# Medicare Bulletin
## Jurisdiction 15

## KENTUCKY & OHIO

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Articles contained in this edition are current as of September 29, 2016.

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Stay Informed and Join the CGS ListServ Notification Service

The CGS Listserv Notification Service is the primary means used by CGS to communicate with Kentucky and Ohio Medicare Part B providers. The Listserv is a free email notification service that provides you with prompt notification of Medicare news including policy, benefits, claims submission, claims processing and educational events. Subscribing for this service means that you will receive information as soon as it is available, and plays a critical role in ensuring you are up-do-date on all Medicare information.

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Need help submitting an electronic claim through myCGS? Refer to the myCGS eClaims Job Aid at http://www.cgsmedicare.com/partb/mycgs/mycgs_eclaims_jobaid.pdf for navigation tips and screen shots. Transitioning from a paper biller to an electronic claim submitter has never been easier!
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Quarterly Provider Update

The Quarterly Provider Update is a comprehensive resource published by the Centers for Medicare & Medicaid Services (CMS) on the first business day of each quarter. It is a listing of all nonregulatory changes to Medicare including transmittals, 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.

To receive notification when regulations and program instructions are added throughout the quarter, go to https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/CMS-Quarterly-Provider-Updates-Email-Updates.html to sign up for the Quarterly Provider Update (electronic mailing list).

We encourage you to bookmark the Quarterly Provider Update website at https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/index.html and visit it often for this valuable information.

If you have any questions, please contact a CGS Customer Service Representative by calling the CGS Provider Contact Center at 1.866.276.9558 and choose Option 1.

Kentucky & Ohio

New and Retired Local Coverage Determinations (LCDs)

CGS Administrators, LLC has four new LCDs that will take effect in October 2016 and one LCD retiring in October 2016.

- **Application of Cellular and/or Tissue Based Products (CTPs) for Wounds of Lower Extremities L34053** will be retiring October 09, 2016. It will be replaced with a new LCD, **Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities L36690**, that will be effective October 10, 2016.
- **LCDs MolDX- CDD: ProMark Risk Score L36675 and MolDX-CDD: Decipher® Prostate Cancer Classifier Assay L36656** will be effective October 10, 2016.
- **Proton Beam therapy L36658** will be effective October 24, 2016.

All comments received were reviewed before the finalization of the LCDs and, if needed, updates were made accordingly. All LCDs will be posted by September 09, 2016, on the Future Kentucky Part B LCDs (https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=228&name=CGS%20Administrators,%20LLC%20(15102,%20MAC%20-%20Part%20B)&DocType=Future&DocStatus=Active&ContrVer=2&CntrctrSelected=228&s=22&bc=AggAAIAAAAAA%3d%3d) and the Future Ohio Part B LCDs (https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=238&name=CGS%20 Administrators,%20LLC%20(15102,%20MAC%20-%20Part%20B)&DocType=Future&DocStatus=Active&ContrVer=2&CntrctrSelected=238&s=22&bc=AggAAIAAAAAA%3d%3d)
Kentucky & Ohio

Comments received on Draft DL36658 Proton Beam Therapy

Below are the comments CGS received during the open comment period for Proton Beam Therapy L36658. The name of the policy was changed to Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities before the policy was finalized.

Comment 1: Commenter requests CGS to delay finalizing the draft policy for 6-12 months. This will allow time to gather data on patients treated since the claim volume is expected to be low.
Response: CGS plans to move ahead with finalizing the draft policy. As new literature becomes available, we will review and take into consideration revising the policy as needed.

Comment 2: Please review indications, conditions, and referenced published evidence in the Model Policy and consider adapting.
Response: CGS has reviewed the ASTRO model policy as well as other comments received during the 45 day open comment period. We have incorporated all changes indicated into the final revised draft LCD.

Comment 3: Seems CGS modeled their draft policy from Wisconsin Physician Services (WPS). The version used as a template was determined to have a technical error in the transition from ICD-9 to ICD-10. After we conducted a detailed analysis numerous codes were found to have been left out of the policy. Upon bringing this to the attention of WPS they retroactively corrected their policy. Please review attachments of analysis and the technical error.
Response: CGS will review the group one and group two list of diagnoses and make additions as needed before finalizing the policy.

Comment 4: Currently in the draft policy malignant neoplasm of the esophagus would not be covered as radiation doses have been shown to have adverse side effects when used near organs of the head and neck, lungs, and heart. Proton beam therapy can significantly reduce the frequency and severity of side effects, often to non-toxic levels or in part even eliminate completely. Please note a Phase II randomized trial is nearing completion. Based on the given expected benefits for the cervical region we ask you please to consider adding ICD-10 codes C15.3-C15.9 to group 2 list of Indications of Coverage.
Response: We will add the esophageal diagnoses to the group two list to be used for patients in approved clinical trials before finalizing the policy.

Comment 5: Draft LCD proposes that the treatment of “solid Tumors in children” by proton beam therapy would be considered medically reasonable and necessary. We believe that the policy should be broader in coverage, covering all pediatric tumors including Hodgkin’s lymphoma.

While Hodgkin’s lymphoma can be cured, at least 20% of children with Hodgkin’s lymphoma will require radiotherapy - the majority requiring it to the mediastinum, exposing the heart and, in female patients, breast tissue to radiation. Based on current literature proton beam therapy, sparing breast tissue has the potential to reduce unnecessary breast dose in young girls with Hodgkin’s Lymphoma by as much as 80% relative to with three-dimensional conformal involved-field photon radiotherapy.

Two additional studies conducted on patients with Hodgkin’s Lymphoma have found that proton beam therapy is predicted to decrease the radiation dosages to major cardiac subunits, lower the risks of radiation induced cardiac mortality for certain cases, and to reduce the risks for secondary lung and breast cancers for young patients receiving thoracic radiotherapy compared to IMRT or conformal photon therapy.

Commenter requests CGS add ICD-10 code C81.00-C81.99 to group 1 list of Indication of Coverage.
Response: CGS will await definitive peer reviewed literature prior to adding these diagnoses to group one in the LCD. As additional literature becomes available, we will review and consider revising the policy to include C81.00-C81.99 in group one in the future. At this time, we will add the diagnoses to group two in the policy as payable as part of a clinical trial.
Comment 6: The Draft LCD proposes that treatment for "left breast tumors" would be covered under Group 2. We agree with this proposal and respectfully request that CGS consider expanding coverage to include certain right-sided breast cancers. Specifically, two patient groups - those treated with accelerated partial breast irradiation (APBI) and patients who require irradiation of the internal mammary lymph nodes - may benefit significantly from proton irradiation as compared to x-rays.

Please add coverage to group 2 for selected patients with right-sided breast cancer who will receive APBI or who require internal mammary lymph node irradiation.

Response: CGS will include ICD-10 codes for right breast in the group two lists of diagnoses for patients in approved clinical trials before finalizing the policy.

Comment 7: The Draft LCD proposes that, "If the patient cannot clearly meet the criteria for coverage but desires Proton beam radiotherapy based on a marketed theoretical advantage, the claim should be billed with the appropriate modifier appended to the treatment delivery code. (See Coding Guidelines)." However, the coding guidelines section does not discuss the use of modifiers under this, or other circumstances. It is unclear whether CGS expects to deny coverage for other uses of proton therapy or is allowing for individual claim determinations.

Given the nature of certain cancers that some Medicare beneficiaries fight, we request that CGS modify the policy to allow for individual claim review for beneficiaries with other unique circumstances or rare cancers that are not explicitly covered by the policy. We respectfully request that CGS consider revising the language as follows: "Claims for coverage that include any indication not listed in this policy must be supported by medical documentation for coverage consideration."

Response: CGS has a well defined and published appeals process that allows for non-covered diagnoses to be adjudicated based on literature and provider/specialty society opinion received by the appeals team. In addition, the CMD is available to discuss the issue on a case-by-case basis with the provider and appeals team. No prior authorization program is available for proton beam treatments at this time in the Medicare Program.

Kentucky & Ohio

Comments for L36690 Application of Skin Substitutes for Wounds, Lower Extremities

Below are the comments CGS received during the open comment period for Application of Skin Substitutes for Wounds, Lower Extremities L36690. The name of the policy was changed to Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities before the policy was finalized.

Comment 1: Several commenters support and encourage the new draft LCD for applying skin substitutes for wounds. Many support the LCD’s statement that “all products with FDA clearance/approval or designated 361 HCT/P exemptions used in accordance with the product’s individual application guidelines will be equally considered for the purpose of this LCD”. This expansion will enable physicians to make appropriate decision on medically necessary CTP products.

Response: Thank you.

Comment 2: Commenter supports the proposed LCD’s updated classification of products into four groups defined as human skin allograft, allogeneic matrices, composite matrices, and acellular matrices.

Response: Thank you.

Comment 3: Several commenters are concerned with the specific conservative care parameters required prior to application specific to venous stasis ulcers (VLU) be present for three months with conservative care for at least 30 days. Literature supports the four week observation period for all wounds and ulcers.

Requested revision of this to, presence of a venous stasis ulcer that has been unresponsive to appropriate wound care for at least 30 days with documented compliance.

Several commenters ask what CGS considers appropriate wound care.
**Response:** The LCD is very clear as to what CGS considers appropriate wound care and those 4 weeks or more of wound care are required.

The LCD states:

Standard treatment of chronic lower extremity ulcers or skin loss (e.g., DFU or VLU) primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant and inciting medical issues (blood glucose control, tobacco use). Maintenance of a therapeutic environment with appropriate dressings to preclude further trauma facilitates development of healthy granulation tissue and encourages re-epithelialization. A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 4 weeks of optimization, including all aspects of standard therapy, is considered a chronic non-healing wound and falls into the auspices of this LCD. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy.

**Comment 4:** Comment received requesting draft LCD include coverage only for products that meets threshold based on clinical efficiency and published studies as outlines in CMS program integrity manual chapter 13.

**Response:** The LCD already does this by accepting products that are FDA approved and/or meet FDA requirements for cellular based tissue products.

**Comment 5:** Add to human skin grafts from placenta/cord human tissue as well as cadavers.

**Response:** CGS will remove the term cadavers from the first bullet point under bioengineered skin substitutes.

**Comment 6:** Under regulatory status #1 commenter would like the following information added, products are recovered, processed, and distributed in compliance with FDA Good Tissue Practices and American Association of Tissue Banks (AATB) standards, maintain the necessary registration with the FDA, and undergo routine FDA inspection.

**Response:** CGS will add to the policy before finalizing.

**Comment 7:** Request to add the following under #10 in the documentation requirements: “each product material is for single-use only, and is not for use on multiple patients.”

**Response:** CGS will add before finalizing the policy.

**Comment 8:** Commenter would like a list of covered products to be included since Medicare Advantage programs use the Medicare MAACs LCD and if a list of covered products is not given the advantage program switched to a commercial payer policy.

**Response:** A list of covered product is included in the draft policy and will be included in the final version. A list of application HCPCS codes is also included in the CPT/HCPCS section.

**Comment 9:** Commenter would like the language above group 2 list of CPT/HCPCS codes to include the following language but would prefer the removal of the list of products from the policy.

The policy states that “all products ... will be equally considered ... and may be considered reasonable and necessary,” yet the policy states in Group 2 Paragraph, only the HCPCS codes listed may be covered: “Any HCPCS code that is not included in this list will not be separately reimbursed.” Specific to this second statement in Group 2 Paragraph, a concern is that the list may not be inclusive of all Cellular and/or Tissue Based Products for Wounds (CTPs). This could result in excluding new products that are subject to this draft LCD. The commenter believes that misinterpretation and omission of products may result.

The commenter requests that frequent and routine updates be scheduled to ensure the list remains current. In addition, since some products are FDA cleared, rather than approved, or are not subject to FDA approval or clearance, we request that the terminology in Group 2 Paragraph, “FDA approval” be modified. Commenter proposes the following language: “May not be an all-inclusive list. New products and HCPCS codes will be considered eligible for coverage subject to meeting the necessary regulatory requirements and criteria of this policy.” We respectfully request that this language be considered and addressed prior to issuing this policy in final.

**Response:** CGS agrees to add the language requested before finalizing.

**Comment 10:** Commenter would like CGS to use the old title, Application Cellular and/or Tissue-based Products for Wounds, Lower Extremities, for the new policy as well as replace skin substitutes with cellular and/or tissue-based products for wounds (CTPs).

Several commenters would like skin substitutes to be replaced with Cellular Tissue based products (CTPs) as this is a more accurate term to describe the products than skin substitutes. As well as FDA does not allow these products to be called skin substitutes because they do not actually substitute for skin.

**Response:** CGS will change the title and all references of skin substitutes to read cellular or tissue based products (CTP) before finalizing the policy.
**Comment 11:** Would like the following sentence deleted as it implies there is no data supporting the improvement in response time for any CTP covered in the policy over standard care when there is clinical evidence available for many of the products in the policy that support improved healing for wounds that failed to progress with standard care approaches.

Currently, no product has demonstrated individual superiority for the treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) of the lower extremity, and, frequently such products are utilized inappropriately.

**Response:** The sentence above will be kept in the policy as it states that there is no individual product that shows superiority.

**Comment 12:** Commenter has several changes in wording in the policy they would like to see take place before the draft becomes final.

- **Commenter** has several changes in wording in the policy they would like to see take place before the draft becomes final.

  - "A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 4 weeks of optimization, including SOC, is considered a chronic non-healing wound and falls into the auspices of this LCD. The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy."

This is not always clinically possible some can be corrected and are appropriate to correct prior to the application. There are systemic conditions that contribute to the wound response to healing that are not always correctable or require correction prior to treating a patient with a CTP.

Please consider revising the sentence to, The fundamental basis for non-healing of a wound is of paramount importance and must be assessed and treated as appropriate per patient prior to consideration of additional therapy.

**Response:** We agree that systemic illnesses can and do influence wound healing. That is why we require control of these systemic processes prior to designating failure of standard care. We do not plan on changing this sentence or requirement at this time.

For purposes of this LCD a Failed Response is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

A failed response can also be when there has been minimal response from baseline depth or size.

Please consider revising to, For purposes of this LCD a Failed Response is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has had minimal or no change in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

**Response:** CGS does not see any significant change in language requested by the commenter. To add the word "minimal" clouds the intent of the LCD and will lead to confusion in the provider community.

- Please consider revising this sentence, "Medicare covers application of skin substitutes to Ulcers or Wounds with Failed Response that are:"
  - Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base.

Since some of the products in the policy also have coverage indications for covering tendon and/or muscle to, Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts (except when a CTP product has an indication for these structures), with a clean granular base.

**Response:** CGS will review the language and clarify if the product is approved for use involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts as indicated by package labeling it would be the exception and allowed.

Application of a skin substitute graft for lower extremity chronic wound (DFU and VLU) will be covered when the following conditions are met for the individual patient: “Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.”

Neuropathic ulcers are a distinct type of ulcer. Diabetes is but one cause of neuropathy and not all patients with diabetic foot ulcers have neuropathy. Please consider revising to Presence of neuropathic ulcers and diabetic foot ulcer(s) having failed to respond to documented conservative wound care measures of greater than four weeks …
Response: CGS will change the language for this before finalizing the policy.

Several commenters would like the following paragraph removed as it is problematic with the language “specifically FDA-labeled or cleared for use” would eliminate any of the allograft and amniotic tissues that do not have specific labeling or clearance-based indications for use. We do not believe this is your intention.

The language “considered to be biologic dressings” is incorrect. None of the listed products in the draft policy are a dressing. They are all reviewed as ‘biological’ materials, tissues, substrates or matrices and approved through FDA processes and under conditions of manufacturing distinct from those required for a simple wound dressing.

The FDA recognizes different regulatory pathways for CTPs: PMA, 510K, HDE, BLA and HCT/Ps. CTPs have different regulatory pathways depending on the source of the tissue.

A CTP promotes wound healing by interacting directly or indirectly with the body tissues.

There is direct biological effect in the wound bed as a result. The role of CTPs is not to cover and protect wounds but rather to stimulate endogenous healing, although whether or not an individual CTP is capable of exerting effects on wound healing must be determined by adequate evidence. Yet, a wound dressing is a material that is utilized for covering and protecting a wound, helping to maintain an optimal wound environment, and shield the wound against the environment without exerting any direct effect in the wound bed. As such, it is not correct for CGS to determine that a CTP, which is being regulated as a human HCT/P with the FDA and has broad indications not specified in its labeling, to eliminate its use based on its regulatory classification, or to designate it as a wound dressing. Furthermore, none of the products that maintain a HCPCS Q code are or should be considered a wound dressing. This is simply clinically and scientifically inaccurate.

The CMS allows separate Part B coverage and payment as biologicals in the physician office. They are not part of an E&M service.

All listed products, unless they are specifically FDA-labeled or cleared for use in the types of wounds being treated, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and not separately reimbursed.

The statement above also contradicts the following language in the policy which commenters are in agreement with as it is more accurate and represents the Q code products.

All products with FDA clearance/approval or designated 361 HCT/P exemption used in accordance with that product’s individualized application guidelines will be equally considered for the purpose of this LCD and may be considered reasonable and necessary.

Response: CGS will change the language to be more clinically accurate before finalizing the policy.

Consider changing the 10 application to 12 since some of the products labeling is for weekly applications. The policy already limits treatment to 12 weeks with a CPT and also limits continued use of a product if there is no response within “a period of four weeks past start of therapy” as this would be considered “unsuccessful treatment”. There may be cases with very large and complex wounds, that more than 10 applications would be necessary to achieve closure. It seems unethical to withhold treatment that is effective just because there is a narrow time frame. For a majority of wounds treated with a CTP, there will be less than 12 applications. The total applications should match the indications for use of all the listed products.

Consider, not to exceed 12 applications or treatments. In situations where more than one specific product is used during an episode, it is expected that the combined number of applications or treatments will still not exceed 12. There may be exceptions for very large wounds or those associated with autoimmune compromised conditions with appropriate documentation.

Response: At this time CGS has no plans to change the number of applications in the draft before finalizing the policy. If the scenario presented were to occur, then the medical record would have clear documentation as to the medical necessity of such a treatment plan. Upon review/appeal the appropriate evidence will be reviewed. If we see that this happens frequently we will reassess changing the number of applications.

Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counseling must be in the medical record.

It is reasonable to require documenting a patient’s smoking history and that they have received counseling on the effects of smoking on surgical outcomes. It is also reasonable to recommend a patient receive treatment for smoking cessation. However, it is unrealistic and adds no value to require the physician to document “outcome of counseling”. Patients can say one thing and do another. There is no way a physician can monitor the patient’s smoking behavior outside of the time they are in an office or clinic. Please revise this to remove the outcome of counseling from this sentence.

Response: Stating the smoking status of a patient in the record would de facto document the outcome of the smoking cessation counseling. No change will be made at this time.
**Comment 13:** Please add the following codes that appear in the 2017 proposed rule for the hospital OPPS:

- Q4128  Flex hd, AlloPatch hd, or Matrix hd, per square centimeter
- Q4138  BioDfence Dryflex, per square centimeter
- Q4143  Repriza, per square centimeter
- Q4146  Tensix, per square centimeter
- Q4150  Allowrap ds or dry, per square centimeter

**Response:** Since this rule is not finalized at this time CGS cannot add these codes at this time. Once the rule is finalized, changes may be made.

**Comment 14:** Commenter would like AlloPatch added to covered list as it is currently listed in the Application of Cellular and/or Tissue Based Products (CTPs) for Wounds of lower Extremities L34053.

**Response:** CGS will add any products that were added to the current policy after the drafting of DL36690 before it is finalized.

**Comment 15:** Comment received concerning that the following is unclear as to what combination therapy is and how it would limit the use of CTPs for a patient.

- Simultaneous use of more than one product is not covered.

**Response:** CGS has seen providers use combinations of various products on one wound. At this time, combination therapy, or using more than one product on one wound, is not covered.

**Comment 16:** Would like CGS to recognize podiatrists as providers who can and do treat patients with wounds. As well as any other qualified health care professional in which this service is permitted to be performed within their state practice act.

**Response:** As long as the provider stays within their scope of practice, CGS will pay them for their medically necessary services. The LCD is very clear that the treating physician must be actively treating any comorbid condition that may be hindering wound healing and that expertise must be able to be validated on request. The physician managing the systemic processes must be clearly identified. CGS will clarify that a provider treating a wound caused by a systemic condition would need to document they are aware of the condition and the patient is under the care of Dr. ___ for said condition unless (s)he is the one providing the care.

**Comment 17:** Comments received that would like the 12 week limitation be removed and simply state follow the FDA labeling as CTPs are only applied every 2-3 weeks with multiple treatments in a span of time beyond 12 weeks. The provider would need to justify going beyond the 12 weeks. Also while CGS is permitting a clinician to change treatment options, this policy is still limiting a physician’s ability to change course in treating their patients upon the realization that the product chosen is not successfully working in their patient, or when the health status or wound changes. As such, this policy is not only limiting treatment options for the clinician, it is inhibiting a patient from receiving the best optimal treatment. As well as at time one CTP is used to achieve one goal and then another is utilized for closure of the wound.

**Response:** CGS is happy to review individual product’s labeling to determine if they require or have evidence that states the majority of treatments exceed our limitations. This LCD has regulatory guidance for the most common accepted application frequency. Exceptions do occur and CGS will handle these on a case-by-case basis on appeal as needed.

**Comment 18:** Commenter would like language change concerning non-healing full thickness chronic wounds. While agreeing CTPs should not be used for wounds with a sinus tract. However, full-thickness wounds due to diabetes or venous disease as well as full thickness wounds that are the result of an abscess, trauma or injury often have exposed tendon, muscle or bone that can be appropriately treated with some CTPs that are indicted for with for wounds with exposed tendon, muscle or bone.

Please revise to:

- “Lower extremity partial-or full-thickness diabetic ulcers, and venous ulcers not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base” (except when a CTP has an indication for use over tendon, muscle, joint or bone. Use of a CTP in a wound with a sinus tract is not covered.)
- “Presence of a full thickness skin loss ulcer (any location) that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.” If these full-thickness wounds involve exposed tendon, muscle or bone, only CTPs with indications for use over these structures will be covered.
Response: CGS is happy to review individual product's labeling to determine if they require or have evidence that states the majority of treatments exceed our limitations. This LCD has regulatory guidance for the most common accepted application frequency. Exceptions do occur and CGS will handle these on a case-by-case basis on appeal as needed.

Comment 19: Would like the following removed from the limitations section since combination of therapies are used to enhance the healing of the patient. “Combination therapy with any skin substitute (CTP) will be considered not reasonable and necessary.”

Response: CGS CMDs require published peer reviewed literature in order to validate this request. CGS is happy to review this literature, if supplied by the commenter, and opine.

Kentucky & Ohio

Comments for L36675 MolDX- CDD: ProMark Risk

Below are the comments MolDX received during the open comment period for MolDX- CDD: ProMark Risk L36675.

Comment 1: Criteria for Coverage We understand the rationale for consistency in the coverage criteria of the prognostic assays that have received LCDs under MolDx. We would, however, ask Palmetto to evaluate whether the ‘Patient Stage’ criteria should be modified to include certain men with intermediate risk prostate cancer. The most recent NCCN Prostate Cancer Guidelines (NCCN Prostate Cancer Guidelines Version 2.2016) now include a statement about the use of AS in certain intermediate risk men. On PROS-4 of these guidelines it is noted that, “Patients with favorable intermediate-risk prostate cancer (predominant Gleason grade 3 [i.e., Gleason score 3+4 = 7], and percentage of positive biopsy cores <50%, and no more than one NCCN intermediate risk factor) may be considered for active surveillance.” Given that men fitting these criteria may now be making choices about active surveillance, we believe it is important to allow access to advanced prognostic assays that can inform these decisions. We recommend that the LCD reference the NCCN Version 2.2016 guidelines.

Response: NCCN version 3.2016 specifies “Patients with favorable intermediate-risk prostate cancer (predominate Gleason grade 3 [i.e., Gleason score 3+4=7], and percentage of positive biopsy cores <50 percent, and no more than one NCC intermediate risk factor) may be considered for active surveillance." Published data does not include the group of patients and no nationally recognized professional organization includes this group of patients in their AS recommendation. When published data supports inclusion of intermediate risk patients and their national guidelines recommend AS, the policy can be amended.

Comment 2: Certification and Training Registry (CTR) We agree with the goals of the proposed CTR and will work with MolDx on the implementation of the training and data collection requirements under the CTR. We are hopeful that the accumulation of additional data on the impact of ProMark and other advanced prognostic assays via the MolDx CTRs for prostate cancer will enable a transition from the CDD structures in the future.

Response: Your comment is appreciated.

Comment 3: Correction Please change the format of the company name from MetaMark to Metamark in the LCD (the second ‘m’ should be lowercase).

Response: Correction made in LCD.

Comment 4: On the other draft Urologic LCD, Promark Risk Score for prostate cancer (DL 36704), I would ask that you consider adding Gleason 3+4, small volume cancer, PSA <10 as “low risk disease” and therefore a covered indication. The policy as written, divides risk as Gleason 6 or Gleason 7 (low or intermediate risk). Unfortunately, not all Gleason 7 tumors are the same: the ’7’ is the sum of two components and Gleason 3+4 acts as a Gleason 3+3 (6) while Gleason 4+3 acts more aggressively. Thus, the LCD is too simplified and should recognize that a different approach may be reasonable for the lower risk of these two. Thus, an elderly man with PSA<10, T1c-T2 disease, small volume Gleason 3+4 cancer on biopsy should be covered for Promark testing. In fact, this is the most efficient use of this test (moderately older man with more than 10 year life expectancy, small volume cancer, Gleason 3+4, PSA <10 who is considering Active Surveillance or more aggressive treatment). With that minor change, the LCD is fine. Extending this argument, Gleason 3+4, small volume, PSA<10 should also be covered for Prolaris testing (another assay performed on biopsy tissue to further inform the decision to actively treat or watch with Active Surveillance) considering this as low risk disease. This LCD which is already approved should be Reconsidered and Amended.
**Response:** The following response to comment address comment received by Noridian Administrative Services on draft policy DL36704. NCCN version 3.2016 specifies “Patients with favorable intermediate-risk prostate cancer (predominate Gleason grade 3 [i.e., Gleason score 3+4=7], and percentage of positive biopsy cores <50 percent, and no more than one NCC intermediate risk factor) may be considered for active surveillance.” [Emphasis added by author.] Published data does not include this group of patients and no nationally recognized professional organization includes this group of patients in their AS recommendation. When published data supports inclusion of intermediate risk patients and their national guidelines recommend AS, the policy can be amended for ProMark, Prolaris or other comparable assays.

**Kentucky & Ohio**

**MM9659: Healthcare Provider Taxonomy Codes October 2016 Code Set Update**

The Centers for Medicare & Medicaid Services (CMS) has issued the following *Medicare Learning Network® (MLN) Matters* article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9659

**Related Change Request (CR) #:** CR 9659

**Related CR Release Date:** August 26, 2016

**Related CR Transmittal #:** R3597CP

**Implementation Date:** January 3, 2017, except some MACs may implement on October 1, 2016

**What You Need to Know**

CR9659 instructs MACs to obtain the most recent Healthcare Provider Taxonomy Code (HPTC) set and to update their internal HPTC tables and/or reference file. MACs that have the capability to do so will implement the October 2016 HPTC set as early as October 1, 2016, for claims received on or after October 1, 2016. All MACs will implement the HPTC set by January 3, 2017.

**Background**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use the standards adopted under this law for electronically transmitting certain health care transactions, including health care claims.

The standards include implementation guides which dictate when and how data must be sent, including specifying the code sets which must be used. The institutional and professional claim electronic standard implementation guides (X12 837-I and 837-P) each require use of valid codes contained in the HPTC set when there is a need to report provider type or physician, practitioner, or supplier specialty for a claim.

The National Uniform Claim Committee (NUCC) maintains the HPTC set for standardized classification of health care providers, and updates it twice a year with changes effective April 1 and October 1. These changes include the addition of a new code and addition of definitions to existing codes.

You should note that:

1. Valid HPTCs are those that the NUCC has approved for current use.
2. Terminated codes are not approved for use after a specific date.
3. Newly approved codes are not approved for use prior to the effective date of the code set update in which each new code first appears.

4. Specialty and/or provider type codes issued by any entity other than the NUCC are not valid.

CR9659 implements the NUCC HPTC code set that is effective on October 1, 2016, and instructs MACs to obtain the most recent HPTC set at http://www.wpc-edi.com/codes and use it to update their internal HPTC tables and/or reference files.

When reviewing the HPTC code set online, you can identify revisions made since the last release by the color code:

- New items are green
- Modified items are orange, and
- Inactive items are red

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.

Kentucky & Ohio

MM9680: Claim Status Category and Claim Status Codes Update

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html.

MLN Matters® Number: MM9680
Related CR Release Date: August 26, 2016
Related CR Transmittal #: R3599CP
Effective Date: January 1, 2017
Implementation Date: January 3, 2017

Provider Types Affected

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

What You Need to Know

Change Request (CR) 9680 updates, as needed, the Claim Status and Claim Status Category Codes used for the Accredited Standards Committee (ASC) X12 276/277 Health Care Claim Status Request and Response and ASC X12 277 Health Care Claim Acknowledgement transactions.

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 (NCMC) meets at the beginning of each ASC X12 trimester meeting (January/February, June, and September/October) and makes decisions about additions, modifications, and retirement of existing codes. The NCMC allows the industry 6 months for implementation of newly added or changed codes. Codes sets are available at http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-category-codes/ and http://www.wpc-edi.com/reference/codelists/healthcare/claim-status-codes/. Included in the code lists are specific details, including the date when a code was added, changed, or deleted.

All code changes approved during the September/October 2016 committee meeting shall be posted on these sites on or about November 1, 2016. MACs will complete entry of all applicable code text changes and new codes, and terminated use of deactivated codes, by the implementation of CR9680.

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 CR9680 is implemented.

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

Additional Information


If you have 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.
# Kentucky & Ohio


The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9735  
**Related CR Release Date:** August 26, 2017  
**Related CR Transmittal #:** R3603CP  
**Related Change Request (CR) #:** CR 9735  
**Effective Date:** January 1, 2017  
**Implementation Date:** January 3, 2017

### 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 (HH&H) MACs and Durable Medical Equipment (DME) MACs, for services provided to Medicare beneficiaries who are in a Part A covered Skilled Nursing Facility (SNF) stay.

### Provider Action Needed

**STOP – Impact to You**

If you provide services to Medicare beneficiaries in a Part A covered SNF stay, information in Change Request (CR) 9735 could impact your payments.

**CAUTION – What You Need to Know**

CR9735 provides the 2017 annual update of HCPCS Codes for SNF Consolidated Billing (SNF CB) and explains how the updates affect edits in Medicare claims processing systems. By the first week in December 2016, the new code files for Part B processing, and the new Excel and PDF files for Part A processing, will be available at [http://www.cms.gov/SNFConsolidatedBilling](http://www.cms.gov/SNFConsolidatedBilling) and will become effective on January 1, 2017.

**GO – What You Need to Do**

The provider community should read the “General Explanation of the Major Categories” PDF file located at the bottom of each year’s MAC update in order to understand the Major Categories, including additional exclusions not driven by HCPCS codes.

### Background

The Common Working File (CWF) currently has edits in place for claims received for beneficiaries in a Part A covered SNF stay as well as for beneficiaries in a non-covered stay. These edits allow only those services that are excluded from consolidated billing to be separately paid.

Changes to HCPCS codes and Medicare Physician Fee Schedule designations are used to revise these edits to allow MACs to make appropriate payments in accordance with policy for SNF CB, found in the Chapter 6, Section 20.6 (Part A) and Section 110.4.1 (Part B) of the “Medicare Claims Processing Manual,” available for download at [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c06.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c06.pdf).
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.

Kentucky & Ohio

MM9751: Coding Revisions to National Coverage Determination (NCDs)

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9751
Related CR Release Date: August 19, 2016
Related CR Transmittal #: R1708OTN
Related Change Request (CR) #: CR 9751
Effective Date: January 1, 2017 - Unless otherwise noted
Implementation Date: January 3, 2017

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

Background
The translations from ICD-9 to ICD-10 are not consistent 1-1 matches, nor are all ICD-10 codes appearing in a complete General Equivalence Mappings (GEMS) mapping guide or other mapping guides appropriate when reviewed against individual NCD policies. In addition, for those policies that expressly allow MAC discretion, there may be changes to those NCDs based on current review of the 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 as of October 1, 2015.

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. Edits to ICD-10 and other coding updates specific to NCDs will be included in subsequent, quarterly releases as needed.

CR9751 makes adjustments to the following NCDs:

- NCD 20.7 Percutaneous Transluminal Angioplasty (PTA)
- NCD 20.19 Ambulatory Blood Pressure Monitoring (ABPM)
- NCD 20.33 Transcatheter Mitral Valve Repair (TMVR) Therapy
- NCD 40.1 Diabetes Self-Management Training (DSMT)
- NCD 160.18 Vagus Nerve Stimulation (VNS)
- NCD 180.1 Medical Nutrition Therapy (MNT)
- NCD 190.3 Cytogenetic Studies
- NCD 220.6.17 FDG PET for Solid Tumors
- NCD 220.6.20 PET Beta Amyloid in Dementia/Neurological/ Disorders
- NCD 230.18 Sacral Nerve Stimulation (SNS) for Urinary Incontinence
- NCD 260.1 Adult Liver Transplants


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

Your MACs will use default Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) messages where appropriate:

- Remittance Advice Remark Codes (RARC)
  - N386 - 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; with
  - Claim Adjustment Reason Codes (CARC)
    - 50 - These are non-covered services because this is not deemed a “medical necessity” by the payer;
    - 96 - Non-covered charge(s); or
    - 119 Benefit maximum for this time period has been reached.

Group Code PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32, or with occurrence code 32 and a GA modifier, indicating a signed Advance Beneficiary Notice (ABN) is on file). Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).
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.

Kentucky & Ohio
MM9756: October Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9756 Related Change Request (CR) #: CR 9756
Related CR Release Date: August 26, 2016 Effective Date: October 1, 2016
Related CR Transmittal #: R3598CP Implementation Date: October 3, 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.

What You Need to Know
Change Request (CR) 9756 advises providers of fee schedule amounts for codes in effect on October 1, 2016. Make sure your billing staffs are aware of these updates.

Key Points
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 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf), Section 60.

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 fee schedule amounts. ZIP codes for non-continental Metropolitan Statistical Areas (MSA) are not included in the DMEPOS Rural ZIP code file. The DMEPOS Rural ZIP code file is updated on a quarterly basis as necessary.

October quarterly updates are only required for the DMEPOS Rural ZIP Code file containing Quarter 4, 2016 Rural ZIP Code changes. MACs will process claims for DMEPOS items using the Rural ZIP code file for dates of service on or after October 1, 2016.

The October 2016 DMEPOS Rural ZIP Code Public Use File (PUF), containing the rural ZIP codes effective for Quarter 4, 2016, will be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/ for State Medicaid Agencies.
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Kentucky & Ohio

MM9759: Annual Clotting Factor Furnishing Fee Update 2017

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9759
Related CR Release Date: August 26, 2016
Related CR Transmittal #: R3607CP
Related Change Request (CR) #: CR 9759
Effective Date: January 1, 2017
Implementation Date: January 3, 2017

Provider Types Affected
This MLN Matters® Article is intended for physicians and other providers billing Medicare Administrative Contractors (MACs) for services related to the administration of clotting factors provided to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9759 updates the clotting factor furnishing fee for 2017, and announces that for 2017 it is $0.209 per unit. Make sure that your billing staffs are aware of this update to the annual clotting factor furnishing fee for 2017.

Background
The Centers for Medicare and Medicaid Services (CMS) includes the clotting factor furnishing fee in the published national payment limits for clotting factor billing codes. The clotting factor furnishing fee is updated each calendar year based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year.

Effective for dates of service from January 1, 2017, through December 31, 2017, the clotting factor furnishing fee of $0.209 per unit is included in the published payment limit for clotting factors, and it will be added to the payment for a clotting factor when no payment limit for the clotting factor is published either on the Average Sales Price (ASP) Medicare Part B Drug Pricing File or the Not Otherwise Classified (NOC) Pricing File.
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.

Kentucky & Ohio

**MM9766: Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

**MLN Matters® Number:** MM9766  
**Related Change Request (CR) #:** CR 9766  
**Related CR Release Date:** August 26, 2016  
**Effective Date:** January 1, 2017  
**Related CR Transmittal #:** R3600CP  
**Implementation Date:** January 3, 2017

**Provider Types Affected**

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

**Provider Action Needed**

Change Request (CR) 9766 informs MACs of the regular update in the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) defined code combinations per Operating Rule 360 - Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule. Make sure that your billing staffs are aware of these changes.

**Background**

The Department of Health and Human Services (HHS) adopted the Phase III CAQH CORE EFT & ERA Operating Rule Set that was implemented on January 1, 2014, under the Patient Protection and Affordable Care Act. The Health Insurance Portability and Accountability Act (HIPAA) amended the Act by adding Part C—Administrative Simplification—to Title XI of the Social Security Act, requiring the Secretary of HHS (the Secretary) to adopt
standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information.

Through the Affordable Care Act, Congress sought to promote implementation of electronic transactions and achieve cost reduction and efficiency improvements by creating more uniformity in the implementation of standard transactions. This was done by mandating the adoption of a set of operating rules for each of the HIPAA transactions. The Affordable Care Act defines operating rules and specifies the role of operating rules in relation to the standards.

CR9766 deals with the regular update in CAQH CORE defined code combinations per Operating Rule 360 - Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule. CAQH CORE will publish the next version of the Code Combination List on or about October 1, 2016. This update is based on the Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC) updates as posted at the WPC website on or about July 1, 2016. This will also include updates based on Market Based Review (MBR) that CAQH CORE conducts once a year to accommodate code combinations that are currently being used by Health Plans including Medicare as the industry needs them.


**Note:** Per ACA mandate all health plans including Medicare must comply with CORE 360 Uniform Use of CARCs and RARCs (835) rule or CORE developed maximum set of CARC/RARC/Group Code for a minimum set of 4 Business Scenarios. Medicare can use any code combination if the business scenario is not one of the 4 CORE defined business scenarios. With the 4 CORE defined business scenarios, Medicare must use the code combinations from the lists published by CAQH CORE.

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.

**Kentucky & Ohio**

**MM9781: 2017 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

**MLN Matters® Number:** MM9781  **Related Change Request (CR) #:** CR 9781
**Related CR Release Date:** September 9, 2016  **Effective Date:** January 1, 2017
**Related CR Transmittal #:** R3610CP  **Implementation Date:** January 3, 2017

**Provider Types Affected**

This MLN Matters® Article is intended for physicians submitting claims to Medicare Administrative Contractors (MACs) for services provided in Health Professional Shortage Areas (HPSAs) to Medicare beneficiaries.
Provider Action Needed

Change Request (CR) 9781 alerts you that the annual HPSA bonus payment file for 2017 will be made available by the Centers for Medicare & Medicaid Services (CMS) to your MAC and will be used for HPSA bonus payments on applicable claims with dates of service on or after January 1, 2017, through December 31, 2017. You should review Physician Bonuses web page at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HPSAPSAPhysicianBonuses each year to determine whether you need to add modifier AQ to your claim in order to receive the bonus payment, or to see if the ZIP code in which you rendered services will automatically receive the HPSA bonus payment. Make sure that your billing staffs are aware of these changes.

Background

Section 413(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 mandated an annual update to the automated HPSA bonus payment file. CMS automated HPSA ZIP code file shall be populated using the latest designations as close as possible to November 1 of each year. The HPSA ZIP code file shall be made available to contractors in early December of each year. MACs will implement the HPSA ZIP code file and for claims with dates of service January 1 to December 31 of the following year, shall make automatic HPSA bonus payments to physicians providing eligible services in a ZIP code contained on the file.

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.

Kentucky & Ohio

MM9758: Influenza Vaccine Payment Allowances - Annual Update for 2016-2017 Season

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9758
Related CR Release Date: September 9, 2016
Related CR Transmittal #: R3611CP
Effective Date: August 1, 2016
Implementation Date: No later than November 1, 2016

Provider Types Affected

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

Provider Action Needed

Change Request (CR) 9758 informs MACs about the payment allowances for seasonal influenza virus vaccines. These payment allowances are updated on August 1 of each year. The Centers for Medicare & Medicaid Services (CMS) will post the payment allowances for influenza vaccines that are approved after the release of CR9758 at https://www.cms.
Background

The Medicare Part B payment allowance limits for influenza and pneumococcal vaccines are 95 percent of the Average Wholesale Price (AWP) as reflected in the published compendia except when the vaccine is furnished in a hospital outpatient department, Rural Health Clinic (RHC), or Federally Qualified Health Center (FQHC). In these instances, payment for the vaccine is based on reasonable cost.

The Medicare Part B payment allowances for the following Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes below apply for the effective dates of August 1, 2016-July 31, 2017:

- CPT 90653 Payment allowance is pending
- CPT 90655 Payment allowance is pending
- CPT 90656 Payment allowance is pending
- CPT 90657 Payment allowance is pending
- CPT 90661 Payment allowance is pending
- CPT 90685 Payment allowance is pending
- CPT 90686 Payment allowance is pending
- CPT 90687 Payment allowance is pending
- CPT 90688 Payment allowance is pending
- HCPCS Q2035 Payment allowance is pending
- HCPCS Q2036 Payment allowance is pending
- HCPCS Q2037 Payment allowance is pending
- HCPCS Q2038 Payment allowance is pending

Payment for the following CPT/HCPCS codes may be made if your MAC determines their use is reasonable and necessary for the beneficiary, for the effective dates of August 1, 2016-July 31, 2017:

- CPT 90630 Payment allowance is pending
- CPT 90654 Payment allowance is pending
- CPT 90662 Payment allowance is pending
- CPT 90672 Payment allowance is pending
- CPT 90673 Payment allowance is pending
- CPT 90674 Payment allowance is pending
- HCPCS Q2039 Flu Vaccine Adult - Not Otherwise Classified payment allowance is to be determined by your MAC with effective dates of August 1, 2016-July 31, 2017

The Centers for Medicare & Medicaid Services (CMS) will publish the approved payment allowances on the CMS Seasonal Influenza Vaccines Pricing (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html) web page after CR9758 is released and as the information becomes available. Please note that the effective dates for these vaccines will be the date of FDA approval.
Providers should note that:

- All physicians, non-physician practitioners and suppliers who administer the influenza virus vaccination and the pneumococcal vaccination must take assignment on the claim for the vaccine.
- The annual Part B deductible and coinsurance amounts do not apply.
- While your MACs will not search their files either to retract payment for claims already paid or to retroactively pay claims, they will adjust claims that you bring to their attention.

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](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html).

**Kentucky & Ohio**

**MM9761 Revised:**

**Ambulance Staffing Requirements**

The Centers for Medicare & Medicaid Services (CMS) has revised the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html).

**MLN Matters® Number:** MM9761 Revised
**Related Change Request (CR) #:** CR 9761
**Related CR Release Date:** September 12, 2016
**Related CR Transmittal #:** R226BP

**Related Effective Date:** January 1, 2016
**Implementation Date:** December 12, 2016

**Note:** This article was revised on September 13, 2016, due to a revised Change Request (CR). The CR corrected the implementation date in the manual instruction section of the CR to December 12, 2016. The transmittal number, CR release date and the link to the CR also changed. All other information remains the same.

**Provider Types Affected**

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

**Provider Action Needed**

CR 9761 manualizes the Calendar Year (CY) 2016 revisions to the ambulance staffing requirements (80 FR 71078-71080) and provides clarifications on the definitions for ground ambulance services for Advanced Life Support, Level 1 (ALS1), ALS assessment, application for ALS, Level 2 (ALS2), Specialty Care Transport (SCT), Paramedic Intercept (PI), emergency response, and inter-facility transportation. Please make sure your billing staff is aware of these revisions.

**Background**

In the CY 2016 Physician Fee Schedule Final Rule (80 FR 71078-71080), the Centers for Medicare & Medicaid Services (CMS) finalized without modification their proposals to revise:

1. 42 CFR 410.41(b) and the definition of Basic Life Support (BLS) in 42 CFR 414.605, to require that all Medicare covered ambulance transports be staffed by at least two people
who meet both the requirements of state and local laws where the services are being furnished, and the current Medicare requirements;

2. 42 CFR 410.41(b) and the definition of BLS in 42 CFR 414.605 to clarify that for BLS vehicles, one of the staff members must be certified at a minimum as an EMT-Basic; and

3. To delete the last sentence in the definition of BLS in 42 CFR 414.605, which sets forth examples of certain state law provisions.

CR9761 updates Chapter 10, Sections 10.1.2; 30.1; and 30.1.1 of the “Medicare Benefit Policy Manual” (Pub. 100-02) to incorporate these revisions.

**Key Points of CR9761**

**BLS Vehicles**

BLS ambulances must be staffed by at least two people, who meet the requirements of state and local laws where the services are being furnished and where, at least one of whom must be certified at a minimum as an emergency medical technician-basic (EMT-basic) by the State or local authority where the services are being furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from state to state or within a state.

**ALS Vehicles**

Advanced Life Support (ALS) vehicles must be staffed by at least two people, who meet the requirements of state and local laws where the services are being furnished and where at least one of whom must meet the vehicle staff requirements above for BLS vehicles and be certified as an EMT-Intermediate or an EMT-Paramedic by the state or local authority where the services are being furnished to perform one or more ALS services.

**Ambulance Services**

There are several categories of ground ambulance services and two categories of air ambulance services under the fee schedule. (Note that “ground” refers to both land and water transportation.) All ground and air ambulance transportation services must meet all requirements regarding medical reasonableness and necessity as outlined in the applicable statute, regulations and manual provisions.

**Advanced Life Support, Level 1 (ALS1)**

**Definition:** ALS1 is the transportation by ground ambulance vehicle and the provision of medically necessary supplies and services including the provision of an ALS assessment by ALS personnel or at least one ALS intervention.

**ALS Assessment**

**Definition:** An ALS assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient’s reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service. In the case of an appropriately dispatched ALS Emergency service, as defined below, if the ALS crew completes an ALS Assessment, the services provided by the ambulance transportation service provider or supplier may be covered at the ALS emergency level, regardless of whether the patient required ALS intervention services during the transport, provided that ambulance transportation itself was medically reasonable and necessary.

**ALS Intervention**

**Definition:** An ALS intervention is a procedure that is in accordance with state and local laws, required to be done by an emergency medical technician-intermediate (EMT-Intermediate) or EMT-Paramedic.
Application: An ALS intervention must be medically necessary to qualify as an intervention for payment for an ALS level of service. An ALS intervention applies only to ground transports.

Advanced Life Support, Level 1 (ALS1) - Emergency

Definition: When medically necessary, the provision of ALS1 services, in the context of an emergency response.

Advanced Life Support, Level 2 (ALS2)

Definition: ALS2 is the transportation by ground ambulance vehicle and the provision of medically necessary supplies and services including at least three separate administrations of one or more medications by intravenous (IV) push/bolus or by continuous infusion (excluding crystalloid fluids) or ground ambulance transport, medically necessary supplies and services, and the provision of at least one of the following ALS2 procedures:

- Manual defibrillation/cardioversion
- Endotracheal intubation
- Central venous line
- Cardiac pacing
- Chest decompression
- Surgical airway
- Intraosseous line

Application: Crystalloid fluids include but are not necessarily limited to 5 percent Dextrose in water (often referred to as D5W), Saline and Lactated Ringer’s. To qualify for the ALS2 level of payment, medications must be administered intravenously. Medications that are administered by other means, for example, intramuscularly, subcutaneously, orally, sublingually, or nebulized do not support payment at the ALS2 level rate.

IV medications are administered in standard doses as directed by local protocol or online medical direction. It is not appropriate to administer a medication in divided doses in order to meet the ALS2 level of payment. For example, if the local protocol for the treatment of Supraventricular Tachycardia (SVT) calls for a 6 mg dose of adenosine, the administration of three 2 mg doses in order to qualify for the ALS 2 level is not acceptable.

The administration of an intravenous drug by infusion qualifies as one intravenous dose. For example, if a patient is being treated for atrial fibrillation in order to slow the ventricular rate with diltiazem and the patient requires two boluses of the drug followed by an infusion of diltiazem then the infusion would be counted as the third intravenous administration and the transport would be billed as an ALS 2 level of service.

The fractional administration of a single dose (for this purpose, meaning a “standard” or “protocol” dose) of a medication on three separate occasions does not qualify for ALS2 payment. In other words, the administering 1/3 of a qualifying dose 3 times does not equate to three qualifying doses to support claiming ALS2-level care. For example, administering one-third of a dose of X medication 3 times might = Y (where Y is a standard/protocol drug amount), but the same sequence does not equal 3 times Y. Thus, if 3 administrations of the same drug are required to claim ALS2 level care, each administration must be in accordance with local protocols; the run will not qualify at the ALS2 level on the basis of drug administration if that administration was not according to local protocol. The criterion of multiple administrations of the same drug requires that a suitable quantity of the drug be administered and that there be a suitable amount of time between administrations, and that both are in accordance with standard medical practice guidelines.

Examples of drug administration that help explain this policy are in the revised manual sections that are attached to CR9761.
ALS Personnel
Definition: ALS personnel are individuals trained to the level of the emergency medical technician-intermediate (EMT-Intermediate) or paramedic.

Specialty Care Transport (SCT)
Definition: Specialty Care Transport (SCT) is the Inter-facility Transportation (as defined below) of a critically injured or ill beneficiary by a ground ambulance vehicle, including the provision of medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, emergency or critical care nursing, emergency medicine, respiratory care, cardiovascular care, or an EMT-Paramedic with additional training.

Application: SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area. The EMT-Paramedic level of care is set by each state. Medically necessary care that is furnished at a level above the EMT-Paramedic level of care may qualify as SCT.

To be clear, if EMT-Paramedics - without specialty care certification or qualification - are permitted to furnish a given service in a State, then that service does not qualify for SCT. The phrase “EMT-Paramedic with additional training” recognizes that a state may permit a person who is not only certified as an EMT-Paramedic, but who also has successfully completed additional education as determined by the state in furnishing higher level medical services required by critically ill or injured patients, to furnish a level of service that otherwise would require a health professional in an appropriate specialty care area (for example, a nurse) to provide. “Additional training” means the specific additional training that a State requires a paramedic to complete in order to qualify to furnish specialty care to a critically ill or injured patient during an SCT.

Paramedic Intercept (PI)
Definition: Paramedic Intercept services are ALS services provided by an entity that does not provide the ambulance transport. This type of service is most often provided for an emergency ambulance transport in which a local volunteer ambulance that can provide only Basic Life Support (BLS) level of service is dispatched to transport a patient. If the patient needs ALS services such as EKG monitoring, chest decompression, or IV therapy, another entity dispatches a paramedic to meet the BLS ambulance at the scene or once the ambulance is on the way to the hospital. The ALS paramedics then provide services to the patient.

Paramedic intercept services furnished on or after March 1, 1999, are payable separate from the ambulance transport when all the requirements in the following three conditions are met:

I. The intercept service(s) is:
   - Furnished in a rural area (as defined below);
   - Furnished under a contract with one or more volunteer ambulance services; and,
   - Medically necessary based on the condition of the beneficiary receiving the ambulance service.

II. The volunteer ambulance service involved must:
   - Meet Medicare's certification requirements for furnishing ambulance services;
   - Furnish services only at the BLS level at the time of the intercept; and,
   - Be prohibited by state law from billing anyone for any service.

III. The entity furnishing the ALS paramedic intercept service must:
   - Meet Medicare's certification requirements for furnishing ALS services; and,
Bill all recipients who receive ALS paramedic intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

For purposes of the paramedic intercept benefit, a rural area is an area that is designated as rural by a State law or regulation or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent version of the Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features). The current list of these areas is periodically published in the Federal Register. See the “Medicare Claims Processing Manual,” Chapter 15 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c15.pdf), “Ambulance,” Section 20.1.4 for payment of paramedic intercept services.

Inter-facility Transportation
For purposes of SCT payment, an inter-facility transportation is one in which the origin and destination are one of the following:

- A hospital or Skilled Nursing Facility (SNF) that participates in the Medicare program, or
- A hospital-based facility that meets Medicare’s requirements for provider-based status.

Emergency Response
**Definition:** Emergency response is a BLS or ALS1 level of service that has been provided in immediate response to a 911 call or the equivalent. An immediate response is one in which the ambulance provider/supplier begins as quickly as possible to take the steps necessary to respond to the call. The nature of an ambulance’s response (whether emergency or not) does not independently establish or support medical necessity for an ambulance transport. Rather, Medicare coverage always depends on, among other things, whether the service(s) furnished is actually medically reasonable and necessary based on the patient’s condition at the time of transport.

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-LearningNetwork-MLN/MLNMattersArticles/index.html.

Kentucky & Ohio
**MM9748: Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF)**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

- **MLN Matters® Number:** MM9748
- **Related CR Release Date:** September 16, 2016
- **Related CR Transmittal #:** R101GI, R227BP, and R3612CP
- **Related Change Request (CR) #:** CR 9748
- **Effective Date:** October 18, 2016
- **Implementation Date:** October 18, 2016
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) 9748 revises the following Medicare manuals to correct various minor technical errors and omissions:

- “Medicare General Information, Eligibility, and Entitlement Manual”
- “Medicare Benefit Policy Manual” and
- “Medicare Claims Processing Manual”

The revisions of these manuals are intended to clarify the existing content, and no policy, processing, or system changes are anticipated.

Key Points of CR9748
CR9748 includes all revisions as attachments, and selected extracts from these attachments are as follows:

“Medicare General Information, Eligibility, and Entitlement Manual” Revision Summary
- Chapters 4 and 5 of this manual are revised to include references to another manual with related information and a reference to a related regulation.

“Medicare Benefit Policy Manual” Summary of Key Revisions
- In several sections, references to related material in other manuals are included.
- Language is added to refer providers to a list of exclusions from consolidated billing (CB, the SNF “bundling” requirement), which is available at http://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling/index.html.
- Language is added to state that “Medicare’s post-hospital extended care benefit is not designed to provide broad coverage in SNFs of what is commonly regarded as “nursing home” care; that is, long-term, relatively low-level assistance with activities of daily living (see Chapter 16, §110 of the “Medicare Benefit Policy Manual” for a discussion of Medicare’s general coverage exclusion of “custodial” care). Rather, Congress originally enacted this benefit in order to achieve savings in Medicare expenditures on inpatient hospital stays, by creating a less expensive institutional substitute for what would otherwise be the final, convalescent portion of the hospital stay itself. Accordingly, the post-hospital extended care benefit focuses specifically on care that serves as a fairly brief and highly skilled “extension” of a beneficiary’s inpatient hospital stay. In this context, the 3-day qualifying hospital stay requirement serves to target more effectively the limited population that this benefit was originally created to cover: specifically, those beneficiaries who require a relatively intensive but also fairly brief course of SNF care as a continuation of their inpatient hospital stay.”

“Medicare Claims Processing Manual” Key Revision Summary
- In several sections, references to related material in other manuals are included.

Additional Information
The official instruction, CR9748, issued to your MAC regarding this change is available via three transmittals:


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.

Kentucky & Ohio

MM9552: Clarification of Certain Policies in Pub. 100-08, Chapter 15 Regarding the Processing of Form CMS-855R Applications

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9552
Related CR Release Date: September 16, 2016
Related CR Transmittal #: R676PI
Effective Date: December 19, 2016
Implementation Date: December 19, 2016

Provider Types Affected

This MLN Matters® Article is intended for individual suppliers who reassign their Medicare benefits to another supplier or provider.

What You Need to Know

Change Request (CR) 9552 clarifies policies in Chapter 15 (Medicare Enrollment) of the “Medicare Program Integrity Manual” concerning the processing of Form CMS-855R (Reassignment of Medicare Benefits) applications and adds a supplementary guide to this chapter that educates providers and suppliers on the preparation and submission of reassignment applications. A Form CMS-855R application must be completed for any individual who will: (1) reassign his/her benefits to an eligible entity, (2) terminate an existing reassignment, or (3) update the primary practice location listed on the Form CMS-855R. Separate Form CMS-855Rs must be completed for each transaction.

Make sure your billing staffs are aware of the clarifications and supplementary guide, which are discussed below.

Background

CR9552 does not involve any legislative or regulatory policies; it only clarifies existing policy. Key clarifications are:

• If a Form CMS-855R is accompanied by an initial Form CMS-855I or submitted as a “stand-alone” form (that is, a Form CMS-855R is submitted as a new reassignment, such as when an enrolled physician who is operating as a sole proprietor joins a group practice and reassigns his benefits to the group), the effective date of the enrollment and the reassignment shall be consistent with the 30-day rule (that is, the later of the date of filing or the date the reassign or first began furnishing services at the new location) specified in section 15.17 of Chapter 15.

• The Form CMS-855R application is not to be used to:
Report employment arrangements of physician assistants (PAs); employment arrangements for PAs must be reported on the Form CMS-855I.

- Revalidate reassignments; the individual practitioner should only use the Form CMS-855I and list his or her active reassignment information in Section 4B thereof.

A comprehensive supplementary guide is also available that further assists providers/suppliers and MACs on the correct processing of the Form CMS-855R. That guide and the revised manual chapter are attachments to CR9552.

Additional Information

The official instruction, CR9552, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R676PI.pdf

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

Kentucky & Ohio

MM9358: Affordable Care Act - Operating Rules - Requirements for Phase II and Phase III Compliance for Batch Processing

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

**MLN Matters® Number:** MM9358  **Related Change Request (CR) #:** CR 9358

**Related CR Release Date:** September 16, 2016  **Effective Date:** April 1, 2017

**Related CR Transmittal #:** R1716OTN  **Implementation Date:** April 3, 2017

**Provider Types Affected**

This MLN Matters® Article is intended for physicians and providers submitting claims to Medicare Administrative Contractors (MACs), including Home Health and Hospice MACs, for services provided to Medicare beneficiaries.

**What You Need to Know**

Change Request (CR) 9358 requires MACs to meet the connectivity and security requirements for the Phases II and III Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Operating Rules as well as the batch processing requirements for the Phase II CAQH CORE Operating Rules.

**Background**

The Centers for Medicare and Medicaid Services (CMS) is in the process of implementing Operating Rules adopted under Section 1104 of the Affordable Care Act. The Secretary of the Department of Health and Human Services (HHS) named the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules (CORE) as the authoring entity of the Phase I, II, and III Operating Rule. The Operating Rules are intended to provide additional direction and clarification to the Electronic Data Interchange (EDI) standard adopted under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. CMS is currently in the process of implementing the batch requirements for the Phase II rules for the Claim Status Inquiry and Response as well as the Phase III rules for the Electronic Remittance Advice (ERA) and Electronic Funds Transfer (EFT).
HIPAA transactions are referred to in the following manner:

- 276: ASC X12 Health Care Claim Status Request
- 277: ASC X12 Health Care Information Status Notification
- 835: ASC X12 Health Care Claim Payment/Advice
- 999: ASC X12 Implementation Acknowledgment For Health Care Insurance

CR9358 requires the MACs to implement a solution to comply with CAQH CORE Phase II Connectivity Rule 270, including the use of X.509 Client Certificates over SSL. This solution must be able to receive and post the batch 276/277 transactions for using the public internet for the Hypertext Transfer Protocol within a connection encrypted by Transport Layer Security (HTTP/S) transport. The MACs shall accept 276 transactions up until 9pm Eastern time of a business day, which equates to receipt of the 276 within the EDI front-end system for any 276 transactions submitted via either the MAC’s Electronic Data Interchange (EDI) gateway or the public Internet. The MAC must then return the 277 transaction by 7:00 am Eastern time the next business day. The MACs must also track the times of any received inbound messages with the capability to generate a report (audit log) that tracks the 999 response to the inbound 276 as well as date and timestamp for the 277, including the date and time the message was sent in HTTP+MIME or SOAP+WSDL Message Header tags. The MACs must support both Message Envelope Standards and Message Exchanges (HTTP+MIME) and Simple Object Access Protocol and Web Service Definition Language (SOAP+WSDL) Message. The solution must be able to report HTTP server errors with an HTTP 500 Internal Service Error or a HTTP 503 Service Unavailable error message for 276/277/835/999 transactions. The MACs must support Submitter Authentication Standards as detailed in Operating rule 153 for the 276/277/835/999 transactions.

The MACs will also develop and implement a solution using HTTP/S Version 1.1 over the public Internet as a transport method for the 835 in accordance with the Phase III Infrastructure Rule 350, which requires entities to support the Phase II CORE 270 Connectivity Rule Version 2.2.0. If a trading partner decides to transition to exchanging files over the public Internet, and the MAC’s environment does not permit for dual submission/retrieval using CORE and non-CORE connectivity, there will not be a transition period, just a scheduled flash cut. If the MAC’s environment has the ability to support the use of either gateway or public Internet, the MACs shall have discretion to make the business decision on transition and ability to switch between connectivity options.

MACs will make updates to their enrollment procedures, forms and trading partner management system for connectivity over the public Internet. **Enrollment in the Internet needs to be at the trading partner level.**

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](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html).
Kentucky & Ohio

MM9620 Revised: Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease, and Myelodysplastic Syndromes

The Centers for Medicare & Medicaid Services (CMS) has revised the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9620 Revised  Related Change Request (CR) #: CR 9620
Related CR Release Date: July 1, 2016  Effective Date: January 27, 2016
Related CR Transmittal #: R193NCD and R3556CP  Implementation Date: October 3, 2016

Note: This article was revised on September 26, 2016, to correct the language regarding the submission of professional claims on page 4 of the article. All other information remains the same.

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-NetworkMLN/MLNMattersArticles/Downloads/MM8197.pdf and MM8691 at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/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:

- Chapter 1, Section 110.23, of the “Medicare NCD Manual,” which is attached to the CR9620 NCD transmittal at http://www.cms.gov/Regulations-andGuidance/Guidance/Transmittals/Downloads/R191NCD.pdf

Please note, Chapter 1, Section 110.8.1 has been removed from the “NCD Manual” and incorporated into Chapter 1, Section 110.23.

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 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

The official instruction, CR9620, consists of two transmittals. The first updates the “Medicare
Transmittals/Downloads/R3556CP.pdf. The second transmittal updates the “Medicare NCD
R193NCD.pdf.

If you have any questions, please contact your MAC at their toll-free number. That number is
MLNMattersArticles/index.html under - How Does It Work.

Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 26, 2016</td>
<td>The article was revised to correct the language on page 4 regarding professional claims.</td>
</tr>
<tr>
<td>July 5, 2016</td>
<td>The article was revised due to an updated Change Request (CR). That CR revised Shared System Maintainer (SSM) responsibility. The transmittal number, CR release date and link to the transmittal also changed.</td>
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<tr>
<td>May 9, 2016</td>
<td>Initial article release</td>
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</table>
MM9778: Update to Hepatitis B Deductible and Coinsurance and Screening Pap Smears Claims Processing Information

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9778
Related CR Release Date: September 23, 2016
Related CR Transmittal #: R3615CP

Related Change Request (CR) #: CR 9778
Effective Date: December 27, 2016
Implementation Date: December 27, 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.

What You Need to Know

Change Request (CR) 9778 informs MACs about the updates to language regarding coinsurance and deductible for hepatitis B in the Chapter 18, Section 10 of the “Medicare Claims Processing Manual” to show that coinsurance and deductible for hepatitis B virus vaccine are waived. This is not a change in current policy and the CR only updates the manual to show current policy. CR9778 also removes subsection D from Sections 30.8 and 30.9 of Chapter 18 of the manual, which contained incorrect claims processing instructions regarding processing claims with HCPCS code G0476, HPV screening, when submitted on a Type of Bill other than 12X, 13X, 14X, 22X, 23x, and 85X.

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.

Kentucky & Ohio

MM9806: Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2017

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: MM9806
Related CR Release Date: September 23, 2016
Related CR Transmittal #: R3614CP

Related Change Request (CR) #: CR 9806
Effective Date: October 1, 2016
Implementation Date: January 3, 2017
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) 9806 announces changes that will be included in the January 2017 quarterly release of the edit module for clinical diagnosis laboratory services. Make sure your billing staffs are aware of these changes to ensure proper billing to Medicare.

Background
The National Coverage Determinations (NCDs) for clinical diagnostic laboratory services were developed by the laboratory negotiated rulemaking committee and the final rule was published on November 23, 2001. Medicare developed nationally uniform software that was incorporated in the Medicare shared systems so that laboratory claims subject to one of the 23 NCDs (Publication 100-03, Sections 190.12-190.34) were processed uniformly throughout the United States effective April 1, 2003.

CR9806 communicates requirements to Medicare system maintainers and the MACs regarding changes to the NCD code lists used for laboratory claims edit software for January 2017. The changes are a result of coding analysis decisions developed under the procedures for maintenance of codes in the negotiated NCDs and biannual updates of the ICD-10-CM codes. Please see Section II (Business Requirements Table) of CR9806 for the lengthy list of codes added or deleted. Note that where codes are deleted, the effective date of deletion is September 30, 2016 and the effective date for codes added is October 1, 2016.

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.

Kentucky & Ohio

MM9773: October 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

<table>
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<th>MLN Matters® Number: MM9773</th>
<th>Related Change Request (CR) #: CR 9773</th>
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<tr>
<td>Related CR Release Date: August 26, 2016</td>
<td>Effective Date: October 1, 2016</td>
</tr>
<tr>
<td>Related CR Transmittal #: R3601CP</td>
<td>Implementation Date: October 3, 2016</td>
</tr>
</tbody>
</table>

Provider Types Affected
This MLN Matters® Article is intended for Ambulatory Surgical Centers (ASCs) submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.
Provider Action Needed

Change Request (CR) 9773 informs MACs about the updates to the ASC payment system, payment rates for separately payable drugs and biologicals, including descriptors for newly created Level II Healthcare Common Procedure Coding System (HCPCS) codes for drugs and biologicals (ASC DRUG files), the ASC Payment Indicator (ASCPI) file, and the CY 2016 ASC payment rates for covered surgical and ancillary services (ASCFS file). Make sure that your billing staffs are aware of these changes.

Background

CR9773 contains updates to the ASC payment system, payment rates for separately payable drugs and biologicals, descriptors for newly created Level II HCPCS codes for drugs and biologicals (ASC DRUG files), the ASC PI file, and the CY 2016 ASC payment rates for covered surgical and ancillary services. The key points of CR9773 are:

1. **New Separately Payable Procedure Code Effective October 1, 2016**
   Effective October 1, 2016 a new HCPCS code C9744 has been created. Table 1, provides the short and long descriptors and the ASC PI for this new code.

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9744</td>
<td>Abd us w/contrast</td>
<td>Ultrasound, abdominal, with contrast</td>
<td>Z3</td>
</tr>
</tbody>
</table>

2. **Drugs, Biologicals, and Radiopharmaceuticals**
   a. **Drugs and Biologicals with Payments Based on Average Sales Price (ASP) Effective October 1, 2016**
      For CY 2016, payment for non-pass-through drugs, biologicals, and therapeutic radiopharmaceuticals is made at a single rate of ASP plus 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological or therapeutic radiopharmaceutical. In CY 2016, a single payment of ASP plus 6 percent for pass-through drugs, biologicals, and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Updated payment rates effective October 1, 2016, are available in the October 2016 ASC Addendum BB on the Centers for Medicare & Medicaid Services (CMS) website at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html).
   b. **Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates**
      Some drugs and biologicals based on ASP methodology may have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS website on the first date of the quarter at [http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html](http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html). Suppliers who think they may have received an incorrect payment for drugs and biologicals impacted by these corrections may request contractor adjustment of the previously processed claims.
   c. **New CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective October 1, 2016**
      Four new HCPCS codes have been created for reporting drugs and biologicals in the ASC setting effective October 1, 2016. These new codes, their descriptors, and ASC payment indicators are listed in Table 2.
d. Revised Status Indicator for Biosimilar Biological Product

On April 5, 2016, a biosimilar biological product, Inflectra®, was approved by the Food and Drug Administration (FDA). Due to the unavailability of pricing information, Inflectra®, described by CPT code Q5102 (Injection, Infliximab, Biosimilar, 10 mg), is assigned ASC PI= E5 (Surgical procedure/item not valid for Medicare purposes because of coverage, regulation and or statute; no payment made) effective April 5, 2016. Inflectra® was previously assigned a payable payment status of ASC PI= K2 effective April 5, 2016, in the July 2016 update. The payment rate was $0.00. No MAC adjustments or reprocessing of any previously processed claims for this HCPCS code is required.

3. Pass-through Device Offset Payment Amount CR9773 reminds the MACs that the policy for separate payment of an ASC pass-through device was created to recognize the additional costs associated with using this higher cost device whose entire costs are not included in the associated procedure payment rate. Except for a pass-through device that has an FB/FC appended modifier, lower submitted charges/invoice/cost, or some other policy/processing scenario that would result in a reduced pass-through device payment amount, CMS would typically expect to see that ASCs would receive combined payment amounts for both the pass-through device and procedure that exceed the payment rate for that same procedure when it is not offset, and for which no pass-through device is submitted.

3. Coverage Determinations

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

Additional Information


If you have 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.

Table 2 – New CY 2016 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Effective October 1, 2016

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
<th>ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9139</td>
<td>Idelvion, 1 i.u.</td>
<td>Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.</td>
<td>K2</td>
</tr>
<tr>
<td>C9481</td>
<td>Injection, reslizumab</td>
<td>Injection, reslizumab, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9482</td>
<td>Sotalol hydrochloride IV</td>
<td>Injection, sotalol hydrochloride, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9483</td>
<td>Injection, atezolizumab</td>
<td>Injection, atezolizumab, 10 mg</td>
<td>K2</td>
</tr>
</tbody>
</table>
**MM9719 Revised: Editing Update for Screening for Sexually Transmitted Infections**

The Centers for Medicare & Medicaid Services (CMS) has revised the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9719 Revised  
**Related CR Release Date:** September 1, 2016  
**Related CR Transmittal #:** R1713OTN  
**Related Change Request (CR) #:** CR 9719  
**Effective Date:** For claims with dates of service on or after October 1, 2015  
**Implementation Date:** January 3, 2017

**Note:** This article was revised on September 8, 2016, due to an updated Change Request (CR). The CR modified the effective date and made changes to the Background section to reflect that change. The transmittal number CR release date and link to the transmittal also changed. All other information remains the same.

**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 to Medicare beneficiaries.

**Provider Action Needed**

CR 9719 informs MACs about the changes to certain edits that should have been written as line level denials rather than claim denials if you do not report the appropriate diagnosis code. Make sure that your billing staffs are aware of these changes.

**Background**

CR7610, Transmittal 2476, provided billing instructions for Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling to Prevent STIs. It was brought to Centers for Medicare & Medicaid Services (CMS) attention that 072X Type of Bill (TOB) claims containing STI codes and diagnosis V74.5 or V73.89, with dates of service on or after October 1, 2015, were incorrectly being denied. Per CR7610 ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R141NCD.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R141NCD.pdf)), current editing would deny a claim for STI services submitted with diagnosis code V74.5 or V73.89 on a TOB other than 13X, 14X, or 85X (without revenue code 096X, 097X, or 098X).

To correct these problems, CR9719 instructs the MACs to modify existing editing to deny line items on claims for STIs (HCPCS 86631, 86632, 87110, 87270, 87490, 87491, 87810, 87800, 87590, 87591, 87850, 87800, 86592, 86593, 86780, 87340, or 87341) containing ICD-9 code V74.5 or V73.89 (for claims with dates of service before October 1, 2015) and ICD-10 code Z11.3 or Z11.59 (with dates of service on or after October 1, 2015) when submitted on a TOB other than 13X, 14X, or 85X (without revenue code 096X, 097X, or 098X). When denying these line items, MACs will use the following messages:

- **CARC170:** “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 PR (Patient Responsibility) assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed Advance Beneficiary Notice (ABN) is on file).”
CR9719 represents no change in policy. CMS is modifying existing editing to ensure correct payment for claims related to STIs.

Additional Information


Document History

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<th>Description</th>
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<td>September 8, 2016</td>
<td>The article was revised on, due to an updated Change Request (CR). The CR modified the effective date and made changes to the Background section in the CR. The transmittal number CR release date and link to the transmittal also changed.</td>
</tr>
<tr>
<td>August 6, 2016</td>
<td>Initial article released.</td>
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</table>

Kentucky & Ohio

SE1622: 2016-2017 Influenza (Flu)
Resources for Health Care Professionals

The Centers for Medicare & Medicaid Services (CMS) has issued the following Special Edition Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: SE1622
Related CR Release Date: N/A
Related CR Transmittal #: N/A
MLN Matters® Number: SE1622
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

Provider Types Affected

All health care professionals who order, refer, or provide flu vaccines and vaccine administration to Medicare beneficiaries.

What You Need to Know

- Keep this Special Edition MLN Matters® article and refer to it throughout the 2016 - 2017 flu season.
- Take advantage of each office visit as an opportunity to encourage your patients to protect themselves from the flu and serious complications by getting a flu shot.
- Continue to provide the flu shot as long as you have vaccine available, even after the new year.
- Remember to immunize yourself and your staff.

Introduction

The Centers for Medicare & Medicaid Services (CMS) reminds health care professionals that Medicare Part B reimburses health care providers for flu vaccines and their administration.
(Medicare provides coverage of the flu vaccine without any out-of-pocket costs to the Medicare patient. No deductible or copayment/coinsurance applies.)

You can help your Medicare patients reduce their risk for contracting seasonal flu and serious complications by using every office visit as an opportunity to recommend they take advantage of Medicare’s coverage of the annual flu shot.

As a reminder, please help prevent the spread of flu by immunizing yourself and your staff!

**Know What to Do About the Flu!**

**Payment Rates for 2016-2017**

Each year, CMS updates the Medicare Healthcare Common Procedure Coding System (HCPCS) and Current Procedure Terminology (CPT) codes and payment rates for personal influenza (flu) and pneumococcal vaccines. Payment allowance limits for such vaccines are 95 percent of the Average Wholesale Price (AWP), except where the vaccine is furnished in a hospital outpatient department, Rural Health Clinic (RHC), or Federally Qualified Health Center (FQHC). In these cases, the payment for the vaccine is based on reasonable cost.

Annual Part B deductible and coinsurance amounts do not apply. All physicians, non-physician practitioners, and suppliers who administer the influenza virus vaccination and the pneumococcal vaccination must take assignment on the claim for the vaccine.

Effective for services provided on August 1, 2016, through those provided on July 31, 2017, the following Medicare Part B payment allowances for HCPCS and CPT codes apply.

<table>
<thead>
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<th>CPT Codes:</th>
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<tr>
<td><strong>CPT Code</strong></td>
</tr>
<tr>
<td>90630</td>
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<tr>
<th>HCPCS Codes:</th>
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<tr>
<td><strong>HCPCS Code</strong></td>
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<tr>
<td>Q2035</td>
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<tr>
<td>Q2036</td>
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<td>Q2037</td>
</tr>
<tr>
<td>Q2038</td>
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<td>Q2039</td>
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</tbody>
</table>
Educational Products for Health Care Professionals

The Medicare Learning Network® (MLN) has developed a variety of educational resources to help you understand Medicare guidelines for seasonal flu vaccines and their administration.

1. MLN Influenza Related Products for Health Care Professionals
   - Preventive Services chart - [https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html](https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html)
   - MLN Preventive Services Educational Products web page - [https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/ProviderResources.html](https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/ProviderResources.html)

2. Other CMS Resources
   - Prevention General Information - [http://www.cms.gov/Medicare/Prevention/PreventionGenInfo/index.html](http://www.cms.gov/Medicare/Prevention/PreventionGenInfo/index.html)

3. Other Resources
   The following non-CMS resources are just a few of the many available in you may find useful information and tools for the 2016 – 2017 flu season:

   - Other sites with helpful information include:
     > Centers for Disease Control and Prevention - [http://www.cdc.gov/flu](http://www.cdc.gov/flu)
     - Food and Drug Administration - [http://www.fda.gov](http://www.fda.gov)
     - Immunization Action Coalition - [http://www.immunize.org](http://www.immunize.org)
     - Indian Health Services - [http://www.ihs.gov](http://www.ihs.gov)
     - National Alliance for Hispanic Health - [http://www.hispanichealth.org](http://www.hispanichealth.org)
     - National Foundation For Infectious Diseases - [http://www.nfid.org/influenza](http://www.nfid.org/influenza)
     - National Vaccine Program - [http://www.hhs.gov/nvpo](http://www.hhs.gov/nvpo)
     - World Health Organization - [http://www.who.int/en](http://www.who.int/en)
Beneficiary Information
For information to share with your Medicare patients, please visit http://www.medicare.gov.

Kentucky & Ohio

SE1620 Revised: Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template

The Centers for Medicare & Medicaid Services (CMS) has revised the following Special Edition Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2016-MLN-Matters-Articles.html

MLN Matters® Number: SE1620 Revised
Related CR Release Date: N/A
Related CR Transmittal #: N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

NOTE: This article was revised on September 14, 2016, to update the attached manual. The illustrations for the notepad and excel were changed. In the table on page 3 the field name “test name” was removed. All other information is unchanged.

Provider Types Affected
This article is intended for Medicare Part B clinical laboratories who submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries.

What You Need to Know
This guidance is intended to assist the laboratory community in meeting the new requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). The Quick User Guide, which includes guidance for the Fee-For-Service Data Collection System (FFSDCS) CLFS data reporting template, is included as an attachment in this article.

NOTE: The FFSDCS is undergoing its final stage of testing and will not be accessible to the public until November 2016. Laboratories can view the required format for reporting their data through the FFSDCS on the Clinical Laboratory Fee Schedule web page.

Additional Information
For more information about the new private payor rate based payment system including the CLFS final rule, related press release and fact sheet, frequently asked questions on our final policies, and a PowerPoint slide presentation of the new CLFS, visit https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ClinicalLabFeeSched/PAMA-Regulations.html.

If you have questions about requirements for the new CLFS, please email them to the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov.

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-LearningNetwork-MLN/MLNMattersArticles/index.html

Document History

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