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MLN Matters Disclaimer Statement

Below is the CMS Medicare Learning Network (MLN) Matters Disclaimer statement that applies to all MLN Matters articles in this bulletin.

“This article was prepared as a service to the public and is not intended to grant rights or impose obligations. MLN Matters articles may contain references or links to statutes, regulations or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.”

Sources for “Medicare A News” Articles

The purpose of “Medicare A News” is to educate the Noridian Medicare Part A provider community. The educational articles can be advice written by Noridian staff or directives from CMS. Whenever we publish material from CMS, we will do our best to retain the wording given to us; however, due to limited space in our bulletins, we will occasionally edit this material. Noridian includes “Source” following CMS derived articles to allow for those interested in the original material to research it at the CMS website, http://www.cms.gov/manuals. The CMS Change Request (CR) and the date issued will be referenced within the “Source” portion of applicable articles.

CMS publishes a series of educational articles within their Medicare Learning Network (MLN), titled “MLN Matters.” These “MLN Matters” articles are also included in Noridian bulletins. The Medicare Learning Network is a brand name for official CMS national provider education products designed to promote national consistency of Medicare provider information developed for CMS initiatives.
Quarterly Provider Update from CMS

The Quarterly Provider Update is a comprehensive resource published by CMS on the first business
day of each quarter. It is a listing of all non-regulatory changes to Medicare including Change
Requests (CRs), manual changes and any other instructions that could affect providers.

Regulations and instructions published in the previous quarter are also included in the Update.

The purpose of the Quarterly Provider Update is to:

- Inform providers about new developments in the Medicare program;
- Assist providers in understanding CMS programs and complying with Medicare regulations
  and instructions;
- Ensure that providers have time to react and prepare for new requirements;
- Announce new or changing Medicare requirements on a predictable schedule; and
- Communicate the specific days that CMS business will be published in the Federal Register.

Sign up for the Quarterly Provider Update listserv to receive notification when regulations and program
instructions are added throughout the quarter, (electronic mailing list) at http://www.cms.gov/About-CMS/
Agency-Information/Aboutwebsite/index.html?redirect=/AboutWebsite/EmailUpdates/list.asp. Indicate
that you wish to receive the CMS-QPU Listserv on the list of available publications.

The Quarterly Provider Update can be accessed on the CMS website at http://www.cms.gov/
QuarterlyProviderUpdates. We encourage you to bookmark this website and visit it often for this
valuable information.

Source: PM AB-03-075, CR 2686 dated May 23, 2003

Unsolicited or Voluntary Refunds Reminder

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

Background

Medicare carriers and intermediaries and A/B MACs receive unsolicited or voluntary refunds from
providers. These voluntary refunds are not related to any open accounts receivable. Providers billing
intermediaries typically make these refunds by submitting adjustment bills, but they occasionally submit
refunds via check. Providers billing carriers usually send these voluntary refunds by check.

Related Change Request (CR) 3274 is intended mainly to provide a detailed set of instructions for Medicare
carriers and intermediaries regarding the handling and reporting of such refunds. The implementation and
effective dates of that CR apply to the carriers and intermediaries. But, the important message for providers
is that the submission of such a refund related to Medicare claims in no way limits the rights of the Federal
Government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative
remedies arising from or relating to those or any other claims.

Additional Information

The official CMS CR3274 instruction may be viewed at http://www.cms.gov/Regulations-and-Guidance/
Guidance/Transmittals/2004-Transmittals-Items/CMS049838.html and in the Medicare Learning Network

Effective Date: January 1, 2005

Implementation Date: January 4, 2005

Sources: Transmittal 50, CR 3247 dated July 30, 2004; Internet Only Manual (IOM) Medicare
Financial Management Manual, Publication 100-06, Chapter 5, Section 410
Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease, and Myelodysplastic Syndromes

MLN Matters® Number: MM9620
Related Change Request (CR) #: CR 9620
Related CR Release Date: April 29, 2016
Effective Date: January 27, 2016
Related CR Transmittal #: R191NCD and R3509CP
Implementation Date: October 3, 2016

Provider Types Affected
This MLN Matters® Article is intended for physicians and providers submitting stem cell transplantation claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9620, from which this article was developed, notifies providers that effective for claims with dates of service on and after January 27, 2016, for the use of allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for treatment of Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease is covered by Medicare, but only if provided in the context of a Medicare-approved clinical study meeting specific criteria under the Coverage with Evidence Development (CED) paradigm.

CR9620 also clarifies the ICD-9 and ICD-10 diagnosis codes for allogeneic HSCT for treatment of Myelodysplastic Syndromes (MDS) in the context of a Medicare-approved, prospective clinical study under CED. Specifically, for dates of service on or after August 4, 2010, through September 30, 2015, the ICD-9-CM diagnosis codes are 238.72, 238.73, 238.74, or 238.75 AND clinical trial ICD-9-CM diagnosis code V70.7. For dates of service on or after October 1, 2015, the ICD-10-CM diagnosis codes are D46.A, D46.B, D46.C, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, or D46.Z AND clinical trial ICD-10-CM diagnosis code Z00.6. Make sure your billing staff is aware of these determinations.

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

Multiple myeloma is a neoplastic plasma-cell disorder. Myelofibrosis is a stem cell-derived hematologic disorder. Sickle cell disease is a group of inherited red blood cell disorders created by the presence of abnormal hemoglobin genes. On April 30, 2015, the Centers for Medicare & Medicaid Services (CMS) accepted a formal request from the American Society for Blood and Marrow Transplantation (ASBMT) to reconsider its policy and expand coverage of allogeneic HSCT for sickle cell disease, Myelofibrosis, multiple myeloma and rare diseases.

Myelodysplastic Syndrome (MDS) refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. On August 4, 2010, CMS issued a final decision stating that allogeneic HSCT for MDS is covered by Medicare only if provided pursuant to a Medicare-approved clinical study under CED. CR 7137 (see the article, MM7137 at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7137.pdf) provides specific ICD-9 related coding and claims processing requirements regarding this particular coverage decision, and CRs 8197 and 8691 (see MM8197 at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8197.pdf and MM8691 at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8691.pdf) provide ICD-10 related coding requirements. On November 30, 2015, CMS accepted a formal request from the National Marrow Donor Program (NMDP) to clarify the list of ICD-9-CM and ICD-10-CM diagnosis codes covered for allogeneic HSCT for the treatment of MDS in the context of a Medicare-approved clinical study under CED.
On January 27, 2016, CMS issued a final decision to expand national coverage of items and services necessary for research in an approved clinical study via Coverage with Evidence Development (CED) under Section 1862(a)(1)(E) of the Social Security Act (the Act) for allogeneic HSCT for the following indications:

- Multiple Myeloma
- Myelofibrosis
- Sickle Cell Disease

Refer to the following Medicare manual sections for more information regarding this NCD and further billing instructions specific to this NCD and the business requirements specific to CR9620:


In addition to the diagnosis codes detailed at the beginning of this article, providers need to be aware of the other billing requirements, as follows:

**Inpatient Claims**

For claims submitted on type of bill 11X for discharges on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An ICD-10-PCS procedure code of 30230G1, 30230Y1, 30233G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1, 30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, or 30263Y1 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND
- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
  - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
    - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
    - Sickle Cell Disease-ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819

**Outpatient Claims**

For claims submitted on type of bill 13X or 85X for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND
- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
  - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
  - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
  - Sickle Cell Disease-ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819
Method II Critical Access Hospital (CAH) Claims
For claims submitted on type of bill 85X with Revenue Codes 96X, 97X, or 98X for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- Condition code 30, denoting qualifying clinical trial AND
- Value code D4 showing the Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website) along with the appropriate ICD-10-diagnosis code of:
  - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
  - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
  - Sickle Cell Disease-ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819

Professional Claims
For professional claims submitted on type of bill 85X with Revenue Codes 96X, 97X, or 98X for dates of service on or after January 27, 2016, for HSCT for the treatment of Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease, the claim must show:

- An HSCT CPT code of 38240 AND
- The clinical trial ICD-10-CM code of Z00.6 AND
- The Q0 modifier AND
- A Place of Service Code of 19, 21, or 22 along with the appropriate ICD-10-CM diagnosis code of:
  - Multiple Myeloma-ICD-10-CM diagnosis code C90.00, C90.01, or C90.02 OR
  - Myelofibrosis-ICD-10-CM diagnosis code C94.40, C94.41, C94.42, D47.4, or D75.81 OR
  - Sickle Cell Disease-ICD-10-CM diagnosis code D57.00, D57.01, D57.02, D57.1, D57.20, D57.211, D57.212, D57.219, D57.40, D57.411, D57.412, D57.419, D57.80, D57.811, D57.812, or D57.819

For all of the above claims types submitted without the requisite coding, MACs will deny the claims using the following messages:

- Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a ‘medical necessity’ by the payer. 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 http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code - Patient Responsibility (PR) if an Advance Beneficiary Notice (ABN)/Hospital Notice on Non-Coverage (HINN), otherwise Contractual Obligation (CO)

For claims with dates of service prior to the implementation date of CR9620, MACs shall perform necessary adjustments only when the provider brings such claims to the attention of their MAC.

Additional Information
Percutaneous LAAC

MLN Matters® Number: MM9638
Related Change Request (CR) #: CR 9638
Related CR Release Date: May 6, 2016
Effective Date: February 8, 2016
Related CR Transmittal #: R192NCD and R3515CP
Implementation Date: October 3, 2016

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) 9638 informs MACs that the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering percutaneous Left Atrial Appendage Closure (LAAC) through Coverage with Evidence Development (CED) when LAAC is furnished in patients with Non-Valvular Atrial Fibrillation (NVAF) and the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device’s FDA-approved indication and meets all the specified conditions. Make sure that your billing staffs are aware of these changes.

Background
LAAC is a strategy to reduce the risk of stroke by closing the Left Atrial Appendage (LAA) in patients with NVAF. Patients with NVAF, an abnormally rapid, irregular heartbeat, are at an increased risk of stroke. Some evidence suggests that many of the strokes attributed to NVAF originate from the LAA. The LAA is a tubular structure that opens into the left atrium of the heart. LAAC with a percutaneously implanted device could be used in patients with NVAF to reduce cardioembolic stroke risk as a potential alternative to oral anticoagulation.

On February 8, 2016, CMS issued an NCD covering percutaneous LAAC through CED when LAAC is furnished in patients with NVAF and the device has received FDA PMA for that device’s FDA-approved indication and meets all the specified conditions. Coverage requires that patients must have:

- A CHADS2 score $\geq 2$ (Congestive heart failure, Hypertension, Age $>75$, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score $\geq 3$ (Congestive heart failure, Hypertension, Age $\geq 65$, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)
- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record
- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants.

The NCD lists the criteria for the physician and facility criteria and includes a requirement for a multidisciplinary team to be engaged in patient care.

The patient must be enrolled in, and the multidisciplinary team (MDT) and hospital must participate in a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients and 2) tracks the specified annual outcomes for each patient for a period of at least four years from the time of the LAAC. The registry must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved registries will be posted at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html. The process for submitting a registry to Medicare is outlined in the NCD.
For devices and indications that are not approved by FDA, patients must be enrolled in a qualifying FDA-approved Randomized Controlled Trial (RCT). The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved studies will be posted at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html. The process for submitting a clinical research study to Medicare is outlined in the NCD.

LAAC claims with dates of service on or after February 8, 2016, will be billed with temporary level III CPT code 0281T (percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s) left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation) and will be MAC-priced. CMS will issue further instructions, once a permanent CPT level 1 replaces the temporary code.

LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the criteria outlined in the NCD, which is at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R192NCD.pdf.

Additional Billing Instructions
On institutional claims (type of bill 11X), hospitals should show:

- ICD-10 procedure code of 02L73DK (Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach)
- A primary diagnosis code of one of the following:
  - I48.0 – Paroxysmal atrial fibrillation
  - I48.1 – Persistent atrial fibrillation
  - I48.2 – Chronic atrial fibrillation
  - I48.91 – Unspecified atrial fibrillation
- A secondary ICD-10 diagnosis code of Z00.6 – Encounter for examination for normal comparison and control in clinical research program
- Condition Code 30 (Qualifying Clinical Trial), and
- Value Code D4 - Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website)

MACs will fully reject inpatient claims for LAAC with discharges on or after February 8, 2016, when billed without the appropriate procedure, diagnosis, or clinical trial codes, with the following messages:

- Claim Adjustment Reason Code (CARC) 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.
- 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 http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code – Contractual Obligation (CO)

Professional claims with dates of service on or after February 8, 2016, for LAAC under CED will be paid only when billed with the following codes:

- CPT 0281T
- Primary ICD-10 diagnosis code (one of the following):
  - I48.0 – Paroxysmal atrial fibrillation,
  - I48.1 – Persistent atrial fibrillation,
  - I48.2 – Chronic atrial fibrillation,
  - I48.91 – Unspecified atrial fibrillation
- Place of Service code of 21 (inpatient hospital)
• Secondary diagnosis code Z00.6
• Modifier Q0
• Clinical trial number in item 23 of the CMS-1500 form or electronic equivalent

MACs will deny LAAC claims when billed without the appropriate diagnosis codes, with the following messages:

• CARC 50 – These are non-covered services because this is not deemed a “medical necessity” by the payer. 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 http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

• Group Code – Contractual Obligation (CO).

MACs will deny claims for LAAC with 0281T with a POS code other than 21 using the following messages:

• CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. 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 http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

• Group Code – Contractual Obligation (CO).

MACs will return claim lines on professional claims for 0281T as unprocessable when the Q0 modifier is not present using messages:

• CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

• Group Code – Contractual Obligation (CO)

MACs will return claim lines with 0281T as unprocessable when billed without secondary diagnosis code Z00.6 using the following messages:

• CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

• RARC M76: “Missing/incomplete/invalid diagnosis or condition.”

• Group Code – Contractual Obligation (CO)

Finally, failure to include the clinical trial number will result in MACs returning claim lines as unprocessable using the following messages:

• CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

• RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number.

• Group Code – Contractual Obligation (CO)

Note that MACs will not search their files for claims for LAAC with dates of service on or after February 8, 2016, that were processed prior to implementation of CR9638. However, they will adjust such claims that you bring to their attention.
Additional Information

Prolonged Drug and Biological Infusions Started Incident to a Physician’s Service Using an External Pump – Medicare Policy Clarified

MLN Matters® Number: SE1609

Provider Types Affected
This MLN Matters® Special Edition article is intended for all physicians and hospital outpatient departments submitting claims to Medicare Administrative Contractors (MACs) for prolonged drug and biological infusions started incident to a physician’s service using an external pump. Note that this article does not apply to suppliers’ claims submitted to Durable Medical Equipment MACs (DME MACs).

What You Need to Know
Medicare pays for drugs and biologicals which are not usually self-administered by the patient and furnished “incident to” physicians’ services rendered to patients while in the physician’s office or the hospital outpatient department. In some situations, a hospital outpatient department or physician office may:

• purchase a drug for a medically reasonable and necessary prolonged drug infusion,
• begin the drug infusion in the care setting using an external pump,
• send the patient home for a portion of the infusion, and
• have the patient return at the end of the infusion period.

In this case, the drug or biological, the administration, and the external infusion pump is billed to your MAC. However, because prolonged drug and biological infusions started incident to a physician’s service using an external pump should be treated as an incident to service, it cannot be billed on suppliers’ claims to DME MACs.

Background
Under section 1861(s)(2)(A) of the Social Security Act (the Act), Medicare will pay for drugs and biologicals which are furnished “incident to” a physician’s professional service. Under section 1861(s)(2)(B) of the Act, Medicare will pay for drugs and biologicals which are not usually self-administered by the patient furnished as “incident to” physicians’ services rendered to outpatients. In order for Medicare to pay for a drug or biological under section 1861(s)(2)(A) or (B) of the Act, the physician or hospital (respectively) must incur a cost for the drug or biological. Generally, the administration of drugs or biologicals covered by Medicare under the “incident to” benefit (1861(s)(2)(A) and (B)) will start and end while the patient is in the physician’s office or the hospital outpatient department under the supervision of a physician.

However, in some situations a hospital or office may purchase a drug for a medically reasonable and necessary prolonged drug infusion, then begin the drug infusion in the care setting using an external pump, send the patient home for a portion of the infusion duration, and have the patient return at the end of the infusion period. In this case, the drug or biological continues to be covered under section 1861(s)(2)(A) and (B) of the Act and is billable to the MAC even though the entire administration of the drug or biological did not occur in the physician’s office or the hospital outpatient department. Also, the drug or biological continues to meet the requirements for the “incident to” benefit as the physician or hospital incurred a cost for the drug or biological and the administration of the drug began in a physician’s office or hospital “incident to” a physician’s service. For the administration of the drug, the physician supervision rules under 42 CFR Section 410.26(b) (5) and 42 CFR §410.27 (a) (1)(iv) and CMS Publication 100-02, Chapter 15, section 50.3 apply only while the patient is present in the physician’s office or hospital outpatient department. CMS does not provide specific coding guidance; however, appropriate drug administration codes for this situation would describe the services that are provided by the physician or hospital (for example, intravenous infusion, patient monitoring) while the patient is in the office or the outpatient setting.
Medicare’s payment for the administration of the drug or biological billed to the MAC will also include payment for equipment used in furnishing the service. Equipment, such as an external infusion pump used to begin administration of the drug or biological that the patient takes home to complete the infusion, is not separately billable as durable medical equipment for a drug or biological paid under the section 1861(s) (2)(A) and (B) incident to benefit. The MAC may direct use of a code described by CPT or an otherwise applicable HCPCS code for the drug administration service. If necessary, the MAC may direct use of a miscellaneous code for the drug administration if there is no specified code that describes the drug administration service that also accounts for the cost of equipment that the patient takes home to complete the infusion that they later return to the physician or hospital.

Medicare Coverage of Diagnostic Testing for Zika Virus

MLN Matters® Number: SE1615

Provider Types Affected

This MLN Matters® Article is intended for physicians, providers, and clinical diagnostic laboratories who submit claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

This MLN Matters Special Edition Article informs the public that Medicare covers Zika virus testing under Medicare Part B as long as the clinical diagnostic laboratory test is reasonable and necessary for the diagnosis or treatment of a person’s illness or injury. This article reminds laboratories furnishing Zika virus tests to contact their MACs for guidance on the appropriate billing codes to use on claims for Zika virus testing. Furthermore, laboratories should provide resources and cost information as may be requested by the MACs in order for the MACs to establish appropriate payment amounts for the tests.

Background

On February 1, 2016, the World Health Organization (WHO) declared the Zika virus a Public Health Emergency of International Concern (PHEIC). According to the Centers for Disease Control and Prevention (CDC), the Zika virus disease is a nationally notifiable condition that has caused outbreaks in many countries and territories. The virus is primarily spread through the bite of an infected Aedes species mosquito, although other modes of transmission include mother-to-child transmission, blood transfusion and sexual transmission. Currently there are a few diagnostic tests that can determine the presence of the virus. These tests are available through the CDC and CDC-approved state health laboratories. A small number of tests have been issued an Emergency Use Authorization by the Food and Drug Administration (FDA) and may be available through commercial laboratories.

Medicare Part B pays for clinical diagnostic laboratory tests that are reasonable and necessary for the diagnosis or treatment of a person’s illness or injury. Presently there are no specific HCPCS codes for testing of the Zika virus; however, laboratories should contact their local MACs for guidance on the appropriate billing codes to use on claims for Zika virus testing. Furthermore, laboratories should provide resources and cost information as may be requested by the MACs in order for the MACs to establish appropriate payment amounts for the tests.

Additional Information


EDISS Gateway Transition Begins May 23rd for Vendors!

The EDI Support Services (EDISS) Gateway transition will begin May 23, 2016. We are excited about the enhanced support capabilities and the new tools this transition will provide to our EDI support staff to better assist our Submitter Community! In the next several months, EDISS will publish education to keep our community up to date with the transition and to announce the next group of Submitters scheduled to transition.

EDISS Gateway related changes are outlined on the Gateway Transition page of www.edissweb.com. It is vital that all Submitters review this information and understand how the change impacts their organization.

The first phase of the EDISS Gateway transition will focus on our Vendor community, entities that EDISS categorizes as Billing Services, Clearinghouses and Billing Groups.

If your organization’s Trading Partner ID begins with the prefix of ‘BS’, you will be issued new Gateway credentials in the next 1-3 weeks. EDISS will communicate timeframes of the Clearinghouse and Billing Group credential distribution in the following weeks (TPIDs with ‘CH’ and ‘BG’ prefix respectively). Billing Services and Clearinghouses with TPIDs that do not begin with ‘BS’ or ‘CH’ will be transitioned during the direct submitter phases of the EDISS Gateway transition.

Upon receipt of new Gateway credentials, you will have 60 days to transition your electronic transactions into the new Gateway. On the 61st day, your Legacy credentials will be disabled and submissions or file retrieval in the Legacy Gateway will no longer be available. If your organization is not able to transition in the allotted time, please contact EDISS to determine a secondary transition timeframe.

Note: Your EDISS Connect Account Profile fax number and email address will be used for Production credential distribution and password resets for the upcoming transition. EDISS expects Submitters to:

1. Verify your fax number and email address linked to your EDISS Connect profile is current.
   - Failure to have an accurate fax and email address will result in your new Gateway credentials failing to deliver.

2. If the email address tied to your Connect account profile is used across multiple profiles, designate unique addresses for each Connect account profile.
   - If unable to complete this step, the ‘Forgot Password’ feature of the EDISS Gateway SSPR will not function for your organization.

Taking the above action will ensure that new Gateway credentials are received and electronic transaction processing is not interrupted. Instructions on making EDISS Connect profile updates can be found at www.edissweb.com.

The timeline and phases of the new Gateway rollout will be as follows (these dates may be subject to change):

<table>
<thead>
<tr>
<th>Task</th>
<th>Start</th>
<th>Organizations Affected</th>
<th>Summary of Phase</th>
</tr>
</thead>
</table>
| Gateway Pilot    | 1/25/16  | Subset of:• Billing Services  
                     • Clearinghouses  
                     • Direct Submitters | The Pilot Group is comprised of a subset of Network Service Vendors, Clearinghouses, Billing Services and direct Submitters conducting initial production submissions as BETA testers. 

EDISS is processing the following Lines of Business during the Pilot launch: Medicare A/B, IAMCD and BCBSND/WY. |
| Vendor Transition| 5/23/16  | • Billing Services  
                     • Clearinghouses  
                     • Billing Groups  | The Vendor phase of the transition will make up the largest percentage of claim volumes EDISS will see. This phase will include all Lines of Business. |
### Direct Submitter Transition

<table>
<thead>
<tr>
<th>Task</th>
<th>Start</th>
<th>Organizations Affected</th>
<th>Summary of Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Submitter Transition</td>
<td>Upcoming</td>
<td>• JF A &amp; BCND/WY&lt;br&gt;bJF B ND/WY/MT/SD/UT/ID &amp; BSND/WY&lt;br&gt;bJF B AZ/WA/OR/AK&lt;br&gt;bJE A/Legacy &amp; JE B NV/HI&lt;br&gt;bJE B NCA&lt;br&gt;bJE B SCA</td>
<td>The Direct Submitter portion of the transition will be segregated based on state of submission.&lt;br&gt;*The Direct Submitter phase of the transition is broken down by State and will be defined in future distributions and on <a href="http://www.edissweb.com">www.edissweb.com</a></td>
</tr>
</tbody>
</table>

### Final Clean-Up

<table>
<thead>
<tr>
<th>Task</th>
<th>Start</th>
<th>Organizations Affected</th>
<th>Summary of Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Clean-Up</td>
<td>Upcoming</td>
<td>• All un-transitioned Submitters</td>
<td>This phase consists of reaching out to any Submitter who has not yet transitioned into the new solution. The end of this phase will be a hard stop and submission into the Legacy Gateway will be terminated.</td>
</tr>
</tbody>
</table>

Follow the EDISS email distributions and visit [www.edissweb.com](http://www.edissweb.com) to stay up-to-date on current education related to the Gateway transition.

### Noridian Medicare Portal: Third Party Biller Registration

Third party billers are defined as billers who do not directly send the claims to Noridian for processing, but rather send to another billing service or clearinghouse to then be forwarded on to Noridian.

In order for third party billers to register for Noridian Medicare Portal access, the provider must first register as a provider administrator. Once the provider has completed this, the third party biller can then register as a Provider End User.

By completing the registration in this manner, it protects the provider and beneficiary information by giving the provider the ability to remove access if needed.

To learn more, visit the [Noridian Medicare Portal page](http://Noridian Medicare Portal page) of the Noridian website.

### Noridian Medicare Portal: What is a Trading Partner ID?

During the Noridian Medicare Portal registration process, users are asked to enter the provider’s Trading Partner ID. This ID number is referring to the Provider Submitter ID assigned to the billing NPI when registering for an electronic transaction with EDI Support Services (EDISS). Being registered for an electronic transaction is required in order to have access to the Noridian Medicare Portal.

To locate the correct submitter ID to be used during the registration, the provider will need to complete the following steps:

- Identify the individual within your facility that has access to the EDISS Connect account. For example, this would be the person responsible for enrolling the facility in electronic transactions.
- Log into EDISS Connect and look for the blue header within the account.
- Locate the field titled 'SubmitterId' within the blue header.
- Use the ‘SubmitterId’ listed when registering for the Noridian Medicare Portal.

**Note:** The EDISS Connect Registration is a separate registration from the Noridian Medicare Portal Registration. EDISS Connect will only supply the Provider Submitter ID.
To learn more, visit the Noridian Medicare Portal page of the Noridian website.
Noridian Medicare Portal – Dual Role Access

For providers/suppliers with fewer than 25 full-time employees, dual role access is available. The first step in obtaining this access is to ensure the Provider Administrator role is selected on Step 5 of the registration process and “Yes” is selected when being asked if your facility is a small provider/supplier. When the registration is complete, the user can then select “Manage Account”, Navigate to the “Account Access and Roles” tab, and then select the option to change the role to “Provider/Supplier Administrator and End User.” Once the request is completed, this access is processed by Noridian team members who research the size of the provider/supplier company before approving or denying the Dual Role access.

When a Provider Administrator has the Dual Role, they log into the portal and first see the Administrator Main Menu where they can oversee staff access and portal usage. In the top left section of the webpage, the End User Main Menu option is made available and would be used to conduct functionality inquiries.

Below are descriptions of the types of functions that are available to Dual Role users on each of their menu options.
Main Menu | Functions Available
--- | ---
**Administrator** | • Pending Request Approval or Denial  
• Remove User Access  
• Search/Manage Users
**End User** | • Eligibility  
• Claim Status  
• Appeals Submission and Status  
• Remittance Advises  
  • Claim-Specific  
  • Full Remittance (Part B only)  
• Financial Information  
• DME Overpayments  
• Same or Similar (DME Only)  
• PMD Prior Authorization (DME Only)

Additional details can be found on the Browse By Topic / Noridian Medicare Portal section of the website.

**CMS Provider Minute Videos for Part A and Part B Providers and DMEPOS Suppliers**

CMS Provider Minute Videos for Part A and Part B Providers and DMEPOS Suppliers

The Medicare Learning Network has a series of CMS Provider Minute videos on compliance for Part A and Part B providers and Durable Medical Equipment, Prosthetics, Orthotic, and Supplies (DMEPOS) suppliers. These videos have tips to help you properly submit claims with sufficient documentation in order to receive correct payment the first time.

**MLN Connects® Provider eNews – April 7, 2016**

MLN Connects® Provider eNews for April 07, 2016

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In This Edition:

**MLN Connects® Events**

• Open Payments 2016: Prepare to Review Reported Data Call – Last Chance to Register  
• IMPACT Act: Data Element Library Call – Last Chance to Register  
• Medicare Shared Savings Program ACO Application Process Call – Register Now  
• 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call – Register Now  
• National Partnership to Improve Dementia Care and QAPI Call – Register Now

**Other CMS Events**

• March ICD-10 Coordination and Maintenance Committee: Comments on Proposals due April 8

**Medicare Learning Network® Publications and Multimedia**

• Medicare Shared Savings Program and Rural Providers Fact Sheet – Revised  
• ACOs: What Providers Need to Know Fact Sheet – Revised  
• Improving Quality of Care for Medicare Patients: ACOs Fact Sheet – Revised  
• Federally Qualified Health Center Fact Sheet – Revised  
• Critical Access Hospital Booklet – Revised
FYI

- DMEPOS Information for Pharmacies Fact Sheet – Reminder
- Safeguard Your Identity and Privacy Using PECOS Fact Sheet – Reminder

Announcements
- Comprehensive Care for Joint Replacement Model Launched
- CMS Invites QIN-QIOs to Submit Special Innovation Projects
- Open Payments: Physician and Teaching Hospital Review and Dispute Period Began April 1
- Join the Million Hearts® Model: Letter of Intent due April 15
- CMS to Release a CBR on Modifiers 24 and 25 for General Surgeons in April
- 2016 PQRS GPRO Registration Open through June 30
- 2015 Mid-Year QRURs Available
- Find Information on the SNF Value-Based Purchasing Program
- April Quarterly Provider Update Available
- Help Prevent Alcohol Misuse or Abuse

Claims, Pricers, and Codes
- April 2016 Outpatient PPS Pricer File Available

MLN Connects® Provider eNews – April 14, 2016

MLN Connects® Provider eNews for April 14, 2016

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In This Edition:

MLN Connects® Events
- Medicare Shared Savings Program ACO Application Process Call – Last Chance to Register
- 2016 PQRS Reporting: Avoiding 2018 Negative Payment Adjustments Call – Last Chance to Register
- National Partnership to Improve Dementia Care and QAPI Call – Register Now
- How to Register for the 2016 PQRS Group Practice Reporting Option Call – Registration Now Open
- 2015 Mid-Year QRURs Webcast – Registration Now Open

Other CMS Events
- Learn about the SNF Value-Based Purchasing Program at Open Door Forum
- IRF Quality Reporting Program Provider Training

Medicare Learning Network® Publications and Multimedia
- Enforcement of the PHP 20 Hours per Week Billing Requirement MLN Matters® Article – New
- Updates to Medicare’s Organ Acquisition and Donation Payment Policy MLN Matters Article – New
- CMS Provider Minute: CT Scans Video – New
- Medicare Learning Network LM/POS FAQs Booklet – New
- Medicare Quarterly Provider Compliance Newsletter Educational Tool – New
- Provider Enrollment Requirements for Writing Prescriptions for Medicare Part D Drugs MLN Matters Article – Revised
- ICD-10-CM Diagnosis Codes for Bone Mass Measurement MLN Matters Article – Revised
FYI

- Medicare Secondary Payer Provisions Web-Based Training Course – Revised
- Infection Control: Injection Safety Web-Based Training Course – Revised

Announcements
- CMS Launches Largest-Ever Multi-Payer Initiative to Improve Primary Care in America
- Submit Comments on QRDA Implementation Guide for HQR by April 18
- IRF Quality Reporting Program Data Submission Deadline: May 15
- LTCH Quality Reporting Program Data Submission Deadline: May 15
- 2016 eCQMs Annual Update Available
- EHR Incentive Programs 2016 Program Requirements: New Resources
- ICD-10 Coding Resources
- National Healthcare Decisions Day is April 16
- April is National Minority Health Month

Claims, Pricers, and Codes
- April 2016 OPPS Pricer File Update
- Updates to HCPCS Code Set

MLN Connects® Provider eNews – April 21, 2016
MLN Connects® Provider eNews for April 21, 2016
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In This Edition:

MLN Connects® Events
- National Partnership to Improve Dementia Care and QAPI Call – Last Chance to Register
- How to Register for the 2016 PQRS Group Practice Reporting Option Call – Register Now
- 2015 Mid-Year QRURs Webcast – Register Now
- New Audio Recording and Transcript Available

Other CMS Events
- Hospice Quality Reporting Program Webinar
- EHR Incentive Programs: March HIMSS16 Presentations

Medicare Learning Network® Publications and Multimedia
- Screening Pap Tests and Pelvic Examinations Booklet – New
- Hospital Value-Based Purchasing Program Fact Sheet – Revised

Announcements
- Hospital Inpatient PPS and LTCH PPS Proposed Rule for FY 2017
- Check Your 2015 Open Payments Data
- IRF Quality Reporting Program Data Submission Deadline: May 15 – Updated
- LTCH Quality Reporting Program Data Submission Deadline: May 15 – Updated
- 2017 Medicare Shared Savings Program: Notice of Intent to Apply Due by May 31
- CMS to Release a Comparative Billing Report on Psychotherapy and E/M Services in May
FYI

- 2016 Clinical Quality Measure Electronic Reporting: Updated Files
- April is STI Awareness Month: Talk, Test, Treat

Claims, Pricers, and Codes
- Rural Health Clinic Claims Processing Incorrectly

MLN Connects® Provider eNews – April 28, 2016

MLN Connects® Provider eNews for April 28, 2016
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In This Edition:

MLN Connects® Events
- How to Register for the 2016 PQRS Group Practice Reporting Option Call – Last Chance to Register
- 2015 Mid-Year QRURs Webcast – Register Now
- New Audio Recordings and Transcripts Available

Other CMS Events
- Comparative Billing Report on Subsequent Nursing Facility E/M Services Webinar
- Comparative Billing Report on Modifiers 24 and 25: General Surgeons Webinar
- Medicare Learning Network® Publications and Multimedia
- Acute Care Hospital Inpatient Prospective Payment System Booklet – Revised
- New Educational Web Guides Fast Fact

Announcements
- IRFs: Proposed FY 2017 Payment and Policy Changes
- SNFs: Proposed FY 2017 Payment and Policy Changes
- Hospice Benefit: Proposed FY 2017 Updates to the Wage Index and Payment Rates
- Open Payments: Physician and Teaching Hospital Review and Dispute Period Began April 1
- Nursing Homes, IRFs, and LTCHs: Comment on New Quality Measures by May 6
- Hospitals: Submit Comments on New EHR Measure by May 15
- Next Generation ACO Model Letter of Intent Deadline Extended to May 20
- 2016 PQRS GPRO Registration Open through June 30
- Home Health Quality Reporting Program: Quarterly QAO Interim Reports Available
- 2015 Mid-Year QRURs Available
- Track and Improve Your ICD-10 Progress
- Hand Hygiene Day is May 5

Claims, Pricers, and Codes
- Reprocessing Claims for Audiology Services
- Prolonged Drug and Biological Infusions Using an External Pump
MACRA Listening Session: Quality Payment Program Proposed Rule – Register Now

Tuesday, May 10 from 2 to 3 pm ET

To Register: Visit MLN Connects Event Registration. Space may be limited, register early.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) changes the way Medicare rewards clinicians for providing quality care by streamlining multiple quality programs into a new Quality Payment Program tied to Part B Fee-For-Service payments. With the implementation of MACRA and the replacement of the Sustainable Growth Rate, we will pay clinicians participating in the Merit-based Incentive Payment System or Advanced Alternative Payment Models of the Quality Payment Program beginning in 2019.

This listening session is an opportunity for stakeholders to provide CMS early feedback on proposed policy for the Quality Payment Program. We encourage participants to review the proposed rule (CMS-5517-P) prior to the listening session.

We will not consider feedback during the call as formal comments on the rule. See the proposed rule for information on submitting these comments by the close of the 60-day comment period on June 27, 2016.

Target audience: Part B Fee-For-Service clinicians; state and national associations that represent healthcare providers; and other stakeholders.

MLN Connects® Provider eNews – May 5, 2016

MLN Connects® Provider eNews for May 5, 2016

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In This Edition:

MLN Connects® Events
• MACRA Listening Session: Quality Payment Program Proposed Rule — Register Now
• 2015 Mid-Year QRURs Webcast — Register Now
• New Audio Recordings and Transcripts Available

Medicare Learning Network® Publications and Multimedia
• Medicare Coverage of Substance Abuse Services MLN Matters® Article — New
• Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician’s Service Using an External Pump MLN Matters Article — New

Announcements
• CMS Releases NPRM on the Medicare Access and CHIP Reauthorization Act of 2015
• DMEPOS Competitive Bidding: Round 2 Recompete/ National Mail-Order Reccompete Contract Suppliers Announced
• CMS Adds New Quality Measures to Nursing Home Compare
• CMS Publishes Final Rule on Fire Safety Requirements for Certain Health Care Facilities
• CMS Finalizes its Quality Measure Development Plan
• 2017 Medicare Shared Savings Program: Notice of Intent to Apply Period Closes May 31
• New PEPPERs Available for Hospices, SNFs, IRFs, IPFs, CAHs, LTCHs
• CMS to Release a CBR on Podiatry: Nail Debridement and E/M Services in May
• Focusing on Women’s Health

Claims, Pricers, and Codes
• Reprocessing of Selected Dialysis Claims

FYI
MLN Connects® Provider eNews – May 12, 2016
MLN Connects® Provider eNews for May 12, 2016
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In This Edition:

MLN Connects® Events
• 2015 Mid-Year QRURs Webcast – Last Chance to Register

Medicare Learning Network® Publications and Multimedia
• Limiting the Scope of Review on Redeterminations and Reconsiderations of Certain Claims MLN Matters® Article – Revised
• Transitional Care Management Services Fact Sheet – Revised
• Section 1011: Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens Fact Sheet – Revised
• DMEPOS Competitive Bidding Program Fact Sheets – Revised

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• Updates to Data Initiatives Increase Transparency of the Medicare Program
• HHS Awards over $260 Million to Health Centers Nationwide to Build and Renovate Facilities to Serve More Patients
• Open Payments: Physician and Teaching Hospital Review and Dispute Period Ends May 15
• 2016 Electronic Clinical Quality Measures: Updated Files Available
• Teaching Hospitals: Submitting Medicare GME Affiliation Agreements
• May is National Osteoporosis Month

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• Coinsurance Correction for Certain RHC Claims
• Billing Requirements for RHCs

MLN Connects® Provider eNews – May 19, 2016
MLN Connects® Provider eNews for May 19, 2016
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In This Edition:

MLN Connects® Events
• New Audio Recordings and Transcripts Available

Other CMS Events
• Comparative Billing Report on Psychotherapy and E/M Services Webinar
• Medicare Learning Network® Publications and Multimedia
• Part C Appeals: Organization Determinations, Appeals, and Grievances WBT – Revised
• Part D Coverage Determinations, Appeals, and Grievances WBT – Revised
• Resources for Medicare Beneficiaries Booklet – Revised
• How to Use the Searchable Medicare Physician Fee Schedule Booklet – Revised
• Updated MLN Matters® Search Indices
Announcements

• 2017 Medicare Shared Savings Program: Notice of Intent to Apply Period Closes May 31
• SNF Value-Based Purchasing Program: Specifications for New Measure
• 2014 PQRS Experience Report Available
• How to Use ICD-10 and Maintain Your Progress
• Talk to Your Patients about Mental Health

MLN Connects® Provider eNews – May 26, 2016
MLN Connects® Provider eNews for May 26, 2016
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In This Edition:

MLN Connects® Events
• Physician Compare Initiative Call – Registration Now Open
• New Audio Recording and Transcript Available

Other CMS Events
• Comparative Billing Report on Podiatry: Nail Debridement and E/M Services Webinar

Medicare Learning Network® Publications and Multimedia
• PECOS for DMEPOS Suppliers Fact Sheet – Reminder
• New Educational Web Guides Fast Fact

Announcements
• New Quality Payment Program Webpages
• 2016 PQRS GPRO Registration Open through June 30
• Updates to IRIS Software

MLN Connects® Provider eNews – June 2, 2016
MLN Connects® Provider eNews for Thursday, June 2, 2016
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In This Edition:

MLN Connects® Events
• Physician Compare Initiative Call – Register Now
• Quality Measures and the IMPACT Act Call – Registration Now Open
• New Audio Recording and Transcript Available

Other CMS Events
• SNF Quality Reporting Program Provider Training: Reserve Your Hotel Room by June 8

Medicare Learning Network® Publications and Multimedia
• CMS Provider Minute Videos for Part A and Part B Providers and DMEPOS Suppliers
Announcements

• Medicare’s “Big Data” Tools Fight and Prevent Fraud to Yield Over $1.5 Billion in Savings
• Integrated Efforts to Improve Patient Safety and Reduce Hospital Readmissions
• DMEPOS Competitive Bidding Program Round 2 Recompete and National Mail-Order Recompete: List of Contract Suppliers Available
• ICD-10 Resources: Clinical Concepts Series
• June is National Safety Month

Claims, Pricers, and Codes

• July 2016 Average Sales Price Files Available

MLN Connects® Provider eNews – June 9, 2016

MLN Connects® Provider eNews for Thursday, June 9, 2016
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News & Announcements

• Medicare Makes Enhancements to the Shared Savings Program to Strengthen Incentives for Quality Care
• TEP on Refinement of NQF #0678: Nominations due June 10
• New PEPPER for Short-term Acute Care Hospitals and June 21 Webinar
• 2016 PQRS GPRO Registration Open through June 30
• Long-Term Care Facilities: Mandatory Submission of Staffing Data via PBJ Begins July 1
• Antipsychotic Drug use in Nursing Homes: Trend Update
• Home Health Quality of Patient Care Star Ratings TEP Summary Available

Claims, Pricers & Codes

• 2017 ICD-10-PCS Updates Available

Upcoming Events

• Physician Compare Initiative Call – June 16
• IRF Tier Comorbidity Updates: Soliciting Stakeholder Input Call – June 16
• Quality Measures and the IMPACT Act Call – July 7

Medicare Learning Network® Publications & Multimedia

• Updated Information on the IVIG Demonstration MLN Matters® Article – New
• June 2016 Catalog Available
• Medicaid Program Integrity: What Is a Prescriber’s Role in Preventing the Diversion of Prescription Drugs? Fact Sheet – Revised
• Vaccine and Vaccine Administration Payments under Medicare Part D Fact Sheet – Revised
• Reading the Institutional Remittance Advice Booklet – Reminder
• Medicare Enrollment Guidelines for Ordering/Referring Providers Fact Sheet – Reminder
MLN Connects® Provider eNews – June 16, 2016

MLN Connects® Provider eNews for Thursday, June 16, 2016

View this edition as a PDF

News & Announcements

• CMS Proposes Rule to Improve Health Equity and Care Quality in Hospitals
• Second Round of Support and Alignment Networks Announced for Transforming Clinical Practice Initiative
• EHR Incentive Program: Hardship Exception Applications Due July 1
• CMS to Release a CBR on Immunohistochemistry and Special Stains in July
• Track and Improve Your ICD-10 Progress
• Recognizing Men’s Health Month and Men’s Health Week

Upcoming Events

• MIPS: CPIA Performance Category Overview Webinar – June 22
• MIPS Scoring Overview Webinar – June 24
• Quality Measures and the IMPACT Act Call – July 7
• SNF Quality Reporting Program Call – July 12

Medicare Learning Network® Publications & Multimedia

• Hospital-Acquired Conditions and Present on Admission Reporting Provision Fact Sheet – Revised
• Mass Immunizers and Roster Billing Fact Sheet – Revised
• Reading a Professional Remittance Advice Booklet – Reminder

MLN Connects® Provider eNews – June 23, 2016

MLN Connects® Provider eNews for June 23, 2016

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News & Announcements

• Medicare Will Use Private Payor Prices to Set Payment Rates for Clinical Diagnostic Laboratory Tests Starting in 2018
• HHS Announces Major Initiative to Help Small Practices Prepare for the Quality Payment Program
• Comment on the MACRA Proposed Rule by June 27
• 2016 PQRS GPRO Registration Open through June 30
• Hospice Quality Reporting: Annual Payment Update
• Quality Payment Program: What’s Available Online

Claims, Pricers & Codes

• Chronic Care Management Payment Correction for RHCs and FQHCs

Upcoming Events

• Comparative Billing Report on Diabetic Testing Supplies Webinar – June 27
• Understanding the ESRD Measures Manual Webinar – June 28
• Clinical Diagnostic Laboratory Test Payment System Final Rule Call – July 6
• Quality Measures and the IMPACT Act Call – July 7
• SNF Quality Reporting Program Call – July 12

Medicare Learning Network® Publications & Multimedia
• Video Slideshow for QRUR Webcast – New
• DMEPOS Accreditation Fact Sheet – Revised
• MREP Software Fact Sheet – Revised
• Medicare Vision Services Fact Sheet – Revised
• New Educational Web Guides Fast Fact

MLN Connects® Provider eNews – June 30, 2016
MLN Connects® Provider eNews for June 30, 2016
View this edition as a PDF

News & Announcements
• ESRD and DMEPOS: Proposed Updates to CY 2017 Policies and Payment Rates
• Home Health Agencies: Proposed Payment Changes for CY 2017
• July 2016 DMEPOS Fee Schedules Available
• Moratoria Provider Services and Utilization Data Tool
• EHR Incentive Program: Hardship Exception Applications Due by July 1
• CMS to Release a CBR on Physician Assistant Use of Modifier 25 in July
• Updated Inpatient and Outpatient Data Available

Claims, Pricers & Codes
• 2017 ICD-10-CM and ICD-10-PCS Files Available

Upcoming Events
• Clinical Diagnostic Laboratory Test Payment System Final Rule Call – July 6
• DMEPOS Competitive Bidding Program Round 2 Recompete Webinars – July 7 and 12
• Quality Measures and the IMPACT Act Call – July 7
• SNF Quality Reporting Program Call – July 12
• Comparative Billing Report on Diabetic Testing Supplies Webinar – July 27

Medicare Learning Network® Publications & Multimedia
• Medicare Coverage of Diagnostic Testing for Zika Virus MLN Matters® Article – New
• Recovering Overpayments from Providers Who Share TINs MLN Matters Article – New
• Implementation of Section 2 of the PAMPA MLN Matters Article – New
• Physician Compare Call: Audio Recording and Transcript – New
• SBIRT Services Fact Sheet – Reminder
• Remittance Advice Resources and FAQs Fact Sheet – Reminder
Redeterminations and Reconsiderations of Certain Claims – Limiting the Scope of Review – Revised

MLN Matters® Number: SE1521 Revised

This article was revised on May 9, 2016, to provide updated information regarding redetermination requests received by Medicare Administrative Contractors (MACs) or Qualified Independent Contractors (QICs) on or after April 18, 2016.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for physicians, providers, and suppliers who submit claims to MACs for services provided to Medicare beneficiaries.

What You Need to Know

This Special Edition article is being published by the Centers for Medicare & Medicaid Services (CMS) to inform providers of the clarification CMS has given to the MACs and QICs regarding the scope of review for redeterminations (Technical Direction Letter-160305, which rescinds and replaces Technical Direction Letter-150407). This updated instruction applies to redetermination requests received by a MAC or QIC on or after April 18, 2016, and will not be applied retroactively.

Background

CMS recently provided direction to MACs and QICs regarding the applicable scope of review for redeterminations and reconsiderations for certain claims. Generally, MACs and QICs have discretion while conducting appeals to develop new issues and review all aspects of coverage and payment related to a claim or line item. As a result, in some cases where the original denial reason is cured, this expanded review of additional evidence or issues results in an unfavorable appeal decision for a different reason.

For redeterminations and reconsiderations of claims denied following a complex prepayment review, a complex post-payment review, or an automated post-payment review by a contractor, CMS has instructed MACs and QICs to limit their review to the reason(s) the claim or line item at issue was initially denied. Prepayment reviews occur prior to Medicare payment, when a contractor conducts a review of the claim and/or supporting documentation to make an initial determination. Post-payment review or audit refers to claims that were initially paid by Medicare and subsequently reopened and reviewed by, for example, a Zone Program Integrity Contractor (ZPIC), Recovery Auditor, MAC, or Comprehensive Error Rate Testing (CERT) contractor, and revised to deny coverage, change coding, or reduce payment. Complex reviews require a manual review of the supporting medical records to determine whether there is an improper payment. Automated reviews use claims data analysis to identify improper payments. If an appeal involves a claim or line item denied on an automated pre-payment basis, MACs and QICs may continue to develop new issues and evidence at their discretion and may issue unfavorable decisions for reasons other than those specified in the initial determination.

Please note that contractors will continue to follow existing procedures regarding claim adjustments resulting from favorable appeal decisions. These adjustments will process through CMS systems and may suspend due to system edits. Claim adjustments that do not process to payment because of additional system imposed payment limitations, conditions or restrictions (for example, frequency limits or Correct Coding Initiative edits) may result in new denials with full appeal rights. In addition, if a MAC or QIC conducts an appeal of a claim or line item that was denied on pre- or post-payment review because a provider, supplier, or beneficiary failed to submit requested documentation, the contractor will review all applicable coverage and payment requirements for the item or service at issue, including whether the item or service was medically reasonable and necessary. As a result, claims initially denied for insufficient documentation may be denied on appeal if additional documentation is submitted and it does not support medical necessity.

This clarification and instruction applies to redetermination and reconsideration requests received by a MAC or QIC on or after April 18, 2016. It will not be applied retroactively. Appellants will not be entitled to request a reopening of a previously issued redetermination or reconsideration for the purpose of applying this clarification on the scope of review. CMS encourages providers and suppliers to include any audit or review results letters with their appeal request. This will help alert contractors to appeals where this instruction applies.


**Additional Information**


You can also find out more about 1) conducting a redeterminations in 42 CFR 405.948, at [http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1948](http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1948); and 2) conducting a reconsideration in 42 CFR 405.968 at [http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1968](http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1968) on the Internet.

**Redetermination/Reopening Request Submission via the Noridian Medicare Portal or the Improved Interactive Form**

Noridian offers various ways to submit Redetermination/Reopening requests.

- Noridian Medicare Portal – Submit and include documentation electronically. Register now if you are not a current user
- Complete and submit the improved [Part A Redetermination/Reopening Interactive Form](http://www.ecfr.gov/cgi-bin/text-idx?SID=06584dd6a5fc15094e7633ff5f6cb359&mc=true&node=pt42.2.405&rgn=div5#se42.2.405_1948) – Avoid a Dismissal – Include a hand written signature.
  - Fax
  - Mail
  - esMD

Throughout the updated Interactive form, submitters will notice the following.

- Added “Specialty Medical Review Contractor” Type of Request
- Added a hyperlink to the Noridian Medicare Portal
- Created consistent informational fields between Part A and Part B
- Consolidated PO Box # for Overpayment Redeterminations
- Highlighted appeal timelines
- Improved flow for completion

**To increase efficiency of the Appeals process, please submit one claim per request.**
System Specific Enhancements 2014: Move PAP Smear Risk Indicator and TECH/PROF Dates to Screening Auxiliary File

MLN Matters® Number: MM9188
Related CR Release Date: November 5, 2015
Related CR Transmittal #: R1551OTN
Related Change Request (CR) #: CR 9188
Effective Date: April 4, 2016
Implementation Date: April 4, 2016

Provider Types Affected
This MLN Matters® Article is intended for institutional providers and Home Health Agencies (HHAs) submitting inquiries to Medicare Administrative Contractors (MACs) for information on PAP smear services provided to Medicare beneficiaries.

What You Need to Know
CR9188 announces changes to Medicare systems regarding the placement of PAP smear data on Medicare’s internal files. The PAP smear data is displayed on the following provider inquiry screens:
- HIQA – Healthcare inquiry for part A for online transactions
- HIQH – Healthcare inquiry for Home Health for online transactions
- ELGA – Eligibility for part A
- ELGH – Eligibility for Home Health
- HUQA – Healthcare Update Inquiry for part A

The Healthcare Common Procedure Coding System (HCPCS) codes for PAP screening displayed on these screens are P3000, G0123, G0143, G0144, G0145, G0147 and G0148, and the screens can show up to three occurrences per HCPCS.

The other significant change for providers is that on the unformatted provider inquiry, HUQA, PAP information will now be carried in screening data location 4053-4612, instead of 780-784.

Additional Information

Screening for Cervical Cancer with HPV Testing – NCD 210.2.1 – Revised

MLN Matters® Number: MM9434 Revised
Related Change Request (CR) #: CR 9434
Related CR Release Date: February 5, 2016
Effective Date: July 9, 2015
Related CR Transmittal #: R189NCD and R3460CP
Implementation Date: July 5, 2016 (CWF analysis and design), October 3, 2016 (CWF Coding, Testing and Implementation, MCS and FISS implementation; January 3, 2017 (requirement 9434-04.8.2), March 7, 2016 (non-shared MAC edits)

This article was revised on April 22, 2016, to correct the G code in two places on pages 2 and 3. The correct code is G0476. All other information remains the same.

Provider Types Affected
This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.
Provider Action Needed
Change Request (CR) 9434 announces that the Centers for Medicare & Medicaid Services (CMS) has determined that, effective for dates of service on or after July 9, 2015, evidence is sufficient to add Human Papillomavirus (HPV) testing under specified conditions. Make sure that your billing staffs are aware of this change.

Background
Medicare covers a screening pelvic examination and Pap test for all female beneficiaries at 12-month or 24-month intervals, based on specific risk factors; however, current Medicare coverage does not include the HPV testing.

Section 1861(ddd) of the Social Security Act (the Act) (see http://www.ssa.gov/OP_Home/ssact/title18/1861.htm) states that CMS may add coverage of “additional preventive services” through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

• Reasonable and necessary for the prevention or early detection of illness or disability;
• Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and,
• Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS has reviewed the USPSTF recommendations and supporting evidence for screening for cervical cancer with HPV co-testing, and has determined that the criteria were met. Therefore, effective for claims with dates of service on or after July 9, 2015, CMS will cover screening for cervical cancer with HPV co-testing under the following conditions:

• CMS has determined that the evidence is sufficient to add HPV testing once every 5 years as an additional preventive service benefit under the Medicare program, for asymptomatic beneficiaries aged 30 to 65 years in conjunction with the Pap smear test. CMS will cover screening for cervical cancer with the appropriate U.S. Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA-approved labeling, and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations.

A new Healthcare Common Procedure Coding System (HCPCS) code, G0476 (HPV combo assay, CA screen), Type of Service (TOS) 5 (diagnostic lab), has been created for this benefit. This code will:

• Be effective retroactive back to the effective date of July 9, 2015;
• Be included in the January 2016, Integrated Outpatient Code Editor, Outpatient Prospective Payment System, and Medicare Physician Fee Schedule Database;
• Be MAC-priced from July 9, 2015, through December 31, 2016, and during this period code G0476 is paid only when it is billed by a laboratory entity; and,
• Beginning January 1, 2017, this will be priced and paid according to the Clinical Laboratory Fee Schedule (CLFS).

In addition, you should be aware of the following:

1. Your MACs will not apply beneficiary coinsurance and deductibles to claim lines containing HCPCS G0476, HPV screening;

2. Part B MACs shall only accept claims with a Place of Service Code equal to ‘81’, Independent Lab or ‘11’, Office; and

3. Effective for claims with dates of service on or after July 9, 2015, your MACs will deny line-items on claims containing HCPCS G0476, HPV screening, when reported more than once in a 5-year period [at least 4 years and 11 months (59 months total) must elapse from the date of the last screening]. The next eligible dates for this service are shown on all Common Working File (CWF) provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).

When denying a line-item on a claim for this requirement they will use the following messages:

• Claim Adjustment Reason Code (CARC) 119 – “Benefit maximum for this time period or occurrence has been reached;”
• Remittance Advice Remark 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.gov/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 the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code “PR” (Patient Responsibility) if the claim has a GA modifier to show a signed ABN is on file.

4. HCPCS Code G0476 will be paid only for institutional claims submitted on Type of Bill codes (TOB) 12X, 13X, 14X, 22X, 23X, and 85X. Institutional claims on other TOBs will be returned to the provider.

5. Effective for claims with dates of service on or after July 9, 2015, your MACs will deny line-items on claims containing HCPCS G0476, HPV screening, when the beneficiary is less than 30 years of age or older than 65 years of age.

When denying a line-item on claims for this requirement, they will use the following messages:

• CARC 6 – “The procedure/revenue code is inconsistent with the patient’s age.

Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present;”

• RARC N129 – “Not eligible due to the patient’s age;”

• Group Code “CO” if the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code “PR” (Patient Responsibility) if the claim has a GA modifier to show a signed ABN is on file.

6. Effective for claims with dates of service on or after July 9, 2015, you must report the following diagnosis codes when submitting claims for HCPCS G0476:

• ICD-9 (for dates of service prior to October 1, 2015): V73.81, special screening exam, HPV (as primary), and V72.31, routine gynecological exam (as secondary)

• ICD-10: Z11.51, encounter for screening for HPV, and Z01.411, encounter for gynecological exam (general)(routine) with abnormal findings, OR Z01.419, encounter for gynecological exam (general) (routine) without abnormal findings.

Effective on this date, your MACs will deny line-items on claims containing HCPCS Code G0476, HPV screening, when the claim does not contain these codes.

When denying a line-item on claim for this requirement, they will use 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.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD;” and

• Group Code CO.


Additional Information
SSP ACO Qualifying Stay Edits

MLN Matters® Number: MM9568
Related Change Request (CR) #: CR 9568
Related CR Release Date: May 6, 2016
Effective Date: January 1, 2017
Related CR Transmittal #: R1660TN
Implementation Date: January 3, 2017

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

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

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

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

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

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

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

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

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

**System Changes to Implement Section 231 of the Consolidated Appropriations Act, 2016, Temporary Exception for Certain Severe Wound Discharges From Certain LTCHs – Revised**

MLN Matters® Number: MM9599 Revised

Related Change Request (CR) #: CR 9599

Related CR Release Date: June 16, 2016

Effective Date: April 21, 2016

Related CR Transmittal #: R16750TN

Implementation Date: October 3, 2016

This article was revised on June 16, 2016, to reflect an updated Change Request (CR). The CR release date, transmittal number and link to the CR also changed. All other information remains the same.

**Provider Types Affected**

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

**Provider Action Needed**

CR9599 implements a temporary exception for certain wound care discharges from the site neutral payment rate for certain LTCHs. Make sure your billing staffs are aware of this exception.

**Background**

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

In general, in order to be paid at the LTCH PPS standard Federal rate payment amount, an LTCH discharge must either:

- Have been admitted directly from an IPPS hospital during which at least 3 days were spent in an Intensive Care Unit (ICU) or Coronary Care Unit (CCU), but the discharge must not have a principal diagnosis in the LTCH of a psychiatric or rehabilitation diagnosis; or
- Have been admitted directly from an IPPS hospital and the LTCH discharge is assigned to an MS-LTC-DRG based on receipt of ventilator services of at least 96 hours, but must not have a principal diagnosis in the LTCH of a psychiatric or rehabilitation diagnosis.

Section 231 of the Consolidated Appropriations Act, 2016, establishes a temporary exception from the site neutral payment rate for certain patients discharged from certain LTCHs before January 1, 2017. As implemented, this exception applies to discharges occurring on or after April 21, 2016, and prior to January 1, 2017, from LTCHs “identified by the amendment made by Section 4417(a) of the Balanced Budget Act of 1997” and “located in a rural area” or “treated as being so located” pursuant to Section 1886(d)(8)(E) of the Social Security Act when the individual discharged had a “severe wound.” The final payment for discharges that meet the statutory provider-level and discharge-level criteria as implemented by the Centers for Medicare & Medicaid Services (CMS) is based on the LTCH PPS standard Federal payment rate. This temporary statutory exception from the site neutral payment rate was implemented in an interim final rule with comment period (IFC) (published in the Federal Register on April 21, 2016).
Provider-Level Criteria:

The statute specifies that the temporary exclusion for certain discharges from the site neutral payment rate is applicable to an LTCH that is “identified by the amendment made by Section 4417(a) of the Balanced Budget Act of 1997.” As discussed in the IFC, CMS has interpreted the phrase to mean hospitals which are described in 42 CFR Section 412.23(e)(2)(i) that meet the criteria of Section 412.22(f), which are a group of LTCHs commonly referred to as “grandfathered hospitals-within-hospitals” (or grandfathered HwHs).

Note: An HwH is defined in the regulations at 42 CFR 412.22(e) as a hospital which occupies space in a building also used by another hospital or on the campus of another hospital. Therefore, in order to be eligible for this temporary exception, an LTCH must have participated in Medicare as an LTCH and have been co-located with another hospital as of September 30, 1995, and must currently meet the requirements of Section 412.22(f).

Section 412.22(f) requires that, in order to maintain grandfathered status, an HwH must continue to operate under the same terms and conditions including but not limited to the number of beds. There are several reasons for which an LTCH described in Section 412.23(e)(2)(i) may not currently meet the criteria in Section 412.22(f). For example, the LTCH may have more than one location, or the HwH may have increased beds after September 30, 2003 (CMS notes these examples are not intended to be an exhaustive list of the reasons an LTCH may not meet the criteria in Section 412.22(f)). MACs must verify that an LTCH described in Section 412.23(e)(2)(i) currently meets the criteria in Section 412.22(f) in order for the LTCH to be eligible for this temporary exception from the site neutral payment rate for certain wound care discharges. This process will likely involve direct outreach to LTCHs in order to verify the required information. Additional information on the requirement that grandfathered HwHs meet the criteria in § 412.22(f) can be found in the following IPPS rules: FY 1997 IPPS final rule (62 FR 46012); FY 2004 IPPS final rule (68 FR 45463); May 22, 2008 LTCH PPS interim final rule with comment period (73 FR 29703); and FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43980).

The temporary statutory exclusion for certain discharges from the site neutral payment rate is further limited to grandfathered HwH LTCHs that are “located in a rural area” or “treated as being so located” pursuant to Section 1886(d)(8)(E) of the Act. For purposes of this provision, “located in a rural area” refers to LTCHs that are currently located in a rural area as defined under § 412.503 (that is, located in any area outside an urban area, which is an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget)). (Information on the current labor market area geographic classifications used under the LTCH PPS is available in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185)). Section 1886(d)(8)(E) of the Act provides for an urban IPPS hospital that is located in an urban area to be reclassified as a rural hospital if it submits an application in accordance with CMS’ established criteria and meets certain conditions (see Section 412.103). (Additional information on CMS’ policies for IPPS hospitals located in urban areas and that apply for reclassification as rural under § 412.103 can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51595).) For the purpose of implementing the phrase “treated as being so located” pursuant to Section 1886(d)(8)(E) of the Act for the temporary statutory exclusion for certain LTCH discharges from the site neutral payment rate, CMS revised its regulations to “borrow” the existing rural reclassification process for urban IPPS hospitals under § 412.103 and to allow grandfathered HwH LTCHs (defined above) to apply to their CMS Regional Office for treatment as being located in a rural area for the sole purpose of qualifying for this temporary exclusion from the application of the site neutral payment rate.

For grandfathered HwH LTCHs that qualify for this temporary exception for certain wound care discharges from the site neutral payment rate by applying for and satisfying the criteria to reclassify as rural under the provisions of § 412.103, the exception from the site neutral payment rate for qualifying discharges is effective beginning the effective date of the rural reclassification (that is, as of the filing date of the application as specified in § 412.103).

Note: This policy only allows grandfathered HwH LTCHs to apply for this reclassification, and the rural treatment only extends to this statutory temporary exception for certain wound care discharges from the site neutral payment rate, and reclassifying grandfathered HwH LTCH will not be treated as rural under the LTCH PPS for any other reason including, but not limited to, the 25 percent policy and wage index). Any rural treatment under the provisions of § 412.103 for a grandfathered HwH LTCH will expire at the same time as this temporary provision (that is, December 31, 2016).
**Discharge-Level Criteria:**

As implemented, the statutory temporary exclusion for certain discharges from the site neutral payment rate for certain LTCHs is applicable to discharges occurring on or after April 21, 2016, and on or before December 31, 2016, that had a “severe wound.” The statute defines a “severe wound” as, “a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis, or wound with morbid obesity as identified in the claim from the long-term care hospital.”

To implement this statutory definition, CMS has defined wound as “an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.”

To implement this definition, CMS is using ICD-10 diagnosis codes on the claim where ICD-10 diagnosis codes contain sufficient specificity for this purpose or through the use of a payer-specific condition code where the ICD-10 diagnosis codes lack sufficient specificity for this purpose.

For six of the eight statutory categories included in the definition of “severe wound” (stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, fistula, and osteomyelitis), CMS is using the list of ICD-10 diagnosis codes found on the CMS website at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/download.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/download.html).

**Note:** Under the CMS definition of wound, the ICD-10 diagnosis codes used to identify severe wounds in the osteomyelitis category are also part of the ICD-10 diagnosis codes used to identify severe wounds in the fistula category so no separate identification of ICD-10 codes for osteomyelitis is necessary.

The remaining two statutory categories included in the definition of “severe wound” (infected wound and wound with morbid obesity) lack ICD-10 diagnosis codes with sufficient specificity to identify the presence of a “severe” wound, so claims containing such wounds will be identified by using specified “payer-only” condition codes. For the purposes of this provision, CMS has defined a “wound with morbid obesity” as “a wound in those with morbid obesity that require complex, continuing care including local wound care occurring multiple times a day” and an “infected wound” as “a wound with infection requiring complex, continuing care including local wound care occurring multiple times a day.” If an LTCH has a discharge meeting this definition of “wound with morbid obesity” or “infected wound” the LTCH will inform its MAC, and the MAC will then place the payer-only condition code “M4” on the claim for processing.

The presence of that designated payer-only condition code on the claim for qualifying rural (or reclassified rural) grandfathered HwH LTCHs will generate a standard Federal payment rate payment for the claim (that is, exclusion from the site neutral payment rate) consistent with this statutory provision in the LTCH PPS Pricer and claims processing system.

MACs will reprocess claims with a through date (for interim claims) or a discharge date (for final claims) on or after April 21, 2016 through December 31, 2016, when the Temporary Relief Indicator on the Provider Specific File (PSF) equals “Y” and one of the ICD-10 diagnosis codes listed on the CMS website mentioned above is present. The claims shall be reprocessed within 60 days from the implementation date of this change request. MACs will adjust impacted LTCH inpatient claims with a through date (for interim claims) or a discharge date (for final claims) on or after April 21, 2016, through December 31, 2016, processed prior to implementation of CR9599 or after when brought to the attention of the MAC by a qualifying LTCH.

**Note:** Claims for LTCHs which are treated as rural for the purposes of this provision will be reprocessed with a through date (for interim claims) or a discharge date (for final claims) on or after the effective date of the rural reclassification.

**Additional Information**

Enforcement of the PHP 20 Hours per Week Billing Requirement

MLN Matters® Number: SE1607

Provider Types Affected
This MLN Matters® Special Edition Article is intended for Outpatient Prospective Payment System (OPPS) providers submitting Partial Hospitalization Program (PHP) claims to Medicare A/B Medicare Administrative Contractors (MACs) for Partial Hospitalization Program services to Medicare beneficiaries.

What You Need to Know
This article conveys enforcement editing requirements for the “Medicare Benefit Policy Manual,” (Internet-Only Manual 100-02) Chapter 6, and Section 70.3 which describes coverage of Partial Hospitalization Program (PHP) Services. Make sure your billing staff is aware of these changes. New editing will be implemented in the July 2016 quarterly release of the Integrated Outpatient Code Editor (IOCE). This advance notice is being given to assist PHP providers to prepare for these changes.

Background
PHPs are structured to provide intensive outpatient psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in §1861(ff) of the Social Security Act (the Act). The treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program. It is treatment at a level more intense than outpatient day treatment or psychosocial rehabilitation. Programs providing primarily social, recreational, or diversionary activities are not considered partial hospitalization.

Patients must meet benefit requirements for receiving the partial hospitalization services as defined in §1861(ff) and §1835(a)(2)(F) of the Act. Patients admitted to a PHP must be under the care of a physician who certifies the need for partial hospitalization and require a minimum of 20 hours per week of therapeutic services, as evidenced by their plan of care. The patients also require a comprehensive, structured, multimodal treatment requiring medical supervision and coordination, provided under an individualized plan of care, because of a mental disorder which severely interferes with multiple areas of daily life, including social, vocational, and/or educational functioning. Such dysfunction generally is of an acute nature. In addition, PHP patients must be able to cognitively and emotionally participate in the active treatment process, and be capable of tolerating the intensity of a PHP program.

To enforce the required minimum of 20 hours per week of therapeutic services, the Centers for Medicare & Medicaid Services (CMS) is instituting three (3) new edits into the IOCE in its July 2016 quarterly release. These new edits will enforce a weekly billing requirement. CMS is giving this advance notice to PHP providers so they can prepare the systems to submit claims correctly and plan accordingly.

July 2016 IOCE Editing

<table>
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<tr>
<th>IOCE Edit</th>
<th>FISS Reason Code</th>
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<th>Disposition</th>
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<tbody>
<tr>
<td>95</td>
<td>W7095</td>
<td>Partial hospitalization claim span is equal to or more than 4 days with insufficient number of hours of service</td>
<td>RTP Claim</td>
</tr>
<tr>
<td>96</td>
<td>W7096</td>
<td>Partial hospitalization interim claim from and through dates must span more than 4 days</td>
<td>RTP Claim</td>
</tr>
<tr>
<td>97</td>
<td>W7097</td>
<td>Partial hospitalization services are required to be billed weekly</td>
<td>RTP Claim</td>
</tr>
</tbody>
</table>

Initially, for the first quarter all edits will be set up to Return to Provider (RTP). After the first quarter, CMS will set edit 95 to deny claims.
October 2016 IOCE Editing

<table>
<thead>
<tr>
<th>IOCE Edit</th>
<th>FISS Reason Code</th>
<th>Narrative</th>
<th>Disposition</th>
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<tbody>
<tr>
<td>95</td>
<td>W7095</td>
<td>Partial hospitalization claim span is equal to or more than 4 days with insufficient number of hours of service</td>
<td>Deny Claim</td>
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<tr>
<td>96</td>
<td>W7096</td>
<td>Partial hospitalization interim claim from and through dates must span more than 4 days</td>
<td>RTP Claim</td>
</tr>
<tr>
<td>97</td>
<td>W7097</td>
<td>Partial hospitalization services are required to be billed weekly</td>
<td>RTP Claim</td>
</tr>
</tbody>
</table>

As a reminder, for claims received on or after July 1, 2016, PHP providers are instructed to submit “weekly” claims for Type of Bill 13x with condition code 41 and Type of Bill 76x. Interim billing requirements still apply.

Additional Information
If you have any questions, please contact your MAC at their toll-free number, which may be found at [http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html) on the CMS website.

CLAIMS REVIEWS

**Inpatient Rehabilitation Facility (IRF) – AZ Service Specific Targeted Review Notification**

Noridian Healthcare Solutions (Noridian) is initiating a service specific targeted review for Inpatient Rehabilitation Facility (IRF). This will affect AZ claims containing edit number 50735. Part A Medical Review has identified errors in a service specific probe resulting in the initiation of this review to identify atypical billing.

View the [Inpatient Rehabilitation Facility (IRF) – AZ Service Specific Targeted Review Notification](#)

**Inpatient Rehabilitation Facility (IRF) – OR Service Specific Targeted Review Notification**

Noridian Healthcare Solutions (Noridian) is initiating a service specific targeted review for OR Inpatient Rehabilitation Facility (IRF) claims with Type of Bill (TOB) 111-115, excluding condition codes 04 and 69. Noridian Part A Medical Review has identified errors in a service specific probe resulting in the initiation of this review.

View the [IRF - OR Service Specific Targeted Review Notification](#)

**Inpatient Rehabilitation Facility (IRF) – UT Service Specific Probe Review Notification**

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for UT Inpatient Rehabilitation Facility (IRF) original Type of Bill (TOB) 111-115 claims, excluding condition codes 04 and 69. Noridian Part A Medical Review has analyzed national and local data to identify atypical billing.

View the [IRF- UT Service Specific Probe Review Notification](#)
Inpatient Rehabilitation Facility (IRF) – WY Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for Inpatient Rehabilitation Facility (IRF) claims. This review will impact the state of WY for Inpatient Rehabilitation Facility claims. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the article Inpatient Rehabilitation Facility (IRF) – WY Service Specific Probe Review Notification.

Outpatient Drug J2323-AK, ID, OR, WA Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for the drug Natalizumab with Healthcare Common Procedural Coding System (HCPCS) J2323. This will affect AK, ID, OR, WA claims containing this code. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the Outpatient Drug J2323-AK, ID, OR, WA Service Specific Probe Review Notification.

Chemotherapy Administration – WA Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for CPT 96413, Chemotherapy Administration, Intravenous Infusion Technique. This will affect WA claims containing edit code 50230. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the Chemotherapy Administration - WA Service Specific Probe Review Notification.

Skilled Nursing Facility (SNF) – ND Providers Billing 355000-356499 Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for SNF services. This will affect ND claims containing RUG level RH*. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the Skilled Nursing Facility (SNF) – ND Providers Billing 355000-356499 Service Specific Probe Review Notification.

Nuclear Medicine: Myocardial Perfusion Imaging – AZ Service Specific Targeted Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific targeted review for AZ Nuclear Medicine: Myocardial Perfusion Imaging claims with Type of Bill (TOB) 111-115. Noridian Part A Medical Review has identified errors in a service specific probe resulting in the initiation of this review.

View the Nuclear Medicine: Myocardial Perfusion Imaging - AZ Service Specific Targeted Review Notification.

Nuclear Medicine: Myocardial Perfusion Imaging – WA Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for Current Procedural Terminology (CPT) code 78452, Myocardial Perfusion Imaging. This will affect WA claims containing this code. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the Nuclear Medicine: Myocardial Perfusion Imaging – WA Service Specific Probe Review Notification.
Transthoracic Echocardiography – WA Service Specific Probe Review Notification

Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for Current Procedural Terminology (CPT) code 93306, Transthoracic Echocardiography. This will affect WA claims containing this code. Part A Medical Review has analyzed national and local data to identify atypical billing.

View the Transthoracic Echocardiography – WA Service Specific Probe Review Notification

Clarification of IPF Requirements for Certification, Recertification and Delayed/Lapsed Certification and Recertification

MLN Matters® Number: MM9522
Related Change Request (CR) #: CR 9522
Related CR Release Date: May 13, 2016
Effective Date: August 15, 2016
Related CR Transmittal #: R223BP and R98GI
Implementation Date: August 15, 2016

Provider Types Affected
This MLN Matters® Article is intended for physicians and other specified providers submitting claims to Medicare Administrative Contractors (MACs) to certify and recertify the medical necessity of inpatient psychiatric services provided to Medicare beneficiaries.

What You Need to Know
A physician or other specified providers need to certify the medical necessity of inpatient services. This is required at admission, and if the service is needed for an extended period of time, a recertification is necessary. CR9522 clarifies that your MAC will cease denials of Inpatient Psychiatric Facility (IPF) providers that do not use “the statement” that “the patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel” for recertification when documentation is present that validates (without using any particular words) that the patient continues to need care.

Background
Currently, the IPF Prospective Payment System (PPS) requires facilities to provide “the statement” for recertification. As a result, payments to providers whose documentation validates all the necessary requirements to continue care were being denied because they did not use “the statement.”

CR9522 clarifies physician certification, recertification and delayed/lapsed certification and recertification with respect to IPF services in the “Medicare General Information, Eligibility and Entitlement Manual,” Chapter 4, Section 10.9.and in the “Medicare Benefit Policy Manual,” Chapter 2, Section 30.2.1.

There is also a difference in the content of the certification and recertification. In certification the physician is required to document that the IPF admission was medically necessary for either: (1) treatment which could reasonably be expected to improve the patient’s condition, or (2) diagnostic study.

Key Points of CR9522
• Your MAC will use the beneficiary’s IPF medical record, if the statement “that the patient continues to need, on a daily basis, active treatment furnished directly by or requiring the supervision of inpatient psychiatric facility personnel” is not present in the physician’s recertification documentation, to determine if all the required elements for recertification were met.
• Your MAC will allow providers to adopt any method that permits verification of all the elements IPFs require to continue treatment. No specific procedures or forms are required for certification and recertification. The recertification may be entered on provider generated forms, in progress notes, or in the records (relating to the stay in question) and must be signed by a physician.

• Your MAC will deny IPF claims that do not have timely certifications and recertifications. However, delayed certifications and recertifications will be honored where, for instance, there has been an oversight or lapse, and there is a legitimate reason for the delay. Denial of payment for lack of the required certification and recertification is considered a technical denial, which means a statutory requirement has not been met.

• MACs will allow the reopening of technical denial decisions (initiated by the provider or contractor).

• MACs will reverse any delayed/lapsed certification or recertification denials where the provider later produced a legitimate reason for the delay.

• MACs will review provider explanations/reasons for delayed certification and recertification. The submission of documents must include an explanation for the delay and any medical or other evidence the IPF considers relevant for purposes of explaining the delay.

• MACs will allow the IPF to determine the format of delayed certification and recertification statements, and the method by which they are obtained. A delayed certification may be included with one or more recertifications on a single signed statement. Separate signed statements for each delayed certification and recertification are not required, as they would be if timely certification and recertification had been completed. For all IPF services, a delayed certification may not extend past discharge. An IPF certification or recertification statement may only be signed by a physician.

Additional Information

Coding Revisions to NCDs
MLN Matters® Number: MM9540
Related Change Request (CR) #: CR 9540
Related CR Release Date: April 29, 2016
Effective Date: July 1, 2016
Related CR Transmittal #: R1658OTN
Implementation Date: July 5, 2016, unless otherwise noted

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

What You Need to Know
Change Request (CR) 9540 is the 7th maintenance update of the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) conversions and other coding updates specific to National Coverage Determinations (NCDs). Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.
Background
The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically, CR7818, CR8109, CR8197, CR8691, CR9087, and CR9252. You may review the corresponding MLN Matters® Articles MM7818, MM8109, MM8197, MM8691, MM9087, and MM9252 for these CRs on the Centers for Medicare & Medicaid Services (CMS) website. Some are the result of revisions required to other NCD-related CRs released separately.

Updated NCD coding spreadsheets related to CR9540 are available at http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR9540.zip. CR9540 updates the following 14 NCDs:

- NCD20.29 – Hyperbaric Oxygen Therapy
- NCD90.1 – Pharmacogenomic Testing for Warfarin Response
- NCD110.18 – Aprepitant for Chemotherapy-Induced Emesis
- NCD150.3 – Bone Mineral Density Studies
- NCD160.18 – Vagus Nerve Stimulation for Treatment of Seizures
- NCD160.24 – Deep Brain Stimulation for Essential Tremor
- NCD210.3 – Colorectal Cancer Screening Tests
- NCD210.14 – Screening for Lung Cancer with Low-Dose CT (CR9246)
- NCD230.18 – Sacral Nerve Stimulation for Urinary Incontinence
- NCD260.1 – Adult Liver Transplantation (CR9252, CR8109)
- NCD110.4 – Extracorporeal Photopheresis
- NCD20.33 – Transcatheter Mitral Valve Repair (CR9002, TDL150341, policy effective August 7, 2014
- NCD220.13 – Percutaneous Image-Guided Breast Biospy
- NCD220.4 – Mammograms

MACs will adjust any claims already processed, if erroneously impacted by the above changes, if you bring such claims to their attention.

Additional Information

Screening for Lung Cancer with LDCT – Revised
MLN Matters® Number: MM9246 Revised
Related Change Request (CR) #: 9246
Related CR Release Date: October 15, 2015
Effective Date: February 5, 2015
Related CR Transmittal #: R3374CP and R185NCD
Implementation Date: January 4, 2016

This article was revised on June 24, 2016, to add a link to a related article MM9540. That article provides a ICD-10 code that has been added for Lung Cancer Screening with Low Dose Computed Tomography (LDCT). All other information is unchanged.

Provider Types Affected
This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.
Provider Action Needed
Change Request (CR) 9246 informs MACs that Medicare covers lung cancer screening with LDCT if all eligibility requirements listed in the National Coverage Determination (NCD) are met. Make sure that your billing staffs are aware of these changes.

Background
Section 1861(ddd)(1) of the Social Security Act (the Act) authorizes the Centers for Medicare & Medicaid Services (CMS) to add coverage of “additional preventive services” through the NCD process. The “additional preventive services” must meet all of the following criteria:

- Be reasonable and necessary for the prevention or early detection of illness or disability;
- Be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and
- Be appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS reviewed the evidence for lung cancer screening with low dose computed tomography (LDCT) and determined that the criteria listed above were met, enabling CMS to cover this “additional preventive service” under Medicare Part B.

CMS issued NCD 210.14 on August 21, 2105, that provides for Medicare coverage of screening for lung cancer with LDCT. Effective for claims with dates of service on and after February 5, 2015, Medicare beneficiaries must meet all of the following criteria:

- Be 55–77 years of age;
- Be asymptomatic (no signs or symptoms of lung cancer);
- Have a tobacco smoking history of at least 30 pack-years (one pack-year = smoking one pack per day for one year; 1 pack = 20 cigarettes);
- Be a current smoker or one who has quit smoking within the last 15 years; and,
- Receive a written order for lung cancer screening with LDCT that meets the requirements described in the NCD.

Written orders for lung cancer LDCT screenings must be appropriately documented in the beneficiary’s medical record, and must contain the following information:

- Date of birth;
- Actual pack-year smoking history (number);
- Current smoking status, and for former smokers, the number of years since quitting smoking;
- A statement that the beneficiary is asymptomatic (no signs or symptoms of lung cancer); and,
- The National Provider Identifier (NPI) of the ordering practitioner.

Counseling and Shared Decision-Making Visit
Before the first lung cancer LDCT screening occurs, the beneficiary must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision-making visit that includes the following elements and is appropriately documented in the beneficiary’s medical records:

- Must be furnished by a physician (as defined in section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) as defined in section1861(aa)(5) of the Act); and
- Must include all of the following elements:
  - Determination of beneficiary eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
  - Shared decision-making, including the use of one or more decision aids, to include benefits and harms of screening, follow-up diagnostic testing, over-diagnosis, false positive rate, and total radiation exposure;
- Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of co-morbidities, and ability or willingness to undergo diagnosis and treatment;
- Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and,
- If appropriate, the furnishing of a written order for lung cancer screening with LDCT.

Written orders for subsequent annual LDCT screens may be furnished during any appropriate visit with a physician or qualified non-physician practitioner (PA, NP, or CNS).

There is also specific criteria that the reading radiologist and radiology imaging facility must meet. The radiology imaging facility must collect and submit data to a CMS-approved registry for each LDCT lung cancer screening performed. The data collected and submitted to a CMS-approved registry must include specific elements. Information regarding CMS-approved registries is posted at: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries.html on the CMS website.

**Coinsurance and Deductibles**

Medicare coinsurance and Part B deductible are waived for this preventive service.

**Health Care Common Procedure Coding System (HCPCS) Codes**

Effective for claims with dates of service on and after February 5, 2015, the following HCPCS codes are used for lung cancer screening with LDCT:

- **G0296** – Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)
- **G0297** – Low dose CT scan (LDCT) for lung cancer screening

In addition to the HCPCS code, these services must be billed with ICD-10 diagnosis code Z87.891 (personal history of tobacco use/personal history of nicotine dependence), ICD-9 diagnosis code V15.82.

**NOTE:** Contractors shall apply contractor-pricing to claims containing HCPCS G0296 and G0297 with dates of service February 5, 2015, through December 31, 2015.

**Institutional Billing Requirements**

Effective for claims with dates of service on and after February 5, 2015, providers may use the following Types of Bill (TOBs) when submitting claims for lung cancer screening, HCPCS codes G0296 and G0297: 12X, 13X, 22X, 23X, 71X (G0296 only), 77X (G0296 only), and 85X.

Medicare will pay for these services as follows:

- Outpatient hospital departments – TOBs 12X and 13X - based on Outpatient Prospective Payment System (OPPS);
- Skilled nursing facilities (SNFs) – TOBs 22X and 23X – based on the Medicare Physician Fee Schedule (MPFS);
- Critical Access Hospitals (CAHs) - TOB 85X – based on reasonable cost;
- CAH Method II – TOB 85X with revenue code 096X, 097X, or 098X based on the lesser of the actual charge or the MPFS (115% of the lesser of the fee schedule amount and submitted charge) for HCPCS G0296 only;
- Rural Health Clinics (RHCs) - TOB 71X - based on the all-inclusive rate for HCPCS G0296 only; and
- Federally Qualified Health Centers (FQHCs) – TOB 77X - based on the PPS rate for HCPCS G0296 only.

For outpatient hospital settings, as in any other setting, services covered under this NCD must be ordered by a primary care provider within the context of a primary care setting and performed by an eligible Medicare provider for these services.
Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs),
Group Codes
MACs will use the following CARCs, RARCs, and Group Codes when denying payment for LDCT lung cancer screening, HCPCS G0296 and G0297:

**Submitted on a TOB other than 12X, 13X, 22X, 23X, 71X, 77X, or 85X:**
- **CARC 170** - Payment is denied when performed/billed by this type of provider.
  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** (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file). For modifier GZ, MACs will use CARC 50.

**For TOBs 71X and 77X when HCPCS G0296 is billed on the same date of service with another visit (this does not apply to initial preventive physical exams for 71X TOBs):**
- **CARC 97** - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated.
  Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- **RARC M15** - Separately billed services/tests have been bundled as they are considered components of the same procedure. Separate payment is not allowed.
  NOTE: 77X TOBs will be processed through the Integrated Outpatient Code Editor under the current process.
- **Group Code CO** assigning financial liability to the provider.

**Where a previous HCPCS G0297 is paid in history in a 12-month period (at least 11 full months must elapse from the date of the last screening):**
- **CARC 119** – Benefit maximum for this time period or occurrence has been reached.
- **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.gov/mcd/search.asp](http://www.cms.gov/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** assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

**Because the beneficiary is not between the ages of 55 and 77 at the time the service was rendered (line-level):**
- **CARC 6**: “The procedure/revenue code is inconsistent with the patient’s age.
  Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- **Group Code: CO** (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
  NOTE: For modifier GZ, MACs will use CARC 50.

**Because the claim line was not billed with ICD-10 diagnosis Z87.891:**
- **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.gov/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 assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

NOTE: For modifier GZ, MACs will use CARC 50.

Additional Information
• The official instruction, CR9246, consists of two transmittals:
  • Transmittal R3374CP, which updates the “Medicare Claims Processing Manual;” and
  • Transmittal R185NCD, which updates the “Medicare NCD Manual.”

HCPCS Drug/Biological Code Changes – July 2016 Quarterly Update
MLN Matters® Number: MM9636
Related Change Request (CR) #: CR 9636
Related CR Release Date: May 6, 2016
Effective Date: July 1, 2016
Related CR Transmittal #: R3518CP
Implementation Date: July 5, 2016

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

Provider Action Needed
Change Request (CR) 9636 informs Medicare providers and suppliers that effective for claims with dates of service on or after July 1, 2016, new Healthcare Common Procedure Coding System (HCPCS) codes Q9981 (rolapitant, oral, 1mg); Q9982 (flutemetamol f18 diagnostic); and Q9983 (florbetaben f18 diagnostic) will be payable for Medicare. In addition, the HCPCS code set will contain code Q5102 (Inj., infliximab biosimilar), which is effective for dates of service on or after April 5, 2016. Claims for Q5102 must also have the modifier ZB (Pfizer/hospira). Make sure that your billing staffs are aware of these changes.

Background
The HCPCS code set is updated on a quarterly basis and CR9636 provides that effective July 1, 2016, the HCPCS codes contained in the following table will be established:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Description</th>
<th>Long Description</th>
<th>Type of Service (TOS) Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q9981</td>
<td>rolapitant, oral, 1mg</td>
<td>Rolapitant, oral, 1 mg</td>
<td>1</td>
</tr>
<tr>
<td>Q9982</td>
<td>flutemetamol f18 diagnostic</td>
<td>Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries</td>
<td>4</td>
</tr>
<tr>
<td>Q9983</td>
<td>florbetaben f18 diagnostic</td>
<td>Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries</td>
<td>4</td>
</tr>
</tbody>
</table>

Also, as of July 1, the HCPCS code set will contain code Q5102 (short descriptor – Inj., infliximab biosimilar – and long descriptor – Injection, Infliximab, 10 mg). Code Q5102 will be effective for dates of service on or after April 5, 2016, and will have TOS codes of 1 and P. In addition, claims for Q5102 must also have the modifier ZB (Pfizer/hospira).

Additional Information
Coding Revisions to NCDs – Revised

MLN Matters® Number: MM9631 Revised
Related Change Request (CR) #: CR 9631
Effective Date: October 1, 2016 - unless noted differently in CR9631
Related CR Release Date: June 3, 2016
Related CR Transmittal #: R16720TN
Implementation Date: October 3, 2016

This article was revised on June 6, 2016, to reflect the revised CR9631 issued on June 3, 2016. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

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

Provider Action Needed
CR9631 is the 8th maintenance update of International Classification of Diseases, Tenth Revision (ICD-10) conversions and other coding updates specific to national coverage determinations (NCDs). The majority of the NCDs included are a result of feedback received from previous ICD-10 NCD CRs, specifically CR7818, CR8109, CR8197, CR8691, CR9087, CR9252, and CR9540, while others are the result of revisions required to other NCD-related CRs released separately. Review MLN Matters® Articles MM7818, MM8109, MM8197, MM8691, MM9087, MM9252, and MM9540 for information pertaining to these CR’s.

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

No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process. Updated NCD coding spreadsheets related to CR9631 are available at https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR9631.zip.

Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed. No policy-related changes are included with these updates. Any policy-related changes to NCDs continue to be implemented via the current, long-standing NCD process.

To be specific, CR9631 makes adjustments to the following NCDs:

- NCD 20.4 – Implantable Automatic Defibrillators
- NCD 20.7 – Percutaneous Transluminal Angioplasty (PTA)
- NCD 20.9 – Artificial Hearts
- NCD 20.29 – Hyperbaric Oxygen Therapy
- NCD 50.3 – Cochlear Implants
- NCD 110.18 – Aprepitant
- NCD 210.3 – Colorectal Cancer Screening
- NCD 220.4 – Mammography
- NCD 230.9 – Cryosurgery of Prostate
- NCD 260.9 – Heart Transplants
• NCD 210.4 – Smoking/Tobacco-Use Cessation Counseling
• NCD 210.4.1 – Counseling to Prevent Tobacco Use

Additional Information
The official instruction, CR 9631, issued to your MAC regarding this change is available at

JW Modifier: Drug Amount Discarded/Not Administered to any Patient –
Second Revision

MLN Matters® Number: MM9603 Revised
Related Change Request (CR) #: CR 9603
Related CR Release Date: June 9, 2016
Effective Date: January 1, 2017
Related CR Transmittal #: R3539CP
Implementation Date: January 3, 2017

This article was revised on June 10, 2016, to reflect the revised CR9603 issued on June 9. The CR was revised to change the effective and implementation dates. The article is revised accordingly. In the article, the CR release date, transmittal number and link to the CR were also changed. All other information remains the same.

Provider Types Affected
This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for drugs or biologicals administered to Medicare beneficiaries.

Provider Action Needed
The Centers for Medicare & Medicaid Services (CMS) issued CR 9603 to alert MACs and providers of the change in policy regarding the use of the JW modifier for discarded Part B drugs and biologicals.

Effective January 1, 2017, providers are required to:
• Use the JW modifier for claims with unused drugs or biologicals from single use vials or single use packages that are appropriately discarded (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals) and
• Document the discarded drug or biological in the patient’s medical record when submitting claims with unused Part B drugs or biologicals from single use vials or single use packages that are appropriately discarded.

Make sure that your billing staffs are aware of these changes. Remember that the JW modifier is not used on claims for CAP drugs and biologicals.

Background
The “Medicare Claims Processing Manual,” Chapter 17, Section 40 provides policy detailing the use of the JW modifier for discarded Part B drugs and biologicals. The current policy allows MACs the discretion to determine whether to require the JW modifier for any claims with discarded drugs or biologicals, and the specific details regarding how the discarded drug or biological information should be documented.

Be aware in order to more effectively identify and monitor billing and payment for discarded drugs and biologicals, CMS is revising this policy to require the uniform use of the JW modifier for all claims with discarded Part B drugs and biologicals.

Additional Information
The official instruction, CR9603, issued to your MAC regarding this change is available at
Medicare Coverage of Substance Abuse Services
MLN Matters® Number: SE1604

Provider Types Affected
This MLN Matters® Special Edition article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for substance abuse services provided to Medicare beneficiaries.

What You Need to Know
While there is no distinct Medicare benefit category for substance abuse treatment, such services are covered by Medicare when reasonable and necessary. The Centers for Medicare & Medicaid Services (CMS) provides a full range of services, including those services provided for substance abuse disorders. This article summarizes the available services and provides reference links to other online Medicare information with further details about these services.

Background
Services for substance abuse disorders are available under Medicare, as long as those services are reasonable and necessary. These services include:

Inpatient Treatment
- Inpatient treatment would be covered if reasonable and necessary.
- Professional services provided during that care would be paid either:
  - as part of the inpatient stay (for professional services provided by clinicians not recognized for separate billing, for instance peer counselors), or
  - separately, to the professional billing for the provided services if they are recognized under Part B and considered separate from the inpatient stay (for instance, physicians, and NPPs within their state scopes of practice).
- Any medication provided as part of inpatient treatment would be bundled into the inpatient payment and not paid separately.

Outpatient Treatment
- Similar to inpatient treatment, coverage of outpatient treatment would depend on the provider of the services.
- Pursuant to the Social Security Act, Medicare does not recognize substance abuse treatment facilities as an independent provider type, nor is there an integrated payment for the bundle of services those providers may provide (either directly, or incident to a physician’s service).
- Coverage and payment would be on a service by service basis for those services that are recognized by Medicare. For instance, Medicare could pay for counseling by an enrolled licensed clinical social worker, psychologist or psychiatrist.
- Some services could be provided by auxiliary personnel incident to a physician’s services.
- Medications used in an outpatient setting that are not usually self-administered may be covered under Part B if they meet all Part B requirements.
Partial Hospitalization Program (PHP)

The PHP is an intensive outpatient psychiatric day treatment program that is furnished as an alternative to inpatient psychiatric hospitalization. This means that without the PHP services, the person would otherwise be receiving inpatient psychiatric treatment. Patients admitted to a PHP must be under the care of a physician who certifies and re-certifies the need for partial hospitalization and require a minimum of 20 hours per week of PHP therapeutic services, as evidenced by their plan of care. PHPs may be available in your local hospital outpatient department and Medicare certified Community Mental Health Center (CMHCs). PHP services include:

- Individual or group psychotherapy with physicians, psychologists, or other mental health professionals authorized or licensed by the State in which they practice (for example, licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);
- Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy, if required, must be a component of the physicians treatment plan for the individual;
- Services of other staff (social workers, psychiatric nurses, and others) trained to work with psychiatric patients;
- Drugs and biologicals that cannot be self-administered and are furnished for therapeutic purposes (subject to limitations specified in 42 CFR 410.29);
- Individualized activity therapies that are not primarily recreational or diversionary. These activities must be individualized and essential for the treatment of the patient’s diagnosed condition and for progress toward treatment goals;
- Family counseling services for which the primary purpose is the treatment of the patient’s condition;
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individuals care and treatment of his/her diagnosed psychiatric condition; and
- Medically necessary diagnostic services related to mental health treatment.

Similar to inpatient and individual outpatient treatment, coverage of PHP services would depend on the provider of the services.

MLN Matters® Special Edition article SE1512 titled “Partial Hospitalization Program (PHP) Claims Coding & CY2015 per Diem Payment Rates” is intended for hospitals and Community Mental Health Centers (CMHCs) that submit claims to MACs for PHP services provided to Medicare beneficiaries. In SE1512, CMS reminds hospitals and CMHCs that provide PHP services to follow existing claims coding requirements given in the “Medicare Claims Processing Manual” (Chapter 4, Section 260) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf on the CMS website.

Coverage and payment would be for those PHP services that are recognized by Medicare. For instance, Medicare could pay for psychotherapy by an enrolled licensed clinical psychologist or psychiatrist.

Substance Abuse Treatment by Suppliers of Services

There are individuals under the Medicare Part B program who are authorized as suppliers of services that are eligible to furnish substance abuse treatment services providing the services are reasonable and necessary and fall under their State scope of practice.

These suppliers of services include:
- Physicians (medical doctor or doctor of osteopathy);
- Clinical psychologists;
- Clinical social workers;
- Nurse practitioners;
- Clinical nurse specialists;
- Physician assistants; and,
- Certified nurse-midwives.
Screening, Brief Intervention, and Referral to Treatment (SBIRT) Services

SBIRT is an early intervention approach that targets individuals with nondependent substance use to provide effective strategies for intervention prior to the need for more extensive or specialized treatment. This approach differs from the primary focus of specialized treatment of individuals with more severe substance use, or those who meet the criteria for diagnosis of a substance use disorder.

SBIRT services aim to prevent the unhealthy consequences of alcohol and drug use among those who may not reach the diagnostic level of a substance use disorder, and helping those with the disease of addiction enter and stay with treatment. You may easily use SBIRT services in primary care settings, enabling you to systematically screen and assist people who may not be seeking help for a substance use problem, but whose drinking or drug use may cause or complicate their ability to successfully handle health, work, or family issues. For more information on the Medicare’s SBIRT services, refer to Medicare’s fact sheet, “Screening, Brief Intervention, and Referral to Treatment (SBIRT) Services” at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf on the CMS website.

SBIRT consists of three major components:

1. Structured Assessment (Medicare) or Screening (Medicaid): Assessing or screening a patient for risky substance use behaviors using standardized assessment or screening tools;
2. Brief Intervention: Engaging a patient showing risky substance use behaviors in a short conversation, providing feedback and advice; and
3. Referral to Treatment: Providing a referral to brief therapy or additional treatment to patients whose assessment or screening shows a need for additional services.

The first component to the SBIRT process is assessment or screening which uses tools including the World Health Organization’s Alcohol Use Disorders Identification Test (AUDIT) Manual and the Drug Abuse Screening Test (DAST). For more information on SBIRT assessment and screening tools, as well as examples of tools, visit http://www.integration.samhsa.gov/clinical-practice/sbirt/screening on the Internet.

Medicare covers only reasonable and necessary SBIRT services that meet the requirements of diagnosis or treatment of illness or injury (that is, when the service is provided to evaluate and/or treat patients with signs/symptoms of illness or injury) per the Social Security Act (Section 1862(a)(1)(A); see https://www.ssa.gov/OP_Home/ssact/title18/1862.htm on the Internet).

Medicare pays for medically reasonable and necessary SBIRT services furnished in physicians’ offices (by physicians and non-physician practitioners) and outpatient hospitals. In these settings, you assess for and identify individuals with, or at-risk for, substance use-related problems and furnish limited interventions/treatment. To bill Medicare, suppliers of SBIRT services must be:

- Licensed or certified to perform mental health services by the State in which they perform the services;
- Qualified to perform the specific mental health services rendered; and
- Working within their State Scope of Practice Act.

Medicare pays for these services under the Medicare Physician Fee Schedule (PFS) and the hospital Outpatient Prospective Payment System (OPPS). For more information on Medicare’s payment for SBIRT services, refer to the “Medicare Claims Processing Manual” (Chapter 4, Section 200.6) at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf on the CMS website.

Drugs Used to Treat Opioid Dependence

Medicare Part D sponsors must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex®, but must include combination products when medically necessary (for example, Suboxone®). For any new enrollees, CMS requires sponsors to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS’ non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.
A Part D drug is defined, in part, as “a drug that may be dispensed only upon a prescription.” Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (NOTE: Methadone is a Part D drug when indicated for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.

See the “Medicare Prescription Drug Benefit Manual” (Chapter 6, Section 10.8 (Drugs Used to Treat Opioid Dependence)) at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter6.pdf on the CMS website.

Medicare covers diagnostic clinical laboratory services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. For beneficiaries being treated for substance abuse, testing for drugs of abuse when reasonable and necessary can help manage their treatment. Information on the clinical laboratory fee schedule is available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Clinical-Laboratory-Fee-Schedule-Fact-Sheet-ICN006818.pdf on the CMS website.

Additional Information

Providers may want to review the following resources:

- “Summary of Medicare Reporting and Payment of Services for Alcohol and/or Substance (Other than Tobacco) Abuse Structured Assessment and Brief Intervention (SBIRT) Services;” see https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1013.pdf on the CMS website.
- National Coverage Determinations (NCDs): Inpatient Hospital Stays for the Treatment of Alcoholism (130.1); Outpatient Hospital Services for Treatment of Alcoholism (130.2); Chemical & Electrical Aversion Therapy for Treatment of Alcoholism (130.3, 130.4); Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5); Treatment of Drug Abuse (Chemical Dependency) (130.6); Withdrawal Treatments for Narcotic Addictions (130.7): See https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part2.pdf on the CMS website.
Outpatient Drugs Administration Orders

Coverage for outpatient drugs requires that documentation must support that services were properly authenticated or intended by the physician. While a physician order is not required to be signed, the physician must clearly document in the medical record his or her intent that the service or test be performed.

View the “Outpatient Drugs Administration Orders” section of the newly created “Browse by Topic” Drugs, Biologicals and Injections webpage for a listing of practitioners who may sign orders.

Chemotherapy Administration – R1

The Chemotherapy Administration coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) on the CMS Medicare Coverage Database (MCD) website.

Effective Date: July 1, 2016

Article Summary of Changes: This article is revised to:

- Clarify which drugs and HCPCS codes are billed the different CPT administration codes.
- Provide coding instructions for billing chemotherapy administration CPT codes 96401-96549 with drug code
- Change article number from A52935 to A92991. Same article number and content for Jurisdiction F (JF) Part A and Part B
  - Article number A52935 will be retired 6/30/16

View this complete Future Noridian coverage article.

- The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).

Chemotherapy Administration (A52991) – R2

The Chemotherapy Administration coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

Effective Date: July 1, 2016

Summary of Changes: Noridian made the following editorial revisions:

- Added Trademarks as needed.
- Added the following new C codes for OPPS claims effective 07/01/2016
  - C9476 – daratumumab (Darzalex™)
  - C9477 – elotuzumab (Empliciti™) and
  - C9480 – trabectedin (Yondelis®)
- Added Q5102-ZB - infliximab, biosimilar 10 mg (infliximab, biosimilar 10 mg) is effective dates of service 4/05/16 but processed 07/01/16 and after.
- Corrected CPT® code 95659 to 96459 for the description of unlisted chemotherapy procedure.
Chemotherapy Administration (A52991) – R3

The Chemotherapy Administration coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

Effective Date: July 1, 2016

Summary of Changes: Noridian made the following editorial revisions in the article text:

- Corrected the link to the Medicare Claims Processing Manual (MCPM).
- Clarified the sentence about when performed to facilitate a chemo infusion or injection.

IUD (Hormone-Eluting) for Endometrial Hyperplasia – CPT 58999 – Revised

The Intrauterine Device (IUD) (Hormone-Eluting) for Endometrial Hyperplasia-CPT 58999 coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY).

Article Summary of Changes: Appropriate ICD-10 CM diagnoses for endometrial hyperplasia and use of CPT 58999 have been updated.

Effective Date: October 1, 2015
• Select state/contract of interest from Active, Future or Retired column (This link will redirect you to the CMS website.)
• Once in the CMS MCD, select corresponding article title

**Posterior Tibial Nerve Stimulation Coverage A52951 – R2**

The Posterior Tibial Nerve Stimulation Coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) on the CMS Medicare Coverage Database (MCD) website.

**Effective Date:** July 1, 2016

**Article Summary of Changes:** The Jurisdiction F Part A and B articles are being combined. The title of the article will be Posterior Tibial Nerve Stimulation Coverage (A52965). Coverage Guidelines were updated for maintenance therapy to be extended for a "longer time" if patients meet the criteria.

View the complete Noridian coverage article.

• The End User Agreement for Providers will appear if you have not recently visited the website. Select "Accept" (if necessary).

Go to the Noridian Medicare Coverage Articles webpage to:

• View complete list of Noridian coverage articles
• Access the CMS MCD to view a comprehensive revision history for this corresponding article
  • Scroll to bottom of webpage
  • Select state/contract of interest from Active, Future or Retired column (This link will redirect you to the CMS website.)
  • Once in the CMS MCD, select corresponding article title

**Posterior Tibial Nerve Stimulation Coverage A52951 – Retired**

The Posterior Tibial Nerve Stimulation Coverage article has been revised and published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

**Article Summary:** Article A52951 will be retired, effective 06/30/2016. This article is combined with the JEB article A52965. This results in both JFA and JFB having the same final MCD Article number.

**Effective Date:** June 30, 2016

To view the complete Noridian retired coverage article.

• The End User Agreement for Providers will appear if you have not recently visited the website. Select "Accept" (if necessary).
• Scroll to bottom of webpage
• Select state/contract of interest from Retired column (This link will redirect you to the CMS website.)
• Once in the CMS MCD, select corresponding article title
Self-Administered Drug Exclusion List – R6

The Self-Administered Drug Exclusion List coverage article has been revised and/or published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301(OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

Effective Date: 06/27/2016

Summary of Changes: Added the following drugs and sentences in the article text and revision history explanation:

- Dulaglutide, Trulicity® (C9399, J3590), Methotrexate - Solution Auto-injector Non Chemotherapeutic, Otrexup™, Rasuvo® (C9399, J3590), Parathyroid Hormone, Natpara® (C9399, J3590), Peginterferon beta-1a, Plegidy™ (C9399, J3590), Insulin glargine injection, Toujeo® (C9399, J3590) and Exanatide (Byetta®), variable (C9399).
- Any miscellaneous HCPCS codes (J3490, J3590 and C9399) billed to Medicare for drugs that are listed in the Coding Table Information below will be denied.
- This revised article, effective 6/27/2016 combines JFA A53035 into the JFB A53033 article number so that both JFA and JFB contract numbers will have the same final Article number.

View the complete Noridian Self-Administered Drug Exclusion List.

Go to the Noridian Medicare Coverage Articles webpage to:

- View complete list of Noridian coverage articles
- Access the CMS MCD to view a comprehensive revision history for this corresponding article
  - Scroll to bottom of webpage
  - Select state/contract of interest from Active, Future or Retired column (This link will redirect you to the CMS website.)
  - Once in the CMS MCD, select corresponding article title

Sclerosing of Varicose Veins – R4

The Sclerosing of Varicose Veins article has been revised and published under contract numbers: 02101 (AK), 02201 (ID), 02301(OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

Article Summary of Changes: Clarification and appropriate use of CPT® 37421 as an unacceptable choice of procedure codes for treatment of symptoms of varicose veins of the lower extremity regardless of the method used.

Effective Date: July 18, 2016

View the complete Noridian coverage article.

Go to the Noridian Medicare Coverage Articles webpage to:

- View complete list of Noridian coverage articles
- Access the CMS MCD to view a comprehensive revision history for this corresponding article
  - Scroll to bottom of webpage
  - Select state/contract of interest from Active, Future or Retired column (This link will redirect you to the CMS website.)
  - Once in the CMS MCD, select corresponding article title
2016 JF Part A Quarterly Ask-the-Contractor Teleconferences

Below is the listing of the 2015 Part A Quarterly Ask-the-Contractor Teleconferences (ACTs).

- January 21, 2016
- April 21, 2016
- July 21, 2016
- October 20, 2016

ACTs are designed to open communication between providers and Noridian, which allows for timely identification of problems, and sharing information in an informal and interactive question and answer (Q&A) format. No Personal Health Information (PHI) is allowed.

Noridian representatives from various Part A departments are available to address your Medicare questions and concerns. All questions are entertained and the Q&As are posted on our website for provider convenience.

To view ACT dates, times, toll-free number, and Q&As, go to https://med.noridianmedicare.com/web/jfa/education/act.

No registration is required for these calls. Please call in 10 minutes prior, all calls start promptly at the time designated in the schedule listing.

By completing and submitting the Noridian “Ask the Contractor Teleconference Question Submission Form,” providers may ask question(s), up to five (5) days prior, to be answered during the next ACT. Questions submitted with this form will be answered first. Lines will then be opened for additional questions, as time permits. Do not include any Personal Health Information (PHI) or claim specific inquiries on this form. If you have claim specific questions, contact the Provider Contact Center.

Providers will need to have Version 7 or higher of Adobe Reader to use this form.

We look forward to your participation in these important calls.

Medicare Part A ACTs do not address Medicare Part B or Durable Medical Equipment (DME) inquiries. If you are interested in attending a Part B or a DME ACT, select the appropriate link below for more information.

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Recovering Overpayments from Providers Who Share Tax Identification Numbers

MLN Matters® Number: SE1612

Provider Types Affected

This MLN Matters® Article is intended for providers of services and suppliers who share the same Tax Identification Number (TIN) even though they may have different National Provider Identifiers or other billing numbers used to bill Medicare.

What You Need to Know

Section 1866j(6) of the Social Security Act authorizes the Secretary to make any necessary adjustments to the payments of a provider of services or supplier who shares a TIN with a provider of services or supplier that has an outstanding Medicare overpayment. The Secretary of Health and Human Services is authorized to adjust the payments of such a provider of services or supplier regardless of whether it has been assigned a different billing number or NPI from that of the provider of services or supplier with the outstanding Medicare overpayment.
In January 2016, the Centers for Medicare & Medicaid Services (CMS) enhanced its financial accounting system to include a function that allows CMS to recover payments made to a provider of services or supplier that shares the same TIN with a provider of services or supplier that has an outstanding Medicare overpayment across multiple states within a Medicare Administrative Contractor (MAC) jurisdiction.

**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.

**New Release of PEPPER Available for Hospices, SNFs, IRFs, IPFs, CAHs, LTCHs**
The Q4FY15 release of the Program for Evaluating Payment Patterns Electronic Report (PEPPER) for hospices, skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs), critical access hospitals (CAHs) and long-term acute care hospitals (LTCHs) will be available by April 15, 2016.

Hospices, LTCHs and free-standing SNFs and IRFs: To obtain their PEPPER, the Chief Executive Officer, President, Administrator or Compliance Officer of the organization should:

2. Review the instructions and obtain the information required to authenticate access.
   - Note: A new validation code will be required. A patient control number or medical record number from a claim for a traditional Medicare FFS beneficiary with a “from” or “through” date in September 1-30, 2015 will be required.
3. Visit the PEPPER Resources Portal.
4. Complete all the fields.
5. Download the PEPPER.

CAHs, IPFs, and SNF and IRF units of hospitals: PEPPER will be distributed via the QualityNet secure portal by April 15, 2016.

**About PEPPER**
PEPPER summarizes provider-specific data statistics for Medicare services that may be at risk for improper payments. Providers can use the data to support internal auditing and monitoring activities. Visit PEPPERResources.org to access updated resources for using PEPPER, including recorded web-based training sessions, sample PEPPERs and PEPPER User’s Guides, which are available on the applicable “Training and Resources” pages.

PEPPER is distributed by TMF® Health Quality Institute under contract with the Centers for Medicare & Medicaid Services.

**New ST PEPPER now available**
A new release of the Short-Term (ST) Acute Care Program for Evaluating Payment Patterns Electronic Report (PEPPER), with statistics through the first quarter of fiscal year 2016, is available for short-term acute care hospitals nationwide. PEPPER files were recently distributed through a QualityNet secure file exchange to hospital QualityNet Administrators and user accounts with the PEPPER recipient role.

Revised in this release:
- Target area numerator and denominator definitions for three target areas (excisional debridement, spinal fusion and ventilator support) have been revised effective with the first quarter of FY2016 statistics to reflect the transition from ICD-9 to ICD-10 (see the appendices in the ST PEPPER User’s Guide for complete lists of procedure codes included for excisional debridement and spinal fusion). Prior quarters continue to be calculated using the prior numerator/denominator definitions.
• The Single CC/MCC target area now evaluates ICD-10 principal diagnosis codes that are their own CC/MCC, as identified in table 6K of the IPPS final rule.

A Webinar is scheduled for June 21 at 1:00 CT to review these changes with a special focus on the first quarter of ICD-10 statistics; click here for more information.

About PEPPER

PEPPER summarizes hospital-specific data statistics for Medicare severity diagnosis-related groups and discharges at risk for improper payments. It is distributed by TMF® Health Quality Institute under contract with the Centers for Medicare & Medicaid Services. Visit PEPPERresources.org to access resources for using PEPPER, including the PEPPER user’s guide, recorded training sessions, information about QualityNet accounts, frequently asked questions and examples of how other hospitals are using PEPPER.

Do you have questions or comments about PEPPER or need help obtaining your report? Visit our Help Desk. Provide feedback or suggestions regarding PEPPER through our feedback form.

ENROLLMENT

Do Not Forward Initiative Reminder

The Internet Only Manual (IOM) Medicare Claims Processing Manual, Publication 100-04 instructs Part A and Part B Medicare Administrative Contractors (A/B MACs) and carriers to use “return service requested” envelopes when mailing paper checks and remittance advices to providers.

When the post office returns a “return service requested” envelope, the A/B MAC/carrier applies a “do not forward” (DNF) flag to the provider’s Medicare enrollment file. The A/B MAC/carrier will not generate any additional checks for that provider until the provider sends a properly completed change of address form back to the A/B MAC/carrier. We are not required to contact the provider to notify them that the flag has been added to their file.

Upon verifying the new address, the A/B MAC/carrier removes the DNF flag and can again generate payments for the provider. Electronic Funds Transfer (EFT) is required; therefore, when the address change update is completed, the provider will be set up to use EFT and will no longer receive paper checks.

NOTE: Because many providers get paid through EFT, there may be cases where a provider does not have a correct address on file, but the A/B MAC/carrier continues to pay the provider through EFT. It is still the provider’s responsibility to submit and address change update so that remittance notices and special checks would be sent to the proper address.

Noridian encourages providers to enroll or make changes using Internet-based Provider Enrollment, Chain and Ownership System (PECOS) for faster processing time. Applications and changes completed online currently have an average processing time of 10 days. All Medicare providers may use the new enrollment process on the CMS website https://pecos.cms.hhs.gov. To log into this internet-based PECOS, providers will use their NPI Userid and password.

Policy

Effective October 1, 2002, A/B MACs/carriers must use “return service requested” envelopes for hardcopy remittance advices and checks, with respect to providers that have elected to receive hardcopy remittance advices. (PM B-02-023, CR 2038 dated April 12, 2002; Transmittal 1794, CR 2684 dated May 2, 2003)

Implementation Process

1. “Return service requested” envelopes are used for all hardcopy remittance advices starting October 1, 2002. These envelopes will be used for all providers.

2. “Return service requested” envelopes will not be used for beneficiary correspondence, such as Medicare Summary Notices (MSNs) or for overpayment demand letters.
3. When the post office returns a remittance advice due to an incorrect address, A/B MACs/carriers will follow the same procedures as followed for returned checks, that is:
   - Flag the provider’s file DNF.
   - A/B MAC/carrier staff will notify provider enrollment team.
   - A/B MAC/carriers will cease generating any further payments or remittance advice to that provider or supplier until furnished with a new, verified address.

4. When the provider establishes a new, verified address, A/B MACs/carriers will remove the DNF flag and pay the provider any funds which are still being held due to a DNF flag. A/B MAC/carriers must also reissue any remittance advices, which have been held.

5. Previously, CMS only required corrections to the “pay to” address. However, with the implementation of this initiative, CMS requires corrections to all addresses before the contractor can remove the DNF flag and begin paying the provider or supplier again. Therefore, A/B MAC/carriers cannot release any payments to DNF providers until the provider enrollment department has verified and updated all addresses for that provider’s location.

IRS-1099 Reporting
Provider or supplier checks returned and voided during the same year they were issued are not reported on the Internal Revenue Service (IRS) Form 1099 until the returned check is reissued (i.e., the DNF flag is removed and the A/B MAC/carrier reissues payment to the provider.) Checks returned and voided in the current year that were issued in prior years are not netted from the current year’s IRS Form 1099.

Monies withheld because a DNF flag exists on a provider or supplier record are not reported on IRS-1099s until the calendar year in which payment is made (i.e., the point at which the A/B MAC/carrier pays the provider once the DNF flag is removed.) If DNF amounts are erroneously included on IRS-1099 forms, A/B MACs/carriers will issue corrected IRS Form 1099s to affected providers.

Source: IOM Medicare Claims Processing Manual, Publication 100-04, Chapter 22, Section 50.1

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ESRD

MSP ESRD 30 Month Coordination Period Calculator Now Available
To assist providers with the End Stage Renal Disease (ESRD) 30-month coordination period inquiries, Noridian has added a calculator to our website. Providers can enter the ESRD benefit start date and the calculator will provide the coordination period end date.

See the Medicare Secondary Payer (MSP) or the End Stage Renal Disease (ESRD) Services webpage to access this calculator.
ICD-10-CM Diagnosis Codes for Bone Mass Measurement –
Second Revision

MLN Matters® Number: SE1525 Revised
Related Change Request (CR) #: CR9252

This article was revised on April 12, 2016, to clarify the removal of a code (originally stated as M85.8) from the list of codes that providers may report on page 2 of the article. The code that was removed is M85.80 (Other specified disorders of bone density and structure, unspecified site). All other information is the same.

Provider Types Affected
This MLN Matters® Article is intended for clinical diagnostic laboratories and other providers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed
The Centers for Medicare & Medicaid Services (CMS) will implement Change Request (CR) 9252 on January 4, 2016, effective October 1, 2015. (See related MLN Matters® article MM9252.) This CR establishes the list of covered conditions and corresponding ICD-10-CM diagnosis codes approved for Bone Mass Measurement studies according to the requirements set forth in National Coverage Determination (NCD) 150.3. CR9252 and accompanying spreadsheet inadvertently omitted the condition of osteopenia and the ICD-10-CM codes that describe it which are classified to subcategory M85.8-Other specified disorders of bone density and structure. The codes and conditions identified within this subcategory are considered covered indications for bone mass measurement under NCD 150.3 and providers should report these appropriately according to medical documentation. Additional guidance and education as to the updated complete list of covered indications will be forthcoming as CMS continues to review this issue and the systems updates required.

Background
Under ICD-9-CM, the term “Osteopenia” was indexed to ICD-9-CM diagnosis code 733.90 (Disorder of bone and cartilage). This code was listed as a covered condition under the Business requirement 5521.1.1 for CR 5521/NCD 150.3, dated May 11, 2007, when reported with CPT code 77080. (See related MLN Matters article MM5521.) The accompanying Benefit Policy Manual, Publication 100-02, chapter 15, section 80.5.6, Beneficiaries Who May Be Covered, includes: 2. An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

Under ICD-10-CM, the term “Osteopenia” is indexed to ICD-10-CM subcategory M85.8- Other specified disorders of bone density and structure, within the ICD-10-CM Alphabetic Index. The codes within this subcategory were inadvertently omitted from the CMS spreadsheet that accompanied CR 9252 containing the list of covered conditions and corresponding diagnosis codes. These are considered covered for NCD 150.3 indications.

Below is the list of ICD-10-CM diagnosis codes within subcategory M85.8- that providers may report as covered indications in addition to the current list provided in CR 9252 and its accompanying CMS spreadsheet.

• M85.811 Other specified disorders of bone density and structure, right shoulder
• M85.812 Other specified disorders of bone density and structure, left shoulder
• M85.821 Other specified disorders of bone density and structure, right upper arm
• M85.822 Other specified disorders of bone density and structure, left upper arm
• M85.831 Other specified disorders of bone density and structure, right forearm
• M85.832 Other specified disorders of bone density and structure, left forearm
• M85.841 Other specified disorders of bone density and structure, right hand
• M85.842 Other specified disorders of bone density and structure, left hand
• M85.851 Other specified disorders of bone density and structure, right thigh
ICD-10

- M85.852 Other specified disorders of bone density and structure, left thigh
- M85.861 Other specified disorders of bone density and structure, right lower leg
- M85.862 Other specified disorders of bone density and structure, left lower leg
- M85.871 Other specified disorders of bone density and structure, right ankle and foot
- M85.872 Other specified disorders of bone density and structure, left ankle and foot
- M85.88 Other specified disorders of bone density and structure, other site
- M85.89 Other specified disorders of bone density and structure, multiple sites

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.

MEDICAL POLICIES

Active LCDs are Available for You in PDF Format
Providers are able to more quickly access important Medicare coverage guidelines by visiting the Policies section of our website and choosing Local Coverage Determination/Active LCDs.
As of March 23, 2016, the LCDs are published in Portable Document Format (PDF) as a single policy for all states in our Jurisdiction. This is an improvement as it allows printing, searching within the file, and reduces the need to navigate an additional website, the CMS Medicare Coverage Database.
The LCD policies have been the same for Noridian states for this jurisdiction. Only the state and contractor identification number were different. The conversion to a pdf file does not change the LCD policy content but rather merges the state and contractor identification numbers into one single document while streamlining access and search capabilities. Providers routinely access the LCD information from our website as their primary source of Medicare policy information. We trust you will find these enhancements improve your Noridian Medicare website browsing experience and look forward to your feedback.
You may access these important Medicare guidelines by visiting the Active Policy webpage at https://med.noridianmedicare.com/web/fa/policies/lcd/active.

Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy LCD – R6
The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number: L35178

LCD Title: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy

Effective Date: October 1, 2015

Summary of Changes: Added ICD-10-CM codes:
- M46.81 Other specified inflammatory spondylarthropathies, occipito-atlanto-axial region
- M46.82 Other specified inflammatory spondylarthropathies, cervical region
- M46.83 Other specified inflammatory spondylarthropathies, cervicothoracic region
- M46.84 Other specified inflammatory spondylarthropathies, thoracic region
- M46.85 Other specified inflammatory spondylarthropathies, thoracolumbar region
- M46.86 Other specified inflammatory spondylarthropathies, lumbar region
• M46.87 Other specified inflammatory spondylopathies, lumbosacral region
• M46.88 Other specified inflammatory spondylopathies, sacral and sacroccygeal region
• M46.89 Other specified inflammatory spondylopathies, multiple sites in spine
• M47.891 Other spondylosis, occipito-atlanto-axial region
• M47.892 Other spondylosis, cervical region
• M47.893 Other spondylosis, cervicothoracic region
• M47.894 Other spondylosis, thoracic region
• M47.895 Other spondylosis, thoracolumbar region
• M47.896 Other spondylosis, lumbar region
• M47.897 Other spondylosis, lumbosacral region
• M47.898 Other spondylosis, sacral and sacroccygeal region

To access the Noridian Active LCDs from our website, follow the instructions below.
• Go to https://med.noridianmedicare.com/web/ifa/policies/lcd/active
  • The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
• On the “Active LCDs” page, locate the above listed LCD title.
  • This link will direct you to the locally hosted copy of the LCD. You may also view the LCD on the CMS MCD by selecting the appropriate state link at the top of the page and locating the LCD title.

MolDX: Biomarkers in Cardiovascular Risk Assessment Final LCD – Effective June 1, 2016

The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor number 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number/Contractor Determination Number: L36362

LCD Title: MolDX: Biomarkers in Cardiovascular Risk Assessment

Effective Date: June 1, 2016

Summary of LCD: This policy describes the medical indication(s) for individual lipid biomarkers that may be covered under Medicare to characterize a given lipid abnormality or disease, to determine a treatment plan or to assist with intensification of therapy. All non-lipid biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, and hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually are non-covered.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.
• Go to https://med.noridianmedicare.com/web/ifa/policies/lcd/future
  • The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
• On the “Future LCDs” page, locate the above listed LCD title.
  • This link will redirect you to the state specific Future Effective LCD on the CMS website.
**MolDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) Final LCD – Effective June 16, 2016**

The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor number 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

**Medicare Coverage Database Number/Contractor Determination Number:** L36159

**LCD Title:** MolDX: Genetic Testing for Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)

**Effective Date:** June 16, 2016

**Summary of LCD:** This is a non-coverage policy for genetic testing for thrombophilia testing for the Factor V Leiden (FVL) variant in the F5 gene, the G20210G>A (G20210A) variant in the F2 gene and the MTHFR gene which encodes the 5,10-methylenetetrahydrofolate reductase enzyme. Genetic testing for these genes for all risk factors, signs, symptoms, diseases, or conditions, including cardiovascular risk assessment, are non-covered except for pregnant patients when those claims are appealed for coverage with submission of medical records supporting the necessity for testing and specify how testing changed anticoagulant prophylaxis management for the patient.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.

- Go to [https://med.noridianmedicare.com/web/jfa/policies/lcd/future](https://med.noridianmedicare.com/web/jfa/policies/lcd/future)
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
  - On the “Future LCDs” page, locate the above listed CMS Medicare Coverage Database (MCD) number or LCD title and select the coordinating state abbreviation.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.

**Nerve Conduction Studies and Electromyography Final LCD – Effective June 1, 2016**

The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY).

**Medicare Coverage Database Number/Contractor Determination Number:** L36526

**LCD Title:** Nerve Conduction Studies and Electromyography

**Effective Date:** June 1, 2016

**Summary of LCD:** This LCD provides coverage criteria for nerve conduction studies and electromyography and training and certification requirements based on guidelines from the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) and other medical organizations, including the AMA, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, American Neurological Association, the American Board of Physical Therapy Specialties (ABPTS) in Clinical Electrophysiology, and the Department of Veterans Affairs for healthcare providers performing these services.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.

- Go to [https://med.noridianmedicare.com/web/jfa/policies/lcd/future](https://med.noridianmedicare.com/web/jfa/policies/lcd/future)
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
  - On the “Future LCDs” page, locate the above listed CMS Medicare Coverage Database (MCD) number or LCD title and select the coordinating state abbreviation.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.
Non-Covered Services – R12
The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number: L34886
LCD Title: Non-Covered Services
Effective Date: May 31, 2016
Summary of Changes: Removal of CPT codes:
- 82172 – Apolipoprotein
- 83698 – Lipoprotein-Associated Phospholipase A2

To access the Noridian Future Effective LCDs from our website, follow the instructions below.
- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/future
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
- On the Future LCDs page, locate the above listed LCD title.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.

Controlled Substance Monitoring and Drugs of Abuse – Effective June 28, 2016
The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor number 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number/Contractor Determination Number: L36707
LCD Title: Controlled Substance Monitoring and Drugs of Abuse
Effective Date: June 28, 2016
Summary of LCD: This policy provides objective information to assist clinicians with identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.
- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/future
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
- On the “Future LCDs” page, locate the above listed CMS MCD number or LCD title and select the coordinating state abbreviation.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.
MolDX: CDD: Promark Risk Score Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Norian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 03401 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

**Medicare Coverage Database Number:** DL36706

**LCD Title:** MolDX: CDD: Promark Risk Score

**Comment period:** June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Norian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781


The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor number 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

**Medicare Coverage Database Number/Contractor Determination Number:** L36339

**LCD Title:** MolDX: NRAS Genetic Testing

**Effective Date:** July 5, 2016

**Summary of LCD:** This LCD provides limited coverage for NRAS testing for metastatic colorectal cancer. All other NRAS testing is non-covered.

To access the Norian Future Effective LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/future
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
  - On the “Future LCDs” page, locate the above listed CMS Medicare Coverage Database (MCD) number or LCD title and select the coordinating state abbreviation.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.
**MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease LCD – R1**

The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

**Medicare Coverage Database (MCD) Number:** L36186

**LCD Title:** MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

**Effective Date:** April 19, 2016

**Summary of Changes:** LCD is revised to include the following diagnoses per the MolDX Contractor: C88.8, C92.10, C93.10, C94.40, C94.41, C94.42, C94.6, D46.0-D46.9, D46.Z, D47.4, D47.9, D47.Z9, D72.821, D72.829 and D75.9.

To access the Noridian Active LCDs from our website, follow the instructions below.

- The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
- On the “Active LCDs” page, locate the above listed LCD title.
- This link will redirect you to the state specific Active LCD on the CMS website

**Bladder Tumor Markers Draft LCD Published for Review and Comments**

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

**Medicare Coverage Database Number:** DL36680

**LCD Title:** Bladder Tumor Markers

**Comment period:** June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781
Botulinum Toxins Types A and B Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

**Medicare Coverage Database Number:** DL35172

**LCD Title:** Botulinum Toxins Types A and B

**Comment period:** June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781

Percutaneous Endovascular Cardiac Assist Procedures and Devices – R4

The following Noridian coverage requirements for the Percutaneous Endovascular Cardiac Assist Procedures and Devices National Coverage Determination (NCD) have been published under contract numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) 03601 (WY) and 02102 (AK) 02202 (ID) 02302 (OR), 02402 (WA), 03102 (AZ), 03202 (MT), 03302 (ND), 03402 (SD), 03502 (UT) and 03602 (WY) in the CMS Medicare Coverage Database (MCD and on our (Noridian) website.

**NCD:** Percutaneous Endovascular Cardiac Assist Procedures and Devices NCD 20.9.1

**Effective Date:** October 1, 2015

**Article Summary of Changes:** The following revisions were made to this article:

- Changed ICD-10-PCS code from 02HL3DZ back to 5A0221D in Group 1 Paragraph for Part A Providers.
- Change article number from A52944 to A52967. Same article number and content for Jurisdiction F (JF) Part A and Part B
  - Article number A52944 will be retired on 5/15/16.

Read the complete National Coverage Determination requirements article.

- The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).

To view a complete list of all Noridian NCD coverage articles, go to the [National Coverage Determination (NCD)](https://med.noridianmedicare.com/web/jfa/policies/lcd/draft) and select the title of interest.

To view a complete list of all CMS NCDs available, go to [National Coverage Determinations (NCDs)](https://med.noridianmedicare.com/web/jfa/policies/lcd/draft).
Waiver of Face-to-Face Visit for Home Dialysis Patients – Coding guidelines

The Waiver of Face-to-Face Visit for Home Dialysis Patients coverage article has been published for notice under contract numbers: 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY) in the CMS Medicare Coverage Database (MCD) and on our (Noridian) website.

Article Summary: Coding guidelines to request waiver with 52 modifier to the appropriate monthly capitation CPT codes 90963-90966.

Effective Date: July 7, 2016

View the complete Noridian coverage article.

Go to the Noridian Medicare Coverage Articles webpage to:

- View complete list of Noridian coverage articles
- Access the CMS MCD to view a comprehensive revision history for this corresponding article
  - Scroll to bottom of webpage
  - Select state/contract of interest from Active, Future or Retired column (This link will redirect you to the CMS website.)
- Once in the CMS MCD, select corresponding article title

MolDX: Genetic Testing for Lynch Syndrome Final LCD – Effective June 1, 2016

The following Local Coverage Determination (LCD) has completed the Open Public and Carrier Advisory Committee comment period and is now finalized under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY).

Medicare Coverage Database Number/Contractor Determination Number: L36374

LCD Title: MolDX: Genetic Testing for Lynch Syndrome

Effective Date: June 1, 2016

Summary of LCD: This policy provides limited coverage of Lynch Syndrome (LS) genetic testing using a stepped approach for Microsatellite Instability and Immunohistochemistry (MSI/IHC) testing, BRAF gene mutation, MLH1 gene promoter hypermethylation and targeted mismatch repair (MMR) germ-line gene testing for all patients with colorectal cancer diagnosed at age ≤ 70 years of age, and those > 70 years who meet the revised Bethesda LS guidelines.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/ifa/policies/lcd/future
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
  - On the “Future LCDs” page, locate the above listed CMS Medicare Coverage Database (MCD) number or LCD title and select the coordinating state abbreviation.
  - This link will redirect you to the state specific Future Effective LCD on the CMS website.
Hyperbaric Oxygen (HBO) Therapy Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

Medicare Coverage Database Number: DL36686

LCD Title: Hyperbaric Oxygen (HBO)

Comment period: June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781

Intraoperative Neurophysiological Testing Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

Medicare Coverage Database Number: DL36688

LCD Title: Intraoperative Neurophysiological Testing

Comment period: June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781
Laparoscopic Sleeve Gastrectomy LCD Retirement – Effective April 30, 2016

The following JF Local Coverage Determination (LCD) has been retired under contractor 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database Number: L34166

LCD Title: Laparoscopic Sleeve Gastrectomy

Effective Date: April 30, 2016

This LCD is retired and its coverage criteria for 43775 is included in Bariatric Surgery Coverage article A53028. The JFA Bariatric Surgery Coverage article (A53027) is retired and JFA contract numbers are added to the JFB coverage article noted above so that JFA and JFB will have the same MCD article ID. Coverage has not changed from the LCD to its inclusion in the coverage article.

To access the Noridian Retired LCDs from our website, follow the instructions below.

Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/retired

• The End User Agreement for Providers will appear if you have not recently visited the website.
  Select “Accept” (if necessary).
  • On the “Retired LCDs” page, select the state of interest.
• This link will redirect you to the CMS website.
  • Select “Noridian Healthcare Solutions, LLC.” Locate the above listed CMS Medicare Coverage Database (MCD) number and LCD title and select the title of interest.


The following Local Coverage Determination (LCD) has completed the Open Public and Contractor Advisory Committee (CAC) comment period and is now finalized under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY).

Medicare Coverage Database (MCD) Number/Contractor Determination Number: L36368

LCD Title: MolDX-CDD: Genomic Health™ Oncotype DX® Prostate Cancer Assay

Effective Date: July 5, 2016

Summary of LCD: This LCD provides limited coverage for the Oncotype DX® Prostate Cancer Assay (Genomic Health™) to help determine which patients with early stage, needle biopsy proven prostate cancer, can be conservatively managed rather than treated with definitive surgery or radiation therapy.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.

• Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/future
  • The End User Agreement for Providers will appear if you have not recently visited the website.
    Select “Accept” (if necessary).
  • On the “Future LCDs” page, locate the above listed CMS MCD number or LCD title and select the coordinating state abbreviation.
  • This link will redirect you to the state specific Future Effective LCD on the CMS website.
MolDX: Molecular RBC Phenotyping – R1

The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database Number/Contractor Determination Number: L36171

LCD Title: MolDX: Molecular RBC Phenotyping

Effective Date: April 1, 2016

Summary of Changes: The Coverage Guidance section of the policy revised to:

- Add statement “RBC phenotyping of MM patients eligible for daratumumab therapy (anti CD-38) because it interferes with serologic testing and included coverage for Medicare eligible patients “prior to and following treatment with anti-CD-38 therapy for MM.”

- Add to the section for ICD-10 codes: C90.00, C90.01 and C90.02

- Add three (#'s 1, 5 and 12) references to Sources of information and Basis for Decision.

To access the Noridian Active LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/active
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary)
  - On the “Active LCDs” page, locate the above listed LCD title.
  - This link will direct you to the locally hosted copy of the LCD. You may also view the LCD on the CMS MCD by selecting the appropriate state link on the left side of the page and locating the LCD title.

Blepharoplasty, Eyelid Surgery and Brow Lift LCD – R2

The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number: L36281

LCD Title: Blepharoplasty, Eyelid Surgery and Brow Lift

Effective Date: June 23, 2015

Summary of Changes: The correct effective date of the LCD should be 06/23/15 rather than 10/1/15. Revised to reflect the correct effective date and to add the appropriate dates relating to the start and end of the comment period and when the LCD was released to Final status: Comment Period Start Date: 09/13/14; Comment Period End Date: 11/03/14; and Release to Final Date: 04/07/15. The LCD was presented at the September 2014 Open Public Meeting and Contractor Advisory Committee Meeting. Notification was provided through Noridian website posting.

To access the Noridian Active LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/active
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary)
  - On the “Active LCDs” page, locate the above listed LCD title.
  - This link will direct you to the locally hosted copy of the Active LCD. You may also view the LCD on the CMS MCD by selecting the appropriate state link on the left side of the page and locating the LCD title.
Serum Magnesium Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

Medicare Coverage Database Number: DL36700

LCD Title: Serum Magnesium

Comment period: June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781

Single Chamber and Dual Chamber Permanent Cardiac Pacemakers – Billing and Coding – R2

The following Noridian coverage requirements for the Single Chamber and Dual Chamber Permanent Cardiac Pacemakers National Coverage Determination (NCD) have been published under contract numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY) and 02102 (AK), 02202 (ID), 02302 (OR), 02402 (WA), 03102 (AZ), 03202 (MT), 03302 (ND), 03402 (SD), 03502 (UT) and 03602 (WY) in the CMS Medicare Coverage Database (MCD and on our (Noridian) website.

NCD: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers NCD 20.8.3

Effective Date: May 1, 2016

Article Summary: View the following updated information:

- A typographical error regarding CPT code 33229 was corrected in the following statement:
  - The NCD does not address replacement of pacemaker generators. CPT codes 33227, 33228 and 33229 or 33233 are therefore not addressed in this coding article.

- Added the following to the Explanatory Note in the Group 1 Paragraph in the “CPT/HCPCS Codes” section:
  - Group 1 CPT codes apply to Groups 1 and 2 ICD-9-CM and ICD-10-CM Codes.

Read the complete National Coverage Determination requirements article.

- The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).

To view a complete list of all Noridian NCD coverage articles, go to the National Coverage Determination (NCD) and select the title of interest.

To view a complete list of all CMS NCDs available, go to National Coverage Determinations (NCDs) Alphabetical Index.
MEDICAL POLICIES

Spinal Cord Stimulators for Chronic Pain Final LCD – Effective June 1, 2016

The following Local Coverage Determination (LCD) has completed the Open Public and Contractor Advisory Committee (CAC) comment period and is now finalized under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT) and 03601 (WY).

Medicare Coverage Database (MCD) Number/Contractor Determination Number: L36204

LCD Title: Spinal Cord Stimulators for Chronic Pain

Effective Date: June 1, 2016

Summary of LCD: This LCD provides Coverage Indications, Limitations and Medical Necessity criteria for Spinal Cord Stimulators when used for chronic pain along with payable diagnosis codes.

To access the Noridian Future Effective LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/future
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
- On the “Future LCDs” page, locate the above listed LCD title.
  - This link will direct you to the locally hosted copy of the LCD. You may also view the LCD on the CMS MCD by selecting the appropriate state link at the top of the page and locating the LCD title.

Treatment of Ulcers and Symptomatic Hyperkeratoses – R6

The following JF Local Coverage Determination (LCD) has been revised under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

Medicare Coverage Database (MCD) Number: L34199

LCD Title: Treatment of Ulcers and Symptomatic Hyperkeratoses

Effective Date: October 1, 2015

Summary of Changes: LCD revised to add ICD-10-CM codes and combined the JF A and JF B policies into one.

- ICD-10-CM codes T81.32XA, T81.32XD, T81.32XS, T87.41, T87.42, T87.43 and T87.44 were added.
- Change LCD number from L36107 to L34199. Same LCD number and content for Jurisdiction F (JF) Part A and Part B
  - LCD number L36107 will be retired on 5/15/16.

To access the Noridian Active LCDs from our website, follow the instructions below.

- Go to https://med.noridianmedicare.com/web/jfa/policies/lcd/active
  - The End User Agreement for Providers will appear if you have not recently visited the website. Select “Accept” (if necessary).
- On the “Active LCDs” page, locate the above listed LCD title.
  - This link will direct you to the locally hosted copy of the LCD. You may also view the LCD on the CMS MCD by selecting the appropriate state link on the left side of the page and locating the LCD title.
Vitamin D Assay Testing Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

**Medicare Coverage Database Number:** DL34051

**LCD Title:** Vitamin D Assay Testing

**Comment period:** June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Part A Medical Director
  PO Box 6781
  Fargo, ND 58103-6781

MolDX: Breast Cancer Biomarkers to Guide Adjuvant Chemotherapy Draft LCD Published for Review and Comments

The following draft Local Coverage Determination (LCD) has been published for review and comment on the Noridian website for the following contract numbers: 02101 (AK), 03101 (AZ), 02201 (ID), 03201 (MT), 03301 (ND), 02301 (OR), 03401 (SD), 03501 (UT), 02401 (WA) and 03601 (WY).

**Medicare Coverage Database Number:** DL36734

**LCD Title:** MolDX: Breast Cancer Biomarkers to Guide Adjuvant Chemotherapy

**Comment period:** June 2 – August 8, 2016


When sending comments, providers must reference the specific policy to which they are related and email or mail them to:

- policya.drafts@noridian.com
- Noridian Medicare JF Part A
  Attention: Draft LCD Comments
  PO Box 6781
  Fargo, ND 58103-6781


The following JF Draft Local Coverage Determination (LCD) has been retired under contractor numbers 02101 (AK), 02201 (ID), 02301 (OR), 02401 (WA), 03101 (AZ), 03201 (MT), 03301 (ND), 03401 (SD), 03501 (UT), 03601 (WY).

**Medicare Coverage Database Number/Contractor Determination Number:** DL36734

**LCD Title:** MolDX: Breast Cancer Biomarkers to Guide Adjuvant Chemotherapy

**Effective Date:** May 20, 2016

**Summary of LCD Retired:** Since the drafting of this policy, additional information has been identified that we feel will significantly impact this policy and will likely result in a significant revision. As such, we are retiring this draft LCD.
Updating the FISS to Make Payment for Drugs and Biologicals Services for OPPS Providers

MLN Matters® Number: MM9601
Related Change Request (CR) #: CR 9601
Related CR Release Date: April 28, 2016
Effective Date: January 1, 2016
Related CR Transmittal #: R16490TN
Implementation Date: October 3, 2016

Provider Types Affected
This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Home Health & Hospice MACs and Durable Medical Equipment MACs (DME MACs) for services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS).

Provider Action Needed
Change Request (CR) 9601 informs MACs about the implementation of phase 2 of system changes necessary to the Fiscal Intermediary Shared System (FISS) and Integrated Outpatient Code Editor (IOCE) which are necessary to make payment for drugs and biologicals to Outpatient Prospective Payment System (OPPS) providers. Make sure that your billing staffs are aware of these changes.

Background
The Centers for Medicare & Medicaid Services (CMS) pays for all outpatient drugs using the Average Sales Price (ASP) methodology. The schedule for submission of all ASP pricing is statutory per Section 621(a) of the Medicare Modernization Act. Drug manufacturers are required to submit drug ASPs within 30 days of the close of their fiscal quarter. Given the complexity, volume of data, and the number of drugs affected, approximately 6 weeks are required to process, validate, and issue final ASPs for a given quarter. As a result, the ASP rates for drugs furnished on or after January 1, 2016, were not available until mid-December 2015. The ASP rates for drugs furnished on or after April 1, 2016, were not available until mid-March 2016. The ASP rates for drugs furnished on or after July 1, 2016, will not be available until mid-June 2016 and the ASP rates for drugs furnished on or after October 1, 2016, will not be available until mid-September 2016 respectively.

CMS supplies MACs with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis and this file is used for payment to most institutional providers by FISS. OPPS claims were an exception to this process. Payment for OPPS claims were based on tables provided to the OPPS Pricer to account for some of the special processing rules that are unique to OPPS providers (such as, pass-through status necessary and drugs provided solely in the hospital setting).

Starting on October 1, 2016, drug HCPCS on OPPS claims will no longer be priced by the Outpatient PPS Pricer. The fee schedule amount from the ASP drug file or any future drug fee schedule amount will be used by FISS to price covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS. Phase 2 includes logic for FISS to cap the coinsurance amounts for procedures (which include blood and drug services) to the inpatient deductible amount for each calendar year and to insure the rural floor is applied.
The following examples are part of CR9601 to demonstrate the capped inpatient deductible amount:

**Example 1 of inpatient deductible capped amount:**

Drug Line A has a fee of $2,000.00, a payment of $1,600.00, and coinsurance of $400.00.
Drug Line B has a fee of $1,000.00, a payment of $800.00, and coinsurance of $200.00.
Drug Line C has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.
Drug Line D has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.

Highest wage adjusted national coinsurance amount for a procedure line is $888.00.

The Inpatient Part A deductible is $1,288.00 for 2016

$1,288.00 - $888.00 = $400.00 remaining coinsurance to be applied toward inpatient deductible cap.

Drug Lines A-D coinsurance is $800.00.

$400.00 cap remaining / $800.00 drug line(s) coinsurance = 50% reduction to coinsurance due to inpatient deductible cap.

Apply 50% reduction of the coinsurance amounts for each line and add the remaining 50% back into the payment amount.

Drug Line A has a final payment of $1,800.00, and coinsurance of $200.00.
Drug Line B has a final payment of $900.00, and coinsurance of $100.00.
Drug Line C has a final payment of $450.00, and coinsurance of $50.00.
Drug Line D has a final payment of $450.00, and coinsurance of $50.00.

**Example 2 of inpatient deductible capped amount:**

Drug Line A has a fee of $2,000.00, a payment of $1,600.00, and coinsurance of $400.00.
Drug Line B has a fee of $1,000.00, a payment of $800.00, and coinsurance of $200.00.
Drug Line C has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.
Drug Line D has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.

Highest wage adjusted national coinsurance amount for a procedure line is $1,588.00.

The Inpatient Part A deductible is $1,288.00 for 2016

$1,588.00 is greater than $1,288.00. The OPPS Pricer will cap the coinsurance amount to be applied on the highest wage adjusted national coinsurance procedure line prior to application of the cap on the drug lines.

Drug Lines A-D coinsurance is $800.00.

$0 cap remaining / $800.00 = 100% reduction to coinsurance due to inpatient deductible cap.

Drug Line A has a final payment of $2,000.00, and no coinsurance.
Drug Line B has a final payment of $1,000.00, and no coinsurance.
Drug Line C has a final payment of $500.00, and no coinsurance.
Drug Line D has a final payment of $500.00, and no coinsurance.

**Additional Information**

I/OCE Specifications Version 17.2 – July 2016

MLN Matters® Number: MM9661
Related Change Request (CR) #: CR 9661
Related CR Release Date: May 13, 2016
Effective Date: July 1, 2016
Related CR Transmittal #: R3524CP
Implementation Date: July 5, 2016

Provider Types Affected
This MLN Matters® Article is intended for providers submitting claims to Medicare Administrative Contractors (MACs) for outpatient services provided to Medicare beneficiaries and paid under the Outpatient Prospective Payment System (OPPS) and for outpatient claims from any non-OPPS provider not paid under the OPPS.

It is also intended for claims for limited services when provided in a Home Health Agency (HHA) not under the Home Health PPS (HH PPS) or claims for services to a hospice patient for the treatment of a non-terminal illness.

Provider Action Needed
Change Request (CR) 9661 provides the Integrated Outpatient Code Editor (I/OCE) instructions and specifications. Please make sure your billing staff is aware of these updates. Make sure that your billing staffs are aware of these changes.

Background
CR9661 informs the Part A/B MACs, the HHH MACs, and the Fiscal Intermediary Shared System (FISS) that the I/OCE is being updated for July 1, 2016. The I/OCE routes all institutional outpatient claims (which includes non-OPPS hospital claims) through a single integrated OCE.

The modifications of the I/OCE for the July 2016 v17.2 release are summarized in the following table.

<table>
<thead>
<tr>
<th>Type</th>
<th>Effective Date</th>
<th>Edits Affected</th>
<th>Modification</th>
</tr>
</thead>
</table>
| Logic | 7/1/2016       | 95, 96, 97     | Implement new edits under the partial hospitalization program logic for weekly hours of service requirements:  
  • **Edit 95**: Partial hospitalization claim span is equal to or more than 4 days with insufficient number of hours of service (RTP)  
    **Criteria**: A PHP claim From and Through date spans 4 or more days, but less than 8 days, and there are less than 20 hours of services present.  
  • **Edit 96**: Partial hospitalization interim claim From and Through dates must span more than 4 days (RTP)  
    **Criteria**: An interim PHP claim (bill type 763 or 133 with condition code 41) From and Through date spans less than 5 days.  
  • **Edit 97**: Partial hospitalization services are required to be billed weekly (RTP)  
    **Criteria**: A PHP claim From and Through date spans more than 7 days.  

See special processing logic under OPPS (page 7), Appendix C of CR9661-a (Weekly PHP flowchart) and Appendix F(a) (OPPS edits applied by bill type).
<table>
<thead>
<tr>
<th>Type</th>
<th>Effective Date</th>
<th>Edits Affected</th>
<th>Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logic</td>
<td>1/1/2016</td>
<td>98</td>
<td>Implement new edit 98: Claim with pass-through device, drug or biological lacks required procedure (RTP). <strong>Criteria:</strong> A pass-through device, drug or biological HCPCS code is present without an associated, required procedure. See special processing logic under OPPS (page 13), Appendix P (flowchart) and Appendix F(a).</td>
</tr>
<tr>
<td>Logic</td>
<td>1/1/2015</td>
<td>Add program logic to exclude certain blood products (packed red cells and whole blood) from packaging if reported on a comprehensive APC claim (see special processing logic under OPPS, page 9 and Appendix L).</td>
<td></td>
</tr>
<tr>
<td>Logic</td>
<td>4/5/2016</td>
<td>67</td>
<td>Apply mid-quarter FDA approval date for HCPCS code Q5102.</td>
</tr>
<tr>
<td>Logic</td>
<td>4/1/2016</td>
<td>94</td>
<td>Apply the edit if new biosimilar HCPCS code Q5102 is reported without the associated new modifier ZB.</td>
</tr>
<tr>
<td>Logic</td>
<td>7/1/2016</td>
<td>87</td>
<td>Updates to the skin substitute list (Appendix O: move Q4164 from low cost to high cost).</td>
</tr>
<tr>
<td>Logic</td>
<td>1/1/2016</td>
<td>92</td>
<td>Updates to the device and device procedure lists.</td>
</tr>
<tr>
<td>Logic and Field Definition</td>
<td>1/1/2016</td>
<td>Change the program logic to provide unique Payer Value Code QU when a condition for device credit is present, reported with condition code 49, 50, or 53 (see special processing logic under OPPS, page 9 and Table 5).</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td>1/1/2016</td>
<td>Update Appendix L (Comprehensive APC processing) under the inpatient procedure where the patient expired logic to note non-covered SI values are returned as excluded from packaging under comprehensive APCs, but any associated edits are not returned (documentation only, no change to program logic).</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td>1/1/2015</td>
<td>45</td>
<td>Update the reference on page 8 to indicate the change made for edit 45 to include SI = J1 procedures is retroactive to 1/1/2015 (documentation only, no change to program logic).</td>
</tr>
<tr>
<td>Documentation</td>
<td>7/1/2016</td>
<td>Update Table 2 with reference information for the reporting of modifiers.</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td>1/1/2016</td>
<td>Updated special processing logic on page 9 to include reference to the use of the complexity-adjusted comprehensive APC as the look-up for device credit amount when condition code 49, 50, or 53 are present (documentation only, no change to program logic).</td>
<td></td>
</tr>
<tr>
<td>Content</td>
<td>4/1/2016</td>
<td>22</td>
<td>Add modifier ZB (Pfizer/Hospira) to the list of valid modifiers.</td>
</tr>
<tr>
<td>Content</td>
<td>1/1/2015</td>
<td>Modify the valid revenue list for revenue code 940 (Other therapeutic services) to have SI value changed to N if reported with a blank HCPCS code.</td>
<td></td>
</tr>
</tbody>
</table>
**Additional Information**


**Hospital OPPS – July 2016 Update - Revised**

**MLN Matters® Number: MM9658 Revised**
**Related Change Request (CR) #: CR 9658**
**Related CR Release Date: June 28, 2016**
**Effective Date: July 1, 2016**
**Related CR Transmittal #: R3552CP**
**Implementation Date: July 5, 2016**

This article was revised on June 29, 2016, due to an updated Change Request (CR). The CR changed the APC number for the HCPCS code Q5102 from 1761 to 1847 in table 5, Attachment A (page 7 below). Also, business requirement 9658.3 in the CR had incorrect termination date for C9743, C9458, and C9459. The correct termination date should be June 30, 2016, instead of June 30, 2015. The transmittal number and CR release date and link to the transmittal was also changed. All other information remains the same.

**Provider Types Affected**

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

**Provider Action Needed**

CR 9658 describes changes to, and billing instructions for, various payment policies implemented in the July 2016 OPPS update. It identifies the Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions that are reflected in the July 2016 Integrated Outpatient Code Editor (I/OCE) and OPPS Pricer. Make sure that your billing staffs are aware of these changes.
Key Points of CR9658

Key changes to and billing instructions for various payment policies implemented in the July 2016 OPPS updates are as follows:

Billing Instructions for IMRT Planning

The revised Intensity Modulated Radiation Therapy (IMRT) planning billing instructions (in the paragraph, below), that were also included in the April 2016 Update of the Hospital OPPS (CR9549), replace the instructions discussed in the 2016 OPPS final rule at 80 FR 70401-70402 and in the January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS) (CR9486). The effective date of these instructions is January 1, 2016.

These instruction state that payment for the services identified by CPT codes 77014, 77280, 77285, 77290, 77295, 77306 through 77321, 77331, and 77370 are included in the APC payment for CPT code 77301 (IMRT planning). You should not report these codes in addition to CPT code 77301, when provided prior to, or as part of, the development of the IMRT plan.


Upper Eyelid Blepharoplasty and Blepharoptosis Repair

The Centers for Medicare & Medicaid Services (CMS) payment policy does not allow separate payment for a blepharoplasty procedure (CPT codes 15822, 15823) in addition to a blepharoptosis procedure (CPT codes 67901-67908) on the ipsilateral upper eyelid. Any removal of upper eyelid skin in the context of an upper eyelid blepharoptosis surgery is considered a part of the blepharoptosis surgery.

A blepharoplasty cannot be billed to Medicare and the beneficiary cannot be separately charged for a cosmetic procedure regardless of the amount of upper eyelid skin that is removed on a patient receiving a blepharoptosis repair because removal of (any amount) of upper eyelid skin is part of the blepharoptosis repair. In addition, the following are not permitted:

- Operating on the left and right eyes on different days when the standard of care is bilateral eyelid surgery
- Charging the beneficiary an additional amount for a cosmetic blepharoplasty when a blepharoptosis repair is performed
- Charging the beneficiary an additional amount for removing orbital fat when a blepharoplasty or a blepharoptosis repair is performed
- Performing a blepharoplasty on a different date of service than the blepharoptosis procedure for the purpose of unbundling the blepharoplasty or charging the beneficiary for a cosmetic surgery
- Performing blepharoplasty as a staged procedure, either by one or more surgeons (note that under certain circumstances a blepharoptosis procedure could be a staged procedure)
- Billing for two procedures when two surgeons divide the work of a blepharoplasty performed with a blepharoptosis repair
- Using modifier 59 to unbundle the blepharoplasty from the ptosis repair on the claim form; this applies to both physicians and facilities
- Treating medically necessary surgery as cosmetic for the purpose of charging the beneficiary for a cosmetic surgery
- Using an Advance Beneficiary Notice of Noncoverage for a service that would be bundled into another service if billed to Medicare
- In the rare event that a blepharoplasty is performed on one eye and a blepharoptosis repair is performed on the other eye, the services must each be billed with the appropriate RT or LT modifier
Revised Status Indicators (SIs) for Pathology CPT Codes

The SI for CPT code 85396 (Clotting assay whole blood) will change from SI=Q4 (Conditionally packaged laboratory tests) to SI=N (Paid under OPPS; payment is packaged into payment for other services) in the July 2016 update.

- The SI for CPT code 88141 (Cytopath c/v interpret) will change from SI=Q4 to SI=N in the July 2016 update.
- The SI for CPT code 88174 (Cytopath c/v auto in fluid) will change from SI=N to SI=Q4 in the July 2016 update.
- The SI for CPT code 88175 (Cytopath c/v auto fluid redo) will change from SI=N to SI=Q4 in the July 2016 update.

- These codes, their Descriptors, and Status Indicators are listed in table 1.

Table 1 – Pathology CPT Codes with Revised SIs

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>SI</th>
</tr>
</thead>
<tbody>
<tr>
<td>85396</td>
<td>Coagulation/fibrinolysis assay, whole blood (eg, viscoelastic clot assessment), including use of any pharmacologic additive(s), as indicated, including interpretation and written report, per day</td>
<td>N</td>
</tr>
<tr>
<td>88141</td>
<td>Cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician</td>
<td>N</td>
</tr>
<tr>
<td>88174</td>
<td>Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; screening by automated system, under physician supervision</td>
<td>Q4</td>
</tr>
<tr>
<td>88175</td>
<td>Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation; with screening by automated system and manual rescreening or review, under physician supervision</td>
<td>Q4</td>
</tr>
</tbody>
</table>

Reporting for Certain Outpatient Department Services (That Are Similar to Therapy Services) ("Non-Therapy Outpatient Department Services") That Are Adjunctive to Comprehensive APC Procedures

Effective for claims received on or after July 1, 2016, with dates of service on or after January 1, 2015 non-therapy outpatient department services (that are similar to therapy services) that are adjunctive to a comprehensive APC procedure (status indicator (SI) = J1 procedure) (see 80 FR 70326 at https://www.federalregister.gov/articles/2015/11/13/2015-27943/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment) or the specific combination of services assigned to the Observation Comprehensive APC 8011 (SI = J2), should not be reported with therapy CPT codes. This includes services described at 1833(a)(8), namely outpatient physical therapy, outpatient speech-language pathology and outpatient occupational therapy furnished either by therapists or non-therapists and included on the same claim as a comprehensive APC procedure. Non-therapy outpatient department services that are adjunctive to J1 or J2 procedures should be reported without a CPT code and instead should be reported with Revenue Code 0940 (Other Therapeutic Services). The SI for this revenue code will be changed from SI=B to SI=N, indicating that the payment for these services will be packaged into the C-APC payment.

Category III CPT Codes Effective July 1, 2016

The American Medical Association (AMA) releases Category III Current Procedural Terminology (CPT) codes twice per year: in January, for implementation beginning the following July, and in July, for implementation beginning the following January. For the July 2016 update, CMS is implementing in the OPPS nine Category III CPT codes that the AMA released in January 2016 for implementation on July 1, 2016. The SIs and APCs for these codes are shown in Table 2. Payment rates for these services are available in Addendum B of the July 2016 OPPS Update that is posted at https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates.html. Please note that HCPCS code C9743 (Also listed in Table 2) will be deleted June 30, 2016, since it will be replaced with Category III CPT code 0438T effective July 1, 2016. CPT code 0438T will be assigned to the same SI and APC assignment as its predecessor HCPCS code C9743 effective July 1, 2016.
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Long Descriptor</th>
<th>Add Date</th>
<th>Term Date</th>
<th>July 2016 OPPS SI</th>
<th>July 2016 OPPS APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0437T</td>
<td>Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to primary procedure)</td>
<td>07/01/2016</td>
<td>N</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>0438T</td>
<td>Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, include image guidance</td>
<td>07/01/2016</td>
<td>T</td>
<td>5374</td>
<td></td>
</tr>
<tr>
<td>0439T</td>
<td>Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to primary procedure)</td>
<td>07/01/2016</td>
<td>N</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>0440T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve</td>
<td>07/01/2016</td>
<td>J1</td>
<td>5361</td>
<td></td>
</tr>
<tr>
<td>0441T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve</td>
<td>07/01/2016</td>
<td>J1</td>
<td>5361</td>
<td></td>
</tr>
<tr>
<td>0442T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)</td>
<td>07/01/2016</td>
<td>J1</td>
<td>5361</td>
<td></td>
</tr>
<tr>
<td>0443T</td>
<td>Real time spectral analysis of prostate tissue by fluorescence spectroscopy</td>
<td>07/01/2016</td>
<td>T</td>
<td>5373</td>
<td></td>
</tr>
<tr>
<td>0444T</td>
<td>Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral</td>
<td>07/01/2016</td>
<td>N</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>0445T</td>
<td>Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral</td>
<td>07/01/2016</td>
<td>N</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>C9743</td>
<td>Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)</td>
<td>10/01/2015</td>
<td>06/30/2016</td>
<td>T</td>
<td>5374</td>
</tr>
</tbody>
</table>
Drugs, Biologicals, and Radiopharmaceuticals

1. **Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective July 1, 2016**
   
   For CY 2016, payment for both nonpass-through, and 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 of these items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis, as later quarter ASP submissions become available. Updated payment rates effective July 1, 2016, and drug price restatements are available in the July 2016 update of the OPPS Addendum A and Addendum B at [http://www.cms.gov/HospitalOutpatientPPS/](http://www.cms.gov/HospitalOutpatientPPS/).

2. **Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates**
   
   Some drugs and biologicals paid based on the ASP methodology will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the first date of the quarter at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html).

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

3. **Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2016**
   
   Five drugs and biologicals have been granted OPPS pass-through status, effective July 1, 2016. These items, along with their descriptors and APC assignments, are identified in Table 3.

   **Table 3 – Drugs and Biologicals with OPPS Pass-Through Status Effective July 1, 2016**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9476</td>
<td>Injection, daratumumab, 10 mg</td>
<td>G</td>
<td>9476</td>
</tr>
<tr>
<td>C9477</td>
<td>Injection, elotuzumab, 1 mg</td>
<td>G</td>
<td>9477</td>
</tr>
<tr>
<td>C9478</td>
<td>Injection, sebelipase alfa, 1 mg</td>
<td>G</td>
<td>9478</td>
</tr>
<tr>
<td>C9479*</td>
<td>Instillation, ciprofloxacin otic suspension, 6 mg</td>
<td>G</td>
<td>9479</td>
</tr>
<tr>
<td>C9480</td>
<td>Injection, trabectedin, 0.1 mg</td>
<td>G</td>
<td>9480</td>
</tr>
</tbody>
</table>

   *Note on reporting C9479: Each vial of C9479 contains 60 mg, or 10 doses. If one single use vial is used for both patient’s ears with the remainder of the drug in the vial unused, then two units of C9479 should be reported as administered to the patient; any discarded amount should be reported with the JW modifier according to the “Medicare Claims Processing Manual,” Chapter 17 - Drugs and Biologicals, Section 40 - Discarded Drugs and Biologicals.

4. **New Drug HCPCS Code**
   
   Effective July 1, 2016, one new HCPCS code has been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available. This new code is listed in Table 4.

   **Table 4 – New Drug HCPCS Codes Effective July 1, 2016**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>SI</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q9981</td>
<td>rolapitant, oral, 1mg</td>
<td>Rolapitant, oral, 1 mg</td>
<td>K</td>
<td>1761</td>
</tr>
</tbody>
</table>

5. **Biosimilar Biological Product Payment and Required Modifiers**
   
   As a reminder, OPPS claims for separately paid biosimilar biological products are required to include a modifier that identifies the manufacturer of the specific product. The modifier does not affect payment determination, but is used to distinguish between biosimilar products that appear in the same HCPCS code but are made by different manufacturers.

   On April 5, 2016, the second biosimilar biological product, Inflectra®, was approved by the FDA. Table 5 lists the biosimilar HCPCS codes and required modifiers.
Table 5 – Biosimilar Biological Product Payment and Required Modifiers

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

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

One existing skin substitute product has been reassigned from the low cost skin substitute group to the high cost skin substitute group based on updated pricing information. This product is listed in Table 6.

Table 6 – Reassignment of Skin Substitute Product from the Low Cost Group to the High Cost Group Effective July 1, 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Status Indicator</th>
<th>Low/High Cost Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4164</td>
<td>Helicoll, per square cm</td>
<td>N</td>
<td>High</td>
</tr>
</tbody>
</table>

7. Other Changes to CY 2016 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals

Effective July 1, 2016, HCPCS code Q9982, flutemetamol f18 diagnostic, will replace HCPCS code C9459, Flutemetamol F18. The SI will remain G, “Pass-Through Drugs and Biologicals.”

Effective July 1, 2016, HCPCS code Q9983, florbetaben f18 diagnostic, will replace HCPCS code C9458, Florbetaben F18. The SI will remain G, “Pass-Through Drugs and Biologicals.”

Table 7 describes the HCPCS codes changes and effective dates.

Table 7 – Other Changes to CY 2016 HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective July 1, 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>Status Indicator</th>
<th>APC</th>
<th>Added Date</th>
<th>Termination Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9459</td>
<td>Flutemetamol f18</td>
<td>Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries</td>
<td>G</td>
<td>9459</td>
<td>01/01/2016</td>
<td>06/30/2016</td>
</tr>
<tr>
<td>Q9982</td>
<td>flutemetamol f18 diagnostic</td>
<td>Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries</td>
<td>G</td>
<td>9459</td>
<td>07/01/2016</td>
<td></td>
</tr>
<tr>
<td>C9458</td>
<td>Florbetaben f18</td>
<td>Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries</td>
<td>G</td>
<td>9458</td>
<td>01/01/2016</td>
<td>06/30/2016</td>
</tr>
<tr>
<td>Q9983</td>
<td>florbetaben f18 diagnostic</td>
<td>Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries</td>
<td>G</td>
<td>9458</td>
<td>07/01/2016</td>
<td></td>
</tr>
</tbody>
</table>
8. **Changes to OPPS Pricer Logic**

   Effective July 1, 2016, there will be four diagnostic radiopharmaceuticals (2 with new Q-codes replacing the previously used C-codes (as described above in the immediately preceding section g.)) and one contrast agent receiving pass-through payment in the OPPS Pricer logic. For APCs containing nuclear medicine procedures, Pricer will reduce the amount of the pass-through diagnostic radiopharmaceutical or contrast agent payment by the wage-adjusted offset for the APC with the highest offset amount when the radiopharmaceutical or contrast agent with pass-through appears on a claim with a nuclear procedure. The offset will cease to apply when the diagnostic radiopharmaceutical or contrast agent expires from pass-through status. The offset amounts for diagnostic radiopharmaceuticals and contrast agents are the “policy-packaged” portions of the CY 2016 APC payments for nuclear medicine procedures and are on the CMS website.

**Addition of C1713 and C1817 to the List of Devices Allowed for the Device Intensive Procedure Edit**

CMS will be adding C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) and C1817 (Septal defect implant system, intracardiac) to the list of devices allowed for the device intensive procedure edit in the July 2016 release, and will make it retroactive to January 2016.

**Coverage Determinations**

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

Please note that your MACs will adjust, as appropriate, claims brought to their attention with any retroactive changes that were received prior to implementation of July 2016 OPPS Pricer.

**Additional Information**


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**REIMBURSEMENT**

**MPFSDB – July 2016 Quarterly Update**

MLN Matters® Number: MM9633
Related Change Request (CR) #: CR 9633
Related CR Release Date: May 20, 2016
Effective Date: January 1, 2016
Related CR Transmittal #: R3528CP
Implementation Date: July 5, 2016

**Provider Types Affected**

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

**Provider Action Needed**

Change Request (CR) 9633 amends payment files that were issued to your MAC based upon the CY 2016 Medicare Physician Fee Schedule (MPFS) Final Rule published in the Federal Register on November 16, 2015. These payment files are to be effective for services furnished between January 1, 2016, and December 31, 2016. Make sure your billing staff is aware of these changes.
Background
Section 1848(c)(4) of the Social Security Act authorizes the Secretary to establish ancillary policies necessary to implement relative values for physicians’ services.

Key Changes in CR9633
Unless otherwise stated, the changes included in the July update to the 2016 MPFSDB are effective for dates of service on and after January 1, 2016.

The key changes for the July update, effective as of January 1, 2016, are as follows.

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0296</td>
<td>Multiple Surgery = 0; Diagnostic Imaging Family Indicator = 99</td>
</tr>
<tr>
<td>G9678</td>
<td>Procedure Status = C (Effective for services on or after 7-1-2016.)</td>
</tr>
<tr>
<td>10036</td>
<td>Multiple Surgery Indicator = 0</td>
</tr>
<tr>
<td>37188</td>
<td>Multiple Surgery Indicator = 0</td>
</tr>
<tr>
<td>45346</td>
<td>Endo Base Code = 45330</td>
</tr>
<tr>
<td>61651</td>
<td>Multiple Surgery Indicator = 0</td>
</tr>
<tr>
<td>65855</td>
<td>Bilateral Indicator = 1</td>
</tr>
<tr>
<td>69209</td>
<td>PC/TC indicator = 3</td>
</tr>
</tbody>
</table>

The following new codes in CR9636 have also been added to the MPFSDB.

<table>
<thead>
<tr>
<th>CPT/HCPCS Code</th>
<th>Short Descriptor</th>
<th>Procedure Status</th>
<th>RVU</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q5102</td>
<td>Inj., infliximab biosimilar</td>
<td>E</td>
<td>no RVUs</td>
<td>4-5-16</td>
</tr>
<tr>
<td>Q9981</td>
<td>rolapitant, oral, 1mg</td>
<td>E</td>
<td>no RVUs</td>
<td>7-1-16</td>
</tr>
<tr>
<td>Q9982</td>
<td>flutemetamol f18 diagnostic</td>
<td>E</td>
<td>no RVUs</td>
<td>7-1-16</td>
</tr>
<tr>
<td>Q9983</td>
<td>florbetaben f18 diagnostic</td>
<td>E</td>
<td>no RVUs</td>
<td>7-1-16</td>
</tr>
</tbody>
</table>


CPT Codes effective on or after July 1, 2016
The new CPT Category III codes listed below have been added to the MPFSDB effective for dates of service on and after July 1, 2016.

There are no RVUs for these codes, and the following payment policy indicators are the same for each code: Procedure Status = C, Multiple Surgery = 0, Bilateral Surgery = 0, Assistant at Surgery = 0, Co-Surgeons = 0, Team Surgeons = 0, PC/TC = 0, Physician Supervision of Diagnostic Procedures = 09, and Diagnostic Imaging Family = 99. The Global Surgery Days for 0437T, 0439T, and 0443T = ZZZ; the rest are YYY.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0437T</td>
<td>Impltj synth mfcmt abdl wal</td>
<td>Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0438T</td>
<td>Tprnl plmt biodegrdabl mtrl</td>
<td>Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance</td>
</tr>
</tbody>
</table>
### CPT Code | Short Descriptor | Long Descriptor
--- | --- | ---
0439T | Myocrd contrast prfuj echo | Myocardial contrast perfusion echocardiography; at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to code for primary procedure)
0440T | Abltj perc uxttr/perph nrv | Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve
0441T | Abltj perc lxtr/perph nrv | Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
0442T | Abltj perc plex/trncl nrv | Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)
0443T | R-t spctrl alys prst8 tiss | Real time spectral analysis of prostate tissue by fluorescence spectroscopy
0444T | 1st plmt drug elut oc ins | Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral
0445T | Sbsqt plmt drug elut oc ins | Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral

MACs will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, they will adjust claims brought to their attention.

### Additional Information

### DMEPOS Fee Schedule – July 2016 Quarterly Update

**MLN Matters® Number:** MM9642  
**Related Change Request (CR) #:** CR 9642  
**Related CR Release Date:** June 23, 2016  
**Effective Date:** July 1, 2016  
**Related CR Transmittal #:** R3551CP  
**Implementation July 5, 2016**

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

### Provider Action Needed
Change Request (CR) 9642 advises providers of fee schedule amounts for codes in effect on January 1, 2016, and July 1, 2016, for all other changes. The instructions include information on the data files, update factors and other information related to the update of the fee schedule. Make sure your billing staffs are aware of these updates.
Background
The Centers for Medicare & Medicaid Services (CMS) updates the DMEPOS fee schedules on a quarterly basis, when necessary, in order to implement fee schedule amounts for new and existing codes, as applicable, and apply changes in payment policies. The quarterly update process for the DMEPOS fee schedule is located in the “Medicare Claims Processing Manual,” Chapter 23, Section 60 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf).

Payment on a fee schedule basis is required by the Social Security Act (the Act) for Durable Medical Equipment (DME), prosthetic devices, orthotics, prosthetics, and surgical dressings. Also, payment on a fee schedule basis is a regulatory requirement at 42 CFR Section 414.102, for Parenteral and Enteral Nutrition (PEN), splints, casts and Intraocular Lenses (IOLs) inserted in a physician’s office. The Act mandates adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas for the items, based on information from Competitive Bidding Programs (CBPs) for DME. The CBP product categories, HCPCS codes and Single Payment Amounts (SPAs) included in each Round of the CBP are available on the Competitive Bidding Implementation Contractor (CBIC) website (http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home). The changes for the Calendar Year (CY) 2016 are detailed in MM9431.

Adjusted Fee Schedule Amounts
The DMEPOS and PEN fee schedule files contain HCPCS codes that are subject to the adjusted fee schedule amounts as well as codes that are not subject to the fee schedule CBP adjustments. The adjustments to the fee schedule amounts have been phased in for claims with dates of service January 1, 2016, through June 30, 2016, so that each fee schedule amount is based on a blend of 50 percent of the fee schedule amount that would have gone into effect on January 1, 2016, if not adjusted based on information from the CBP, and 50 percent of the adjusted fee schedule amount. As part of this update, for claims with dates of service on or after July 1, 2016, the July quarterly update files include the fee schedule amounts based on 100 percent of the adjusted fee schedule amounts. Information from CBPs that take effect on July 1, 2016 is factored into the adjusted fee schedule amounts effective on July 1, 2016, in accordance with the regulations at 42 CFR 414.210(g)(8).

Fee schedule amounts that are adjusted using information from CBPs will not be subject to the annual DMEPOS covered item update, but will be updated in accordance with 42 CFR 414.210(g)(8) when information from the CBPs is updated. Pursuant to 42 CFR §414.210(g)(4), for items where the Single Payment Amounts (SPAs) from CBPs no longer in effect are used to adjust fee schedule amounts, the SPAs will be increased by an inflation adjustment factor that corresponds to the year in which the adjustment would go into effect (for example, 2016 for this update) and for each subsequent year such as 2017, and 2018.

There are three general methodologies used in adjusting the fee schedule amounts:

1. Adjusted Fee Schedule Amounts for Areas Within the Contiguous United States

   The average of SPAs from CBPs located in eight different regions of the contiguous United States are used to adjust the fee schedule amounts for the states located in each of the eight regions. These regional SPAs (RSPAs) are also subject to a national ceiling (110% of the average of the RSPAs for all contiguous states plus the District of Columbia) and a national floor (90% of the average of the RSPAs for all contiguous states plus the District of Columbia). The methodology applies to enteral nutrition and most DME items furnished in the contiguous United States (those included in more than 10 Competitive Bidding Areas (CBAs)).

   Also, the fee schedule amounts for areas within the contiguous United States that are designated as rural areas are adjusted to equal the national ceiling amounts described above. Regulations at 42 CFR 414.202 define a rural area to be a geographical area represented by a postal ZIP code where at least 50 percent of the total geographical area of the ZIP code is estimated to be outside any Metropolitan Statistical Area (MSA). A rural area also includes any ZIP Code within an MSA that is excluded from a CBA established for that MSA.
2. **Adjusted Fee Schedule Amounts for Areas Outside the Contiguous United States**

   Areas outside the contiguous United States (areas such as Alaska, Guam, Hawaii) receive adjusted fee schedule amounts so that they are equal to the higher of the average of SPAs for CBAs in areas outside the contiguous United States (currently only applicable to Honolulu, Hawaii) or the national ceiling amounts described above and calculated based on SPAs for areas within the contiguous United States.

3. **Adjusted Fee Schedule Amounts for Items Included in 10 or Fewer CBAs**

   DME items included in 10 or fewer CBAs receive adjusted fee schedule amounts so that they are equal to 110 percent of the average of the SPAs for the 10 or fewer CBAs. This methodology applies to all areas, non-contiguous and contiguous.

   In order to apply the rural payment rule for areas within the contiguous United States, the DMEPOS fee schedule file is updated to include rural payment amounts for certain HCPCS codes where the adjustment methodology is based on average regional SPAs. Also, on the PEN file, the national fee schedule amounts for enteral nutrition transitions to statewide fee schedule amounts. For parenteral nutrition, the national fee schedule amount methodology remains unchanged.

   The ZIP code associated with the address used for pricing a DMEPOS claim determines the rural fee schedule payment applicability for codes with rural and non-rural adjusted fee schedule amounts based on information from the CBPs. ZIP codes for non-contiguous areas are not included in the DMEPOS Rural ZIP code file. The DMEPOS Rural ZIP code file is updated on a quarterly basis as necessary.

**Key Points of CR9642**

**Public Use Files (PUFs)**

In October 2015, CMS posted sample 2016 DMEPOS and PEN Medicare payment PUFs that were modified to accommodate the adjusted fee schedule amounts effective January 1, 2016. At that time, CMS communicated that different PUF file formats would be used for the January 2016 Excel file update as opposed to the July 2016 update and all subsequent fee schedule updates. CMS has recently determined that it is necessary to retain separate rural fee fields for each state and not transition, beginning July 1, 2016, to one field titled "Contiguous United States Rural Fee" as previously communicated. Therefore, beginning with the July 2016 update, the July DMEPOS and PEN Excel PUF record layouts will retain the separate rural fees for each state as implemented January 1, 2016. As discussed above, the phase in of adjusted fees are based on 100 percent of the adjusted fee schedule amounts effective July 1, 2016. The rural fee for the contiguous United States, which is equal to the national ceiling amount, applies to all rural areas within the contiguous United States. However, in any case where the application of the adjusted fee methodology results in an increase in the fee schedule amount that would otherwise apply, the rural adjustment for an area/state is not made. Non-contiguous areas are not subject to rural fees under the CY 2016 DMEPOS fee schedule methodology.

The CY 2016 DMEPOS and PEN fee schedules and the July 2016 DMEPOS Rural ZIP code file PUFs will be available for State Medicaid Agencies, managed care organizations, and other interested parties shortly after the release of the data files at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched).

**KU Modifier for Complex Rehabilitative Power Wheelchair Accessories & Seat and Back Cushions**

Section 2 of the Patient Access and Medicare Protection Act (PAMPA) mandates that the adjustments to the CY 2016 fee schedule amounts for certain DME based on information from CBPs not be applied to wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with Group 3 complex rehabilitative power wheelchairs prior to January 1, 2017. Group 3 complex rehabilitative power wheelchair bases are currently described by codes K0848 through K0864 of the HCPCS.

As a result, the fees for wheelchair accessories and seat and back cushions denoted with the HCPCS modifier 'KU' are included in the July 2016 DMEPOS fee schedule file and are effective for dates of service January 1, 2016, through December 31, 2016. The fee schedule amounts associated with the KU modifier represent the unadjusted fee schedule amounts (the CY 2015 fee schedule amount updated by the 2016 DMEPOS covered item update factor of -0.4 percent) for these wheelchair accessory codes.
The codes for wheelchair accessories and seat and back cushions affected by this change along with claims processing instructions are available in CR9520 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3535CP.pdf. In accordance with that article, if brought to their attention, MACs may adjust claims for the Group 3 complex rehabilitative power wheelchair accessories referenced in Attachment A of related CR9520 for dates of service January 1, 2016, through June 30, 2016.

**Discontinuation of KE Modifier for Items in Initial Round 1 CBP**

As part of this update, the fees for certain items included in Round 1 CBP, denoted with the HCPCS pricing modifier ‘KE’, are deleted from the DMEPOS fee schedule file. Program instructions on the implementation of these fees and the list of applicable HCPCS codes were issued via CR6720, dated November 7, 2008 (see related article MM6720).

The KE fees were retained on the fee schedule file for dates of service January 1, 2016, through June 30, 2016, because of the phase-in of the adjusted fee schedule amounts, but are no longer needed.

**Reclassification of Certain DME Included in CBPs**

As part of this update, capped rental fees are established for payment of the following 14 HCPCS codes: E0197, E0140, E0149, E0985, E1020, E1028, E2228, E2368, E2369, E2370, E2375, K0015, K0070, and E0955.

For dates of service on or after July 1, 2016, these HCPCS codes are reclassified from the payment category for inexpensive and routinely purchased DME to payment on a capped rental basis in all areas except the 9 Round 1 Re-compete (Round 1 2014) CBAs. These changes are made to align the payment with the regulatory definition of routinely purchased equipment. Articles MM8822 and MM8566 discuss these program instructions.

When submitting claims, suppliers in areas outside of Round 1 Re-compete CBAs that furnish these 14 HCPCS codes on a capped rental basis use the capped rental modifiers KH, KI, and KJ as appropriate. Beginning January 1, 2017, payment for these codes in all geographic areas will be made on a capped rental basis.

Also, certain HCPCS codes for wheelchair options/accessories (E1020, E1028, E2368, E2369, E2370, E2375, K0015, and E0955) that are furnished to be used as part of a complex rehabilitative power wheelchair (wheelchair base codes K0835 – K0864) can be paid under the associated lump sum purchase option set forth in article MM8566.

The supplier must give the beneficiary the option of purchasing these accessories at the time they are furnished for initial or replacement. If the beneficiary declines the purchase option, the supplier must furnish the items on a capped rental basis and payment shall be made on a monthly rental basis in accordance with the capped rental payment rules.

**Diabetic Testing Supplies (DTS)**

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

As part of the this update, the non-mail order payment amounts on the fee schedule file for the above codes will be updated, effective July 1, 2016, using the SPAs established under the National Mail-Order Re-compete CBP.

As part of this update, the DTS mail order (with KL modifier) fee schedules for all states and territories are removed from the DMEPOS fee schedule file. The SPAs calculated under the National Mail-Order CBPs replace the mail order fee schedule amounts for diabetic testing supply codes listed above. The SPAs are available at http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.

The Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order competitive bidding program. However, in accordance with Section 42 Code of Federal Regulations (CFR) 414.210(g) (7), the fee schedule amounts for mail order DTS furnished in the Northern Mariana Islands are adjusted to equal 100 percent of the SPAs established under the national mail-order competitive bidding program (79 FR 66232).
Because the Northern Mariana Islands adjustment is subject to the 6-month transition phase-in period, the adjusted Northern Mariana Island DTS mail order fees, which were based on 50 percent of the un-adjusted mail order fee schedule amounts and 50 percent of the adjusted mail order SPAs, were provided on the DMEPOS fee schedule file in the Hawaii column of the 8 mail-order (KL) DTS codes listed above for dates of service January 1, 2016, through June 30, 2016.

Beginning July 1, 2016, the fully adjusted mail order fees (the SPAs) will apply for mail order DTS furnished in the Northern Mariana Islands. As part of this update, the Northern Mariana Island DTS transition mail-order payment amounts will no longer appear in the Hawaii column of the fee schedule file and the DTS mail order (KL) fee schedules for all states and territories are removed from the DMEPOS fee schedule file as of July 1, 2016.

**Specific Coding and Pricing Issues**

As part of this update, fees are established for HCPCS codes A6450 and A6451 which were added to the HCPCS file in CY 2004. Claims for codes A6450 and A6451 with dates of service on or after January 1, 2016, that have already been processed may be adjusted to reflect the newly established fees if brought to your MAC’s attention.

**Additional Information**


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**Reporting Principal and Interest Amounts When Refunding Previously Recouped Money on the Remittance Advice (RA) – Revised**

*MLN Matters® Number: MM9168 Revised*
*Related Change Request (CR) #: CR 9168*
*Related CR Release Date: March 24, 2016*
*Effective Date: July 1, 2016*
*Related CR Transmittal #: R1639OTN*
*Implementation Date: July 5, 2016*

This article was revised on April 19, 2016, to reflect the revised CR9168 issued on March 24. In the article, the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

**Provider Types Affected**

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

**Provider Action Needed**

Change Request (CR) 9168 explains to providers who received a favorable appeals decision that it will be easier and consequently more transparent to identify the claim and/or the refund of principal and interest paid by Medicare. Your MAC will make sure that the remittance advices are reporting the refunded principal and interest amounts separately, and provide individual claim information. CR9168 applies to electronic remittance advice (ERA) only.

**Background**

Currently reporting of refunded principal and interest amounts for all related claims on the Remittance Advice (RA) is shown as one lump sum amount. This practice creates problems for the provider community as this is not conducive to posting payment properly. Providers have the money but are not able to identify the claim and/or the refund of principal and interest paid by Medicare.
CR9168 instructs MACs to report the principal and interest separately, and also to provide individual claim information. Specifically, the reporting will be in the Provider Level Balance (PLB) segment of the 835 with an example as follows:

**PLB Details - Reporting Principal Refunds**

- **PLB03-1:** WW to report overpayment recovery (negative sign for the amount in PLB04) being refunded
- **PLB03-2 Positions 1 – 25:** Account Payable (AP) Invoice Number
- **PLB03-2 Positions 26 – 50:** Claim Adjustment Account Receivable (AR) number
- **PLB 04:** Refund Amount (Principal Refund Amount)

**PLB Details - Reporting Interest Refunds**

- **PLB03-2 Positions 1 – 25:** AP Invoice Number
- **PLB03-2 Positions 26 – 50:** Claim Adjustment AR number
- **PLB04:** Interest Amount on Refund

**Additional Information**


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**UPDATES**

**RARC, CARC, MREP, and PC Print Update**

MLN Matters® Number: MM9466  
Related Change Request (CR) #: CR 9466  
Related CR Release Date: April 1, 2016  
Effective Date: July 1, 2016  
Related CR Transmittal #: R3489CP  
Implementation Date: July 5, 2016

**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**

CR9466 updates the Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Code (RARC) lists. It also instructs Medicare system maintainers to update Medicare Remit Easy Print (MREP) and PC Print. Make sure that your billing staffs are aware of these changes and obtain the updated MREP or PC Print software if they use that software.

**Background**

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

The Centers for Medicare & Medicaid Services (CMS) instructs MACs and Shared Systems, if appropriate, to conduct updates based on the code update schedule that results in publication of updated code lists three times a year (around March 1, July 1, and November 1).
Medicare’s Shared System Maintainers (SSMs) are responsible for implementing appropriate code deactivation, making sure that any deactivated code is not used in original business messages, but the deactivated code in derivative messages is allowed. SSMs must make sure that Medicare does not report any deactivated code on or before the effective date for deactivation as posted on the Washington Publishing Company (WPC) website. If any new or modified code has an effective date past the implementation date specified in CR9466, MACs will implement on the date specified on the WPC website. The WPC website is available at http://www.wpc-edi.com/Reference on the Internet.

In case of any discrepancy in the code text as posted on WPC website and as reported in any CR, the WPC version should be implemented.

CR9466 advises the SSMs and MACs to perform the updates posted on the WPC based on the March 1, 2016 CARC and RARC code change lists.

Additional Information

Claim Status Category and Claim Status Codes Update
MLN Matters® Number: MM9550
Related Change Request (CR) #: CR 9550
Related CR Release Date: May 20, 2016
Effective Date: October 1, 2016
Related CR Transmittal #: R3527CP
Implementation Date: October 3, 2016

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) 9550 informs MACs about the changes to Claim Status Category Codes and Claim Status Codes. Make sure that your billing staffs are aware of these changes.

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

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


Included in the code lists are specific details, including the date when a code was added, changed, or deleted.

All code changes approved during the June 2016 committee meeting will be posted on the above mentioned websites on or about July 1, 2016.
The Centers for Medicare & Medicaid Services (CMS) will issue future CRs regarding the need for future updates to these codes. These code changes are to be used in editing of all ASC X12 276 transactions processed on or after the date of implementation and to be reflected in the ASC X12 277 transactions issued on and after the date of implementation of CR9550.

Additional Information

Updates to Pub. 100-04, Chapters 1 and 16 to Correct Remittance Advice Messages
MLN Matters® Number: MM9578
Related Change Request (CR) #: CR 9578
Related CR Release Date: April 29, 2016
Effective Date: October 1, 2016
Related CR Transmittal #: R3510CP
Implementation Date: October 3, 2016

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

Provider Action Needed
If Change Request (CR) 9578 updates Chapter 1 and Chapter 16 of the “Medicare Claims Processing Manual” to reflect the standard format and to correct any non-compliant remittance advice code combinations. Make sure that your billing staffs are aware of the corrected code combinations.

Background
Section 1171 of the Social Security Act requires a standard set of operating rules to regulate the health insurance industry’s use of Electronic Data Interchange (EDI) transactions. Operating Rule 360: Uniform Use of CARCs and RARCs, regulates the way in which group codes, Claims Adjustment Reason Codes (CARCs), and Remittance Advice Remark Codes (RARCs) may be used. The rule requires specific codes which are to be used in combination with one another if one of the named business scenarios applies. This rule is authored by the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE).

Medicare and all other payers must comply with the CAQH CORE-developed code combinations. The business scenario for each payment adjustment must be defined, if applicable, and a valid code combination selected for all remittance advice messages.

CR9578 makes the following code revisions:
1. When a MAC rejects an out of jurisdiction professional claim as unprocessable, the following codes are used:
   • Group Code of CO
   • CARC 109, and
   • RARC N104
2. When a MAC rejects misdirected Railroad Retirement Board claims as unprocessable, the following codes are used:
   • Group Code of CO
   • CARC 109, and
   • RARC N105
3. When a MAC rejects misdirected United Mine Workers Association claims as unprocessable, the following codes are used:
   - Group Code CO
   - CARC 109, and
   - RARC N127

4. In the above 3 situations, RARC MA130 was used previously, but will no longer be used in these situations.

Additional Information

Update to Internet-Only-Manual Publication 100-04, Chapter 18, Section 30.6
MLN Matters® Number: MM9606
Related Change Request (CR) #: CR 9606
Related CR Release Date: May 13, 2016
Effective Date: June 14, 2016
Related CR Transmittal #: R3522CP
Implementation Date: June 14, 2016

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

Provider Action Needed
CR9606 advises the MACs of an update to the “Medicare Claims Processing Manual,” Chapter 18, Section 30.6. CR9606 updates the manual by replacing an incorrect diagnosis code for screening of cervical cancer with HPV testing. The manual shows an incorrect ICD-10 code of Z12.92 and the correct ICD-10 code is Z12.72 (encounter for screening for malignant neoplasm of the vagina). Make sure that your billing staffs are aware of this change.

Additional Information
The official instruction, CR9606, issued to your MAC regarding this change, is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3522CP.pdf. The updated manual section is attached to the CR.
Pub. 100-02, Chapter 11 ESRD - 2016 Update

MLN Matters® Number: MM9541
Related Change Request (CR) #: CR 9541
Related CR Release Date: June 3, 2016
Effective Date: January 1, 2016
Related CR Transmittal #: R224BP
Implementation Date: September 6, 2016

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

What You Need to Know
Change Request (CR) 9541 updates Chapter 11 of the “Medicare Benefit Policy Manual” to reflect the provisions in the Calendar Year (CY) 2016 ESRD Prospective Payment System (PPS) final rule. There are no new coverage policies, payment policies, or codes introduced in CR9541. Specific policy changes and related business requirements were addressed in CR9367, as discussed in MLN Matters article MM9367.

Background
The End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) provides a single payment to ESRD facilities, that is, hospital-based and freestanding facilities, that cover all the resources used in providing an outpatient dialysis treatment. This includes supplies and equipment used to administer dialysis in the ESRD facility or at a patient’s home, drugs, biologicals, laboratory tests, training, and support services.

The ESRD PPS base rate is adjusted for patient-level case mix and facility-level characteristics. For CY 2016, in accordance with the American Taxpayers Relief Act of 2012 (ATRA; Section 632(c)), The Centers for Medicare & Medicaid Services (CMS) analyzed the case-mix payment adjustments using more recent data.

CMS revised the adjustments by changing the adjustment payment amounts based on an updated regression analysis using Calendar Years (CYs) 2012 and 2013 ESRD claims and cost report data. CMS also removed two comorbidity payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because the updated regression analysis conducted enabled CMS to analyze and revise the case-mix payment adjustments, CMS also revised the low-volume payment adjustment and implemented a payment adjustment for rural ESRD facilities.

For CY 2016, in accordance with the Protecting Access to Medicare Act of 2014 (PAMA) (Section 217(c)), CMS finalized a drug designation process for:
1. Determining when a product would no longer be considered an oral-only drug; and
2. Including new injectable and intravenous products into the bundled payment under the ESRD PPS.

Updates to the “Medicare Benefit Policy Manual”
The key clarifications/updates to the “Medicare Benefit Policy Manual” are as follows:

Section 20.2
To the extent a laboratory test is performed to monitor the levels or effects of any of the drugs that were specifically excluded from the ESRD PPS, these tests would be separately billable. The following table lists the drug categories that were excluded from the ESRD PPS and the rationale for their exclusion. Laboratory services furnished to monitor the medication levels or effects of drugs and biologicals that fall in those categories would not be considered to be furnished for the treatment of ESRD.
**DRUG CATEGORIES EXCLUDED FROM THE ESRD PPS BASE RATE FOR THE PURPOSE OF REPORTING LABS**

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Rationale for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulant</td>
<td>Drugs labeled for non-renal dialysis conditions and not for vascular access.</td>
</tr>
<tr>
<td>Antidiuretic</td>
<td>Used to prevent fluid loss.</td>
</tr>
<tr>
<td>Antiepileptic</td>
<td>Used to prevent seizures.</td>
</tr>
<tr>
<td>Anti-inflammatory</td>
<td>May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Used to treat psychosis.</td>
</tr>
<tr>
<td>Antiviral</td>
<td>Used to treat viral conditions such as shingles.</td>
</tr>
<tr>
<td>Cancer management</td>
<td>Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.</td>
</tr>
<tr>
<td>Cardiac management</td>
<td>Drugs that manage blood pressure and cardiac conditions.</td>
</tr>
<tr>
<td>Cartilage</td>
<td>Used to replace synovial fluid in a joint space.</td>
</tr>
<tr>
<td>Coagulants</td>
<td>Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency</td>
</tr>
<tr>
<td>Cytoprotective agents</td>
<td>Used after chemotherapy treatment</td>
</tr>
<tr>
<td>Endocrine/metabolic management</td>
<td>Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia</td>
</tr>
<tr>
<td>Erectile dysfunction management</td>
<td>Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction.</td>
</tr>
<tr>
<td>Gastrointestinal management</td>
<td>Used to treat gastrointestinal conditions such as ulcers and gallbladder disease</td>
</tr>
<tr>
<td>Immune system management</td>
<td>Anti-rejection drugs covered under a separate benefit category.</td>
</tr>
<tr>
<td>Migraine management</td>
<td>Used to treat migraine headaches and symptoms</td>
</tr>
<tr>
<td>Musculoskeletal management</td>
<td>Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions</td>
</tr>
<tr>
<td>Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs</td>
<td>Not a function performed by an ESRD facility</td>
</tr>
<tr>
<td>Pulmonary system management</td>
<td>Used for respiratory/lung conditions such as opening airways and newborn apnea</td>
</tr>
<tr>
<td>Radiopharmaceutical procedures</td>
<td>Includes contrasts and procedure preparation</td>
</tr>
<tr>
<td>Unclassified drugs</td>
<td>Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Covered under a separate benefit category</td>
</tr>
</tbody>
</table>

Also, effective January 1, 2016, the lipid panel is no longer considered to be a renal dialysis service. However, if the panel is furnished for the treatment of ESRD it is the responsibility of the ESRD facility and should be reported on the facility’s claim.
**Section 20.3**

The ESRD PPS functional category is a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. The Drug Designation Process is dependent on the functional categories, as discussed in Section 20.3.1., below in this article.

Drugs and biologicals always considered to be renal dialysis services are those used for access management, anemia management, bone and mineral metabolism management, and cellular management. ESRD facilities are responsible for furnishing these drugs directly or under arrangement. This includes any drug or biological that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility.

Erythropoiesis Stimulating Agents (ESAs), such as epoetin alfa (EPOGEN®) and darbepoetin alfa (ARANESP®) when furnished to Medicare ESRD patients are always considered to be renal dialysis services and included in the ESRD PPS. Monthly dosages of these ESAs are subject to Medicare’s ESA claims monitoring policy. See the “Medicare Claims Processing Manual,” Chapter 8, Section 60.4.1 for more information on the ESA monitoring policy.

ESA dose edits are applied prior to pricing so that ESAs are not overvalued in determining eligibility for outlier payments.

Drugs and biologicals included in the ESRD PPS base rate that may be used for both the treatment of ESRD and for reasons other than the treatment of ESRD are those used as antiemetics, anti-infectives, antipruritics, anxiolytics, excess fluid management, fluid and electrolyte management including volume expanders, and pain management. ESRD facilities are responsible for furnishing these drugs directly or under arrangement when they are prescribed for the treatment of ESRD. This includes any drug or biological that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility.

ESRD facilities are responsible for furnishing antibiotics for access site infections directly or under arrangement. When antibiotics are used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis, the antibiotics are included in the ESRD PPS and may not be paid separately. This includes antibiotics that may be added to a patient’s dialysate solution for the purposes of vascular access-related and peritonitis infections.

Any other drugs (other than those categories described above and below) when used for the treatment of ESRD are also included in the ESRD PPS. For example,

- Patient A experiences nausea or pain during a hemodialysis dialysis treatment and requires medications. Any medication furnished during the dialysis treatment or after the treatment is considered a renal dialysis service and may not be billed separately.
- Patient B experiences anxiety with dialysis treatments and is prescribed anti-anxiety medication during and between the dialysis treatments. Any medications furnished in preparation for the dialysis treatment, during the dialysis treatment or after the dialysis treatment, is considered a renal dialysis service and may not be billed separately.
- Any drug or biological added to patient dialysate solutions.

**Functional Categories Included in the ESRD Base Rate but May be Used for Dialysis and Non-Dialysis Purposes**

<table>
<thead>
<tr>
<th>Category</th>
<th>Rationale for Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiemetic</td>
<td>Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category.</td>
</tr>
<tr>
<td>Anti-infectives</td>
<td>Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs.</td>
</tr>
<tr>
<td>Antipruritic</td>
<td>Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis.</td>
</tr>
<tr>
<td>Anxiolytic</td>
<td>Drugs in this classification have multiple actions. Use within an ESRD functional category includes treatment of restless leg syndrome related to dialysis.</td>
</tr>
</tbody>
</table>
### Category Rationale for Association

<table>
<thead>
<tr>
<th>Category</th>
<th>Rationale for Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess Fluid Management</td>
<td>Drug/fluids used to treat fluid excess/overload.</td>
</tr>
<tr>
<td>Fluid and Electrolyte Management Including Volume Expanders</td>
<td>Intravenous drugs/fluids used to treat fluid and electrolyte needs.</td>
</tr>
<tr>
<td>Pain Management</td>
<td>Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain.</td>
</tr>
</tbody>
</table>

Oral-only forms of renal dialysis drugs and biologicals that have no other form of administration will be included in the ESRD PPS as a Part B renal dialysis service. Implementation of renal dialysis oral-only drugs has been delayed until January 1, 2025.

### Section 20.3.1 – Drug Designation Process

1. **Definition of a New Injectable or Intravenous Product**
   
   A new injectable or intravenous product is an injectable or intravenous product that is approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service.

2. **Determination**
   
   To make the determination as to whether a product is a new injectable or intravenous drug or biological; whether the new injectable or intravenous drug or biological is a renal dialysis service; and whether the new injectable or intravenous drug or biological fits into an existing functional category CMS will:
   
   - Review the new product’s FDA labeling data and information;
   - Review the new product’s information presented for obtaining a HCPCS code; and
   - Conduct an internal medical review following the announcement of the new product’s FDA and HCPCS decision.

   If a new injectable or intravenous drug is used to treat or manage a condition for which there is an ESRD PPS functional category, the new drug would be considered included in the ESRD PPS bundled payment and no separate payment is available. If the new injectable or intravenous drug is used to treat or manage a condition for which there is not an ESRD PPS functional category, the following steps occur:
   
   - The new injectable or intravenous drug or biological would be paid for using a transitional drug add-on payment adjustment;
   - At the next rulemaking opportunity, CMS would add a new functional category applicable to the new injectable or intravenous drug or biological being used in the treatment of ESRD;
   - The new injectable or intravenous product would be added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

3. **Transitional Drug Add-On Payment Adjustment**
   
   If the new injectable or intravenous drug or biological is used to treat or manage a condition for which there is not an ESRD PPS functional category, CMS will pay for the drug or biological using a transitional drug add-on payment adjustment. The transitional drug add-on payment is based on payment methodologies under Section 1847A and would continue for a period of 2 years. During the time that injectable or intravenous drugs and biologicals are paid the transitional drug add-on payment adjustment, the drug or biological is not considered an outlier service.
4. **Determination of When an Oral-Only Renal Dialysis Service Drug or Biological is No Longer Oral-Only**

An oral-only renal dialysis service drug or biological is a drug or biological with no injectable equivalent or other form of administration other than an oral form. An oral-only renal dialysis service drug or biological is no longer considered oral-only when a non-oral version of the oral-only drug or biological is approved by the FDA.

**Section 60**

Based on the refinement of the ESRD PPS, effective January 1, 2016, adult case-mix payment adjustments are made for four comorbidity categories (two acute and two chronic) as discussed in detail in the revised section 60, which also includes detailed examples. The revised Section 60 is included as part of CR9541 and the Web address for accessing the CR is in the Additional Information section of this article.

In addition, the revised Section 60 shows that beginning January 1, 2016, the ESRD PPS provides a 1.008 percent payment adjustment for ESRD facilities located in a rural Core Based Statistical Area.

**Additional Information**


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**Medicare’s Organ Acquisition and Donation Payment Policy – Update**

**MLN Matters® Number: SE1608**

**Provider Types Affected**

This MLN Matters® Special Edition article is intended for all providers and suppliers who submit claims or Medicare cost reports (MCRs) to Medicare Administrative Contractors (MACs) for organ procurement, transplant, and histocompatibility laboratory services provided to Medicare beneficiaries.

**What You Need to Know**

This article is intended to assist providers and suppliers by offering information and resources to clarify Medicare’s organ acquisition and donation payment policy for organ procurement, transplant, and histocompatibility laboratory services provided to Medicare beneficiaries. The information does not convey any new or changed policy, but conveys clarification language in the “Provider Reimbursement Manual (PRM),” CMS Pub. 15-1, chapter 31. This clarification is provided to ensure appropriate reporting of organ acquisition costs, including those in a living Kidney Paired Donation (KPD) exchange, to achieve proper Medicare reimbursement.

**Background**

CMS issued chapter 31 of the PRM to clarify Medicare’s payment policy regarding organ acquisition costs, formerly found in chapter 27, sections 2770 through 2775.4. In response to questions raised by the transplant community, chapter 31 clarifies the accounting and reporting of KPD exchange costs in the MCR. The chapter also clarifies the appropriate methodology for counting organs.

- **Section 3106** clarifies the accounting for costs of services in a living KPD exchange, provides a detailed example of an exchange, and summarizes the example in a chart.
- **Section 3115** clarifies the methodology for counting organs, including those procured and transplanted en bloc.

**Highlights from Section 3106, Kidney Paired Donations**

- KPDs are similar to directed living donations; however, when the living donor and recipient do not match, they can consent to participate in a KPD matching program that matches living donor/recipient pairs with other living donor/recipient pairs. KPD exchanges can occur when two or more living donor/recipient pairs match each other; often, the living donor and matched recipient are at different certified transplant centers (CTCs).
The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the MCR of the recipient’s CTC. Similarly, when a recipient and donor do not match and elect to participate in a KPD matching program, the costs of the initial living donor evaluations are incurred by the original intended recipient’s CTC, regardless of whether the living donor actually donates to their original intended recipient, a KPD matched recipient, or does not donate at all.

In a KPD exchange, once the donor is matched with a recipient, any additional tests requested by the recipient’s CTC, but performed by the donor’s CTC are billed as charges reduced to cost to the recipient’s CTC and included as acquisition costs on the MCR of the recipient CTC. This is true regardless of whether an actual donation occurs.

When a donor’s CTC procures and sends a kidney to a recipient’s CTC, the donor’s CTC bills the recipient’s CTC the donor CTC’s charges reduced to cost for the reasonable costs associated with procuring, packaging, and transporting the kidney. The donor’s CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient’s CTC against its kidney acquisition costs. The recipient’s CTC records these costs as part of its kidney acquisition costs, the amounts billed by the donor’s CTC for the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor’s CTC. These costs must be reasonable and necessary.

When a donor’s CTC does not procure a kidney, but the donor travels to the recipient’s CTC for the procurement, the reasonable costs associated with the procurement are included on the MCR of the recipient’s CTC. Travel expenses of the living donor are not allowable Medicare costs.

**Highlights from Section 3115, Counting Organs**

Organ procurement organizations (OPOs) and CTCs are responsible for accurately counting both Medicare and non-Medicare organs to ensure that costs are properly allocated on the MCR. The OPO and CTC must count organs procured and transplanted en bloc (two organs transplanted as one unit) as one organ. This can include, but is not limited to, en bloc kidneys and en bloc lungs.

Medicare usable organs include organs transplanted into Medicare beneficiaries (excluding Medicare Advantage beneficiaries), organs that had partial payments by a primary insurance payer in addition to Medicare, organs sent to other CTCs, organs sent to OPOs and kidneys sent to military renal transplant centers (MRTCs) that have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor. Medicare usable organs do not include organs used for research, organs sent to veterans’ hospitals, organs sent outside the United States, organs transplanted into non-Medicare beneficiaries, organs that were totally paid by primary insurance other than Medicare, organs that were paid by a Medicare Advantage plan, organs procured from a non-certified OPO and kidneys sent to MRTCs that do not have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor.

Kidneys counted as Medicare kidneys include those sent to CTCs, certified OPOs, or MRTCs (with a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor). It does not include kidneys sent to foreign countries, VA hospitals, or MRTCs (without a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988, and approved by the contractor), or those used for research.

**Information and Resources**

The following resources are available to find additional information regarding Medicare’s organ acquisition and donation payment policy:

- PRM Transmittal 471 containing – CMS Pub. 15-1, chapter 31;
- PRM – CMS Pub. 15-2, chapters 33 and 40;
- “Medicare Claims Processing Manual” – CMS Pub. 100-04; and
RHCs HCPCS Reporting Requirement and Billing Updates

MLN Matters® Number: SE1611
Effective Date: October 1, 2016
Implementation Date: October 3, 2016

Provider Types Affected
This MLN Matters® Special Edition Article is intended for Rural Health Clinics (RHCs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed
This article provides information to assist RHCs in meeting the requirements to report the HCPCS code for each service furnished along with the revenue code on claims to Medicare effective for dates of service on or after April 1, 2016. Make sure your billing staff is aware of these instructions.

Background
From April 1, 2016, through September 30, 2016, all charges for a visit will continue to be reported on the service line with the qualifying visit HCPCS code, minus any charges for preventive services, using revenue code 052x for medical services and/or revenue code 0900 for mental health services. This guidance is available in MLN Matters Article MM9269 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9269.pdf. The RHC Qualifying Visit List (QVL) can be accessed on the RHC Center Page located at https://www.cms.gov/center/provider-type/rural-health-clinics-center.html.

In April 2016, CMS instructed RHCs to hold claims only for a billable visit shown in red on the RHC QVL until October 1, 2016. Upon billing these claims and/or for claim adjustments beginning on October 1, 2016, RHCs shall add modifier CG (policy criteria applied) to the line with all the charges subject to coinsurance and deductible. The subsequent paragraph explains modifier CG further.

Beginning on October 1, 2016, the MACs will accept modifier CG on RHC claims and claim adjustments. RHCs shall report modifier CG on one revenue code 052x and/or 0900 service line per day, which includes all charges subject to coinsurance and deductible for the visit. For RHCs, the coinsurance is 20 percent of the charges. Therefore, coinsurance and deductible will be based on the charges reported on the revenue code 052x and/or 0900 service line with modifier CG. RHCs will continue to be paid an all-inclusive rate (AIR) per visit.

Coinsurance and deductible are waived for the approved preventive health services in Table 1. When a preventive health service is the primary service for the visit, RHCs should report modifier CG on the revenue code 052x service line with the preventive health service. Medicare will pay 100% of the AIR for the preventive health service.

Table 1: Approved Preventive Health Services with Coinsurance and Deductible Waived

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0101</td>
<td>Ca screen; pelvic/breast exam</td>
</tr>
<tr>
<td>G0296</td>
<td>Visit to determ LDCT elig</td>
</tr>
<tr>
<td>G0402</td>
<td>Initial preventive exam</td>
</tr>
<tr>
<td>G0436</td>
<td>Tobacco-use counsel 3-10 min</td>
</tr>
<tr>
<td>G0437</td>
<td>Tobacco-use counsel &gt;10</td>
</tr>
<tr>
<td>G0438</td>
<td>Ppps, initial visit</td>
</tr>
<tr>
<td>G0439</td>
<td>Ppps, subseq visit</td>
</tr>
<tr>
<td>G0442</td>
<td>Annual alcohol screen 15 min</td>
</tr>
<tr>
<td>G0443</td>
<td>Brief alcohol misuse counsel</td>
</tr>
<tr>
<td>G0444</td>
<td>Depression screen annual</td>
</tr>
</tbody>
</table>
### UPDATES

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0445</td>
<td>High inten beh couns std 30 min</td>
</tr>
<tr>
<td>G0446</td>
<td>Intens behave ther cardio dx</td>
</tr>
<tr>
<td>G0447</td>
<td>Behavior counsel obesity 15 min</td>
</tr>
<tr>
<td>Q0091</td>
<td>Obtaining screen pap smear</td>
</tr>
</tbody>
</table>

Each additional service furnished during the visit should be reported with the most appropriate revenue code and charges greater to or equal to $0.01. The additional service lines are for informational purposes only. MACs will continue to package/bundle the additional service lines, which do not receive the AIR.

When the patient, subsequent to the first visit, suffers an illness or injury that requires additional diagnosis or treatment on the same day, the subsequent medical service should be billed using revenue code 052x and modifier 59. Beginning on October 1, 2016, RHCs can also report modifier 25 to indicate the subsequent visit was distinct or independent from an earlier visit furnished on the same day. When modifier 59 or modifier 25 is reported, RHCs will receive the AIR for an additional visit. This is the only circumstance in which modifier 59 or modifier 25 should be used.

Finally, note that the HCPCS reporting requirements have no impact in the way that telehealth or chronic care management services are reimbursed.