for the additional tests will be required upon request. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

First Coast recommends providers be familiar with medical necessity indications and documentation requirements for Polysomnography services as indicated in the Polysomnography and Sleep Testing LCD. LCDs are available through the CMS Medicare coverage database at *http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

First Coast actions

In response to the potential overutilization of *CPT® 95810* and *CPT® 95811*, First Coast will implement a prepayment medical review audit for services that exceed the utilization guidelines outlined in LCD L29949, implementation date May 5, 2015.

Widespread probe notification for subsequent nursing facility care services billed with the 24 modifier

First Coast Service Options Inc. (First Coast) conducted a widespread probe (WSP) in response to an aberrant billing pattern identified for *Current Procedural Terminology* (*CPT®*) codes *99308*, *99309* and *99310* (subsequent nursing facility care) in 2012 when billed with the *24* modifier. The results of the WSP yielded a 65.63 percent error rate. First Coast plans to complete an additional WSP of subsequent nursing facility care service for dates of service July 1, 2014, to February 28, 2015, to determine the effectiveness of the provider outreach and education activities. The widespread probe will include *CPT®* codes *99308* and *99309*.

Upcoming provider outreach and educational events

Medicare "Ask-the-Contractor" teleconference (ACT): Chronic Care Management

When: Wednesday, April 29
Time: 11:30 a.m.-1:00 p.m. **Type of event:** Webcast

http://medicare.fcso.com/Events/279017.asp

First Coast's fee schedule lookup

When: Tuesday, May 5
Time: 11:30 a.m.-noon **Type of event:** Webcast

http://medicare.fcso.com/Events/278626.asp

Note: Unless otherwise indicated, all First Coast educational offerings are considered to be "ask-the-contractor" events, "webcast" type of event, designated times 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 *www.fcsouniversity.com*, 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, *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.

MLN Connects®

MLN Connects® Provider eNews for April 23, 2015

MLN Connects® Provider eNews for April 23, 2015

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In this edition:

MLN Connects® National Provider Calls

- Medicare Acute Care Quality and Reporting Programs – Registration Now Open
- New MLN Connects® National Provider Call Audio Recording and Transcript
- CMS Events
- Special Open Door Forum: Home Health Electronic and Paper Clinical Templates

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- Proposed FY 2016 Skilled Nursing Facility Payment and Policy Changes
- Proposed FY 2016 Inpatient and Long-Term Care Hospital Payment and Policy Changes
- DMEPOS Competitive Bidding Round 1 2017 Announced
- National Minority Health Month
- CMS Releases Hospital Compare Star Ratings
- New Hospice Reports Available in CASPER
- CMS to Release Transthoracic Echocardiography Comparative Billing Report in May
- CMS to Award Special Innovation Projects for Partnership-Driven Quality Improvement Projects
- CMS is Accepting Suggestions for Potential PQRS Measures

Claims, Pricers, and Codes

- Coordination of Benefits Issue Impacting Outpatient Hospital Claims
- Updated: Correcting the Display Issue for OPPS Claims Where Value Code "FD" Is Present

Medicare Learning Network® Educational Products

- "Independent Diagnostic Testing Facilities" Podcast – *Released*
- "Vaccine and Vaccine Administration Payments under Medicare Part D" Fact Sheet – *Revised*
- "Home Health Prospective Payment System" Fact Sheet – *Revised*
- "Medicare Fraud and Abuse: Prevention, Detection, and Reporting" Web-Based Training Course – *Revised*
- New Medicare Learning Network® Educational Web Guides Fast Fact

Get ready for ICD-10

On October 1, 2015, the health care industry will transition from ICD-9 to ICD-10 codes for diagnoses and inpatient procedures.

This transition is going to change how you do business—from registration and referrals to superbills and software upgrades. But that change doesn't have to be overwhelming.

The Centers for Medicare & Medicaid Services has the following resources to help your practice prepare for the transition.

Online ICD-10 guide

ICD-10 basics for large medical practices

MLN Connects® Provider eNews for April 2, 2015

MLN Connects® Provider eNews for April 2, 2015
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In this edition:

MLN Connects® National Provider Calls

- Medicare Shared Savings Program ACO: Preparing to Apply for 2016 – Last Chance to Register
- Open Payments (Sunshine Act) 2015: Prepare to Review Reported Data – Register Now
- How to Register for the PQRS Group Practice Reporting Option in 2015 – Register Now
- Medicare Shared Savings Program ACO: Application Process – Register Now
- New MLN Connects® National Provider Call Audio Recording and Transcript

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- Notices of Intent to Apply for Medicare Shared Savings Program January 1, 2016, Start Date Due by May 29
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- Quarterly Provider Update for April 2015
- CMS is Accepting Suggestions for Potential PQRS Measures

Claims, Pricers, and Codes

- Modifications to HCPCS Code Set
- Partial Hospitalization Program Claims Coding and Payment Rates for CY 2015
- New RARC Alerts Providers about Upcoming Transition to ICD-10

Medicare Learning Network® Educational Products

- "Preventive Services" Educational Tool – Revised
- "Long Term Care Hospital Prospective Payment System" Fact Sheet – Revised
- "Clinical Laboratory Fee Schedule" Fact Sheet – Revised
- "Medicare Appeals Process" Fact Sheet – Reminder
- "Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians" Fact Sheet – Reminder
- *Medicare Learning Network*® Product Available In Electronic Publication Format

MLN Connects® Provider eNews for April 9, 2015

MLN Connects® Provider eNews for April 9, 2015
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In this edition:

MLN Connects® National Provider Calls

- Open Payments (Sunshine Act) 2015: Prepare to Review Reported Data – Last Chance to Register
- How to Register for the PQRS Group Practice Reporting Option in 2015 – Last Chance to Register
- Medicare Shared Savings Program ACO: Application Process – Register Now

CMS Events

- Volunteer for ICD-10 End-to-End Testing in July – Forms Due April 17
- Webinar for Comparative Billing Report on Ophthalmology

Announcements

- Results From March 2015 ICD-10 Acknowledgement Testing Week
- Prepare for a Successful Transition to ICD-10 with Medicare Testing Resources
- 2015 PV-PQRS GPRO Registration is Now Open
- Open Payments Physician and Teaching Hospital Review and Dispute Period Began April 6
- EHR Stage 3 Proposed Rule: Comment Period Closes May 29
- Medscape Article for CME Credit: Public Reporting on Quality and Payments

Claims, Pricers, and Codes

- Mass Adjustment of OPPS Claims with APC 1448
- April 2015 Outpatient Prospective Payment System Pricer File Update
- January 2015 PPS Provider Data Available – Revised

Medicare Learning Network® Educational Products

- "Food and Drug Administration Approval of First Biosimilar Product" MLN Matters® Article – Released
- "Discontinued Coverage of Vacuum Erection Systems (VES) Prosthetic Devices in Accordance with the Achieving a Better Life Experience Act of 2014" MLN Matters® Article – Released
- "Partial Hospitalization Program (PHP) Claims Coding & CY2015 per Diem Payment Rates" MLN Matters® Article – Released

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MLN Connects® Provider eNews for April 16, 2015

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MLN Connects® National Provider Calls

- MLN Connects® National Provider Calls
- Medicare Shared Savings Program ACO: Application Process – Last Chance to Register

CMS Events

- Volunteer for ICD-10 End-to-End Testing in July – Forms Due April 17

Announcements

- April is Sexually Transmitted Infections Month
- Is Your National Association an MLN Connects® Partner?
- LTCH Quality Reporting Program Data Submission Deadline: May 15
- IRF Quality Reporting Program Data Submission Deadline: May 15

- Notices of Intent to Apply for Medicare Shared Savings Program January 1, 2016, Start Date Due by May 29
- Proposed Rule Outlines EHR Requirements for Providers for 2015 through 2017

Medicare Learning Network® Educational Products

- "Medicare Quarterly Provider Compliance Newsletter [Volume 5, Issue 3]" Educational Tool – Released
- *Medicare Learning Network®* Product Available In Electronic Publication Format

ENEWS

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- "Medicare Information for Advanced Practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants" Booklet – Revised
- "The ABCs of the Initial Preventive Physical Examination (IPPE)" Educational Tool – Revised
- "The ABCs of the Annual Wellness Visit (AWV)" Educational Tool – Revised "Medicare Learning Network® Suite of Products & Resources for Billers and Coders" Educational Tool – Reminder
- "*Medicare Learning Network®* Suite of Products & Resources for Inpatient Hospitals" Educational Tool – Reminder
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Additional Resources

Updates to the 'Medicare Internet-Only Manual' for skilled nursing facility providers

***Note**: This article was revised April 8, 2015, to reflect the revised change request (CR) 8997 issued April 3. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same. This information was previously published in the March 2015 Medicare B Connection, Pages 46-48.*

Provider types affected

This *MLN Matters*® article is intended for physicians, providers, and suppliers submitting claims to Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries who are in a skilled nursing facility (SNF).

Provider action needed

CR 8997 updates sections of the *Medicare Benefit Policy Manual* and the *Medicare Claims Processing Manual* in regards to SNF policy and billing. If you provide services to Medicare beneficiaries in a SNF stay, information in CR 8997 could impact your payments.

Background

CR 8997 updates two chapters of the *Medicare Claims Processing Manual* and one chapter of the *Medicare Benefit Policy Manual*. The following summarizes these manual updates:

"Medicare Benefit Policy Manual," Chapter 8

Section 20.2.3: (Readmission to SNF)

- If an individual who is receiving covered post-hospital extended care, leaves a SNF and is readmitted to the same or any other participating SNF for further covered care within 30 days of the last covered skilled day, the 30-day transfer requirement is considered to be met; and
- **The same is true if the beneficiary remains in the SNF to receive custodial care following a covered stay, and subsequently develops a renewed need for covered care there within 30 consecutive days**. Thus, the period of extended care services may be interrupted briefly and then resumed, if necessary, without hospitalization preceding the **resumption** of SNF **coverage**.

"Medicare Claims Processing Manual," Chapter 6

Section 20.1.1.2: Hospital's "Facility Charge" in Connection with Clinic Services of a Physician

- When a beneficiary receives clinic services from a hospital-based physician, the physician in this situation would bill his or her own professional services directly to the Part B **MAC** and would be reimbursed at the facility rate of the Medicare physician fee schedule – which does not include overhead expenses.
- The hospital historically has submitted a separate Part B "facility charge" for the associated overhead expenses to its Part A **MAC**. The hospital's facility charge does not involve a separate service (such as a diagnostic test) furnished in addition to the physician's professional service; rather, it represents solely the overhead expenses associated with furnishing the professional service itself.
- Accordingly, hospitals bill for "facility charges" under the physician evaluation and management (E&M) codes in the range of 99201-99245 and **G0463 (for hospitals paid under the outpatient prospective payment system)**.
- E&M codes, representing the hospital's "facility charge" for the overhead expenses associated with furnishing the professional service itself, are excluded from SNF consolidated billing (CB). Effective for claims with dates of service on or after January 1, 2006, Medicare's common working file will bypass CB edits when billed with revenue code 0510 (clinic visit) with an E&M HCPCS code in the range of *99201-99245* **and, effective January 1, 2014, with HCPCS code G0463**.

Section 30.1: Health Insurance Prospective Payment System (HIPPS) Rate Code

- The HIPPS rate code consists of the three-character resource utilization group (RUG) code that is obtained from the "grouper" software program followed by a two digit assessment indicator (AI) that specifies the type of assessment associated with the RUG code obtained from the grouper. **Providers may access the *Resident Assessment Instrument* (RAI) manual located at** *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html*.

Section 30.2: Coding PPS Bills for Ancillary Services

When coding PPS bills for ancillary services associated with a Part A inpatient stay, the traditional revenue codes will continue to be shown, for example, 0250 Pharmacy, 042x Physical Therapy, in conjunction with the appropriate entries in service units and total charges.

- SNFs are required to report the number of units based on the procedure or service.
- For therapy services, that is revenue codes 042x, 043x, and 044x, units represent the number of calendar days of therapy provided. For example, if the beneficiary received physical therapy, occupational therapy or speech-language pathology on May 1, that would be considered one calendar day and would be

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billed as one unit.

- SNFs are required to report the actual charge for each line item, in Total Charges.

Section 30.3: Adjustment Requests

Adjustment requests based on corrected assessments must be submitted within 120 days of the service "through" date. The "through" date will be used to calculate the period during which adjustment requests may be submitted based on corrected RAI assessments. The "through" date indicates the last day of the billing period for which the HIPPS code is billed. Adjustment requests based on corrected assessments must be submitted within 120 days of the "through" date on the bill. For HIPPS changes resulting from an MDS correction, providers must append a condition code D2 on their adjustment claim. An edit is in place to limit the time for submitting this type of adjustment request to 120 days from the service "through" date.

CMS expects that most HIPPS code corrections will be made during the course of the beneficiary's Medicare Part A stay. Therefore, providers that routinely submit corrections after the beneficiary's Part A stay has ended may be subject to focused medical review.

Adjustment requests to change a HIPPS code may not be submitted for any claim that has already been medically reviewed. This applies whether or not the medical review was performed either pre- or post-payment. All adjustment requests submitted are subject to medical review. Information regarding medical review is located in the *Medicare Program Integrity Manual*.

Section 40.3.5.2: Leave of Absence

- Leave of absence (LOA) days are shown on the bill with revenue code 018X and LOA days as units. However, charges for LOA days are shown as zero on the bill, and the SNF cannot bill the beneficiary for them except as specified in Chapter 1 of this manual at section 30.1.1.1. Occurrence span code 74 is used to report the LOA from and through dates.
- Providers should review the RAI manual to clarify situations where an LOA is not appropriate, for example observation stays in a hospital lasting greater than 24 hours.

Medicare Claims Processing Manual, Chapter 13

Section 90.5 (Transportation of Equipment Billed by a SNF to a MAC)

- When a SNF resident receives a portable x-ray service during the course of a Medicare-covered stay in the SNF, only the service's professional component

(representing the physician's interpretation of the test results) is a separately billable physician service under Part B (see Section 20 of Chapter 6).

- By contrast, the technical component representing the procedure itself, including any associated transportation and setup costs, would be subject to consolidated billing (CB) (the SNF "bundling" requirement for services furnished to the SNF's Part A residents), and must be included on the SNF's Part A bill for the resident's covered stay (bill type 21x) rather than being billed separately under Part B.

Additional information

The official instruction for CR8997 was issued to your MAC via two transmittals. The first transmittal updates the *Medicare Claims Processing Manual* and it is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3230CP.pdf*. The second updates the *Medicare Benefit Policy Manual* and it is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R204BP.pdf*. If you have any questions, please contact your MAC at their toll-free number. That number is available at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html* under - How Does It Work?

MLN Matters® Number: MM8997 *Revised*
Related Change Request (CR) #: CR 8997
Related CR Release Date: April 3, 2015
Effective Date: June 15, 2015
Related CR Transmittal #: R3230CP and R204BP
Implementation Date: June 15, 2015

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877-660-1759 (speech and hearing impaired)

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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

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877-847-4992

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

The SPOT help desk

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

Addresses

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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

Q2 Administrators, LLC
Part B QIC South Operations
ATTN: Administration Manager
P.O. Box 183092
Columbus, Ohio 43218-3092

General inquiries

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

Email**:** *FloridaB@fcso.com*
Online form: *http://medicare.fcso.com/Feedback/161670.asp*

Provider enrollment

Provider Enrollment
P.O. Box 44021
Jacksonville, FL 32231-4021

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

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Jacksonville, FL 32231-4071

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

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Medicare Education and Outreach
P.O. Box 45157
Jacksonville, FL 32232-5157

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Fraud and abuse complaints
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Jacksonville, FL 32232-5087

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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
http://medicare.fcso.com

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

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

First Coast University
http://www.fcsouniversity.com/

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email: *FCSOSPOTHelp@FCSO.com*

Addresses

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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

Reconsiderations
Q2 Administrators, LLC
Part B QIC South Operations
ATTN: Administration Manager
P.O. Box 183092
Columbus, Ohio 43218-3092

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Email: *medical.policy@fcso.com*

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P.O. Box 44078
Jacksonville, FL 32231-4078

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Jacksonville, FL 32231-4071

Overpayments
Medicare Part B Debt Recovery
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Jacksonville, FL 32231-4141

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Fraud and abuse complaints
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Jacksonville, FL 32232-5087

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Centers for Medicare & Medicaid Services

http://www.cms.gov

First Coast University

http://www.fcsouniversity.com/

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Centers for Medicare & Medicaid Services

http:// www.medicare.gov

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

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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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P.O. Box 2078
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Email: *medical.policy@fcso.com*

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Jacksonville, FL 32231-4078

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Jacksonville, FL 32231-4071

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