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What’s Inside...

Administration
CMS Quarterly Provider Update ................................................................. 3
Going Beyond Diagnosis ............................................................................. 3
Get Your Medicare News Electronically ..................................................... 5
Claim Status Category and Claim Status Codes Update .......................... 8
2017 Annual Update for the Health Professional Shortage Area (HPSA)
  Bonus Payments ................................................................................... 10
Clarification of Certain Policies in Pub. 100-08, Chapter 15 Regarding the Processing of
  Form CMS-855R Applications ............................................................... 11

Drugs and Biologicals
Influenza Vaccine Payment Allowances - Annual Update for 2016-2017 Season .......... 12
2016-2017 Influenza (Flu) Resources for Health Care Professionals ....................... 14

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
October Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics, and
  Supplies (DMEPOS) Fee Schedule ......................................................... 17

Education
Educational Events Now Available ............................................................. 19

Electronic Data Interchange (EDI)
Healthcare Provider Taxonomy Codes October 2016 Code Set Update .................... 20
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) .................... 22
Affordable Care Act - Operating Rules - Requirements for Phase II and Phase III
  Compliance for Batch Processing ................................................................ 24

The Part B Medicare Advisory contains coverage, billing and other information for Part B. This information is not
intended to constitute legal advice. It is our official notice to those we serve concerning their responsibilities and
obligations as mandated by Medicare regulations and guidelines. This information is readily available at no cost
on the Palmetto GBA website. It is the responsibility of each facility to obtain this information and to follow the
guidelines. The Part B Medicare Advisory includes information provided by the Centers for Medicare & Medicaid
Services (CMS) and is current at the time of publication. The information is subject to change at any time. This bulletin
should be shared with all health care practitioners and managerial members of the provider staff. Bulletins are available at no-cost from our website at http://www.PalmettoGBA.com/JMB.

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on Dental Procedures and Nomenclature is published in Current Dental Terminology (CDT), Copyright © 2015
American Dental Association (ADA). All rights reserved.
### Fee Schedules and Reimbursement

- Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2016 Update ......................................................... 26
- Annual Clotting Factor Furnishing Fee Update 2017 ................................................................................................................................. 28

### Medicine

- Coding Revisions to National Coverage Determination (NCDs) .............................................................................................................. 29

### Ambulance

- Ambulance Staffing Requirements .................................................................................................................................................. 31

### Ambulatory Surgical Center (ASC)

- October 2016 Update of the Ambulatory Surgical Center (ASC) Payment System ................................................................. 36

### Laboratory

- Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template ........................................ 39
- Quick User Guide for Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template ............................................................................................... 40

### Skilled Nursing Facility

- Overview of the Skilled Nursing Facility Value-Based Purchasing Program ........................................................................................................... 47
- Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) ................................................ 50

### Etcetera

- Medical Director’s Desk .............................................................................................................................................................. 53
- CMS e-News .................................................................................................................................................................................. 67

### CMS Provider Minute Videos

The Medicare Learning Network has a series of CMS Provider Minute Videos ([https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Multimedia.html](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Multimedia.html)) on a variety of topics, such as psychiatry, preventive services, lumbar spinal infusion, and much more. The videos offer tips and guidelines to help you properly submit claims and maintain sufficient supporting documentation. Check the site often as CMS adds new videos periodically to further help you navigate the Medicare program.
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 non-regulatory changes to Medicare including program memoranda, 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
- 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, sign up for the Quarterly Provider Update listserv (electronic mailing list) at https://public.govdelivery.com/accounts/USCMS/subscriber/new?pop=t&qsp=566.

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

**Going Beyond Diagnosis**

**Preventing Payment Errors by Improving Provider-Payer Communication**

A failure to communicate is the number one cause of Medicare claims denials. Palmetto GBA’s Going Beyond Diagnosis (GBD) process helps reduce Medicare denials by supporting the dissemination of best practices and process improvements. The GBD Blog was established to provide a platform for discussing the challenges and complexities of communicating health care encounters and to provide potential solutions to identify the root causes for specific communication errors.

The GBD Blog and Twitter ID @BeyondDx are part of Palmetto GBA’s innovative strategy for increasing the capacity of Medicare providers to improve the quality of healthcare records and effectively decrease the claims payment error rate. The success of this social media approach to communicating with healthcare stakeholders depends on your active participation.

True innovation requires collaboration. Please join the on-line GBD community by visiting the GBD Blog at http://palmgba.com/gbd/ or signing-up to follow us on Twitter @BeyondDx.
Palmetto GBA Advanced Clinical Editing System (P-ACE)

Palmetto GBA Advanced Clinical Editing System (P-ACE) is available to all direct submitters as well as those who transmit claims via clearinghouses/billing services. New CEM ‘Smart edits’ will appear on claim rejection reports (277CA) as Palmetto GBA deploys P-ACE to the electronic claim submission process for professional claims.

- P-ACE returns pre-adjudicated claims information through claim acknowledgement transaction reports sent by your clearinghouse based on the Medicare 277CA
- All direct submitters will receive the Medicare 277CA report with the new smart edits
- Claims failing the pre-adjudication editing process are not forwarded to the claims adjudication system
- P-ACE will work with your current clearinghouse/billing service workflow so you can modify claims before the MCS system receives them

After you have reviewed the Smart Edit, if you choose not to change the claims, you can resubmit in its original format and it will pass to the MCS claims adjudication system for processing. P-ACE is available to you at no cost! No downloads or software is required. P-ACE is incorporated in your normal EDI stream.

Unsure what the P-ACE Smart Edit means?
Smart Edits are not directives, but rather considerations for appropriate claims processing based upon the information submitted on the claim. Medicare will continue to require that all documentation and coverage requirements are met prior to providers making the claim change.

To use the P-ACE Smart Edit Lookup tool, enter the P-ACE Smart Edit # from/for the claim. On the second screen you will see the P-ACE Smart Edit Message, description, and any additional information pertinent to your claim. Only P-ACE Smart Edit #’s listed in the Advance Clinical Editing page table will display.
Get Your Medicare News Electronically

The Palmetto GBA Medicare listserv is a wonderful communication tool that offers its members the opportunity to stay informed about:

- Medicare incentive programs
- New legislation concerning Medicare
- Fee Schedule changes
- And so much more!

**How to register to receive the Palmetto GBA Medicare Listserv:**

Go to [http://tinyurl.com/PalmettoGBAListserv](http://tinyurl.com/PalmettoGBAListserv) and select “Register Now.” Complete and submit the online form. Be sure to select the specialties that interest you so information can be sent.

**Note:** Once the registration information is entered, you will receive a confirmation/welcome message informing you that you’ve been successfully added to our listserv. You must acknowledge this confirmation within 3 days of your registration.

**CallBack Assist**

CallBack Assist was implemented to improve the wait times during peak calling periods of the day. CallBack Assist allows providers to opt out for a same-day callback from a customer service representative (CSR). Typically, the callback occurs within one hour. This feature is a contact center best practice among the industry. Providers are encouraged to try this new option when offered to avoid long wait times for assistance.

**eServices Makes Asking a Medicare Question Easier!**

Palmetto GBA is pleased to announce the newest addition to our eService options—Secure eChat! This innovative feature allows providers to interact with designated Palmetto GBA staff so they can receive real-time assistance locating information on any topics or specialties they are searching for on the Palmetto GBA website or within the eServices online portal. The Secure eChat feature also allows users to dialogue with an online operator who can assist with patient or provider specific inquiries or address questions that require the sharing of PHI information! Using Secure eChat is simple! This free portal is available to all Medicare providers as long as you have a signed Electronic Data Interchange (EDI) Enrollment Agreement on file with Palmetto GBA. Once in the eServices portal, from the bottom right corner select either Medicare Inquiries or eServices Help. If you do not have an eServices account, you can get started by clicking this eServices link [https://www.onlineproviderservices.com/ecx_improvev2/](https://www.onlineproviderservices.com/ecx_improvev2/). The Secure eChat feature is available during business hours to assist providers.

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Now You Can Access Your Personal Data to See Who Has Been Using Your NPI

Electronic Utilization (eUtilization) reports are now available in the eServices online provider portal. eUtilization reports provide rendering providers and ordering and referring providers access to their personal data. This data can be reviewed to ensure providers are aware of when and by whom their NPI is being used for billing Medicare services and when their NPI is entered on a Medicare claim as the ordering referring physician. This will provide providers with the ability to identify possible misuse of their NPI. Providers will be able to select a period from 1-12 months for the previous 12 months of data. This data will be updated monthly so that providers can trend their data over time.

Ordering and Referring
This function enables an individual physician to view all Medicare claims billed where their NPI was entered as the ordering and referring provider for a beneficiary. The report will also allow providers to click and see a summary by the type of code for the services billed.

Rendering
This will allow an individual provider who is part of a group practice or multiple groups to pull a data report for their NPI, which will enable them to view their utilization for each associated provider ID for a specified time period.

How to Sign Up to Receive This Data:
In order to access your data, you will need to have an eServices account. You can sign up at http://www.palmettogba.com/eservices

eDelivery Reminder: Are You Getting Your Greenmail?

Palmetto GBA would like to remind providers that you have the option to receive letters electronically through eServices. Gaining access to these letters is a simple process! To start receiving your Medicare letters, such as prior authorization or first level redeterminations decision letters electronically, you must be signed up for our eServices online provider portal. Once you have signed into eServices, select the Admin tab, next you can choose your eDelivery preferences. Just click the drop down box to choose eDelivery of the letters you would like to receive via greenmail. You can also select ‘User Email Notification’ to start receiving emails when your letters are available in eServices for you. Selecting this choice is so easy and allows you to receive your letters faster!

Once you have chosen the eDelivery option, all of the letters you selected will come to you electronically, even if you sent in your request via fax or mail.
Want to stay informed about the latest changes to the Medicare Program? Get connected with the Medicare Learning Network® (MLN) – the home for education, information, and resources for health care professionals.

The Medicare Learning Network® is a registered trademark of the Centers for Medicare & Medicaid Services (CMS) and the brand name for official CMS education and information for health care professionals. It provides educational products on Medicare-related topics, such as provider enrollment, preventive services, claims processing, provider compliance, and Medicare payment policies. MLN products are offered in a variety of formats, including training guides, articles, educational tools, booklets, fact sheets, web-based training courses (many of which offer continuing education credits) – all available to you free of charge!

The following items may be found on the CMS web page at:
• MLN Catalog: is a free interactive downloadable document that lists all MLN products by media format. To access the catalog, scroll to the “Downloads” section and select “MLN Catalog.” Once you have opened the catalog, you may either click on the title of a product or you can click on the type of “Formats Available.” This will link you to an online version of the product or the Product Ordering Page.
• MLN Product Ordering Page: allows you to order hard copy versions of various products. These products are available to you for free. To access the MLN Product Ordering Page, scroll to the “Related Links” and select “MLN Product Ordering Page.”
• MLN Product of the Month: highlights a Medicare provider education product or set of products each month along with some teaching aids, such as crossword puzzles, to help you learn more while having fun!

Other resources:
• MLN Publications List: contains the electronic versions of the downloadable publications. These products are available to you for free. To access the MLN Publications go to: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications.html. You will then be able to use the “Filter On” feature to search by topic or key word or you can sort by date, topic, title, or format.

MLN Educational Products Electronic Mailing List
To stay up-to-date on the latest news about new and revised MLN products and services, subscribe to the MLN Educational Products electronic mailing list! This service is free of charge. Once you subscribe, you will receive an e-mail when new and revised MLN products are released.

To subscribe to the service:
1. Go to https://list.nih.gov/cgi-bin/wa.exe?A0=mln_education_products-l and select the ‘Subscribe or Unsubscribe’ link under the ‘Options’ tab on the right side of the page.
2. Follow the instructions to set up an account and start receiving updates immediately – it’s that easy!

If you would like to contact the MLN, please email CMS at MLN@cms.hhs.gov.

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Claim Status Category and Claim Status Codes Update

MLN Matters® Number: MM9680
Related Change Request (CR) #: CR 9680
Related CR Release Date: August 26, 2016
Effective Date: January 1, 2017
Related CR Transmittal #: R3599CP
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

Continued >>
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

Appeals Calculator Self-Service Tool
Did you know you can use the appeals calculator to determine the timely filing date of your appeals request? All you have to do is select which level of appeal you are in and enter the date you received the response to your previous appeal. After clicking “Find Deadline,” the timely filing limit date will appear. This tool is very helpful to assure that you are filing your appeals on time. Providers may appeal claims that are partially or fully denied, as long as the claim has ‘appeal rights’. Different levels of appeals have different timelines in which the appeal rights are valid. Access the Appeals Calculator tool under Forms/Tools on the home page to calculate the your claims appeal deadlines.
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 webpage 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
Clarification of Certain Policies in Pub. 100-08, Chapter 15 Regarding the Processing of Form CMS-855R Applications

MLN Matters® Number: MM9552
Related Change Request (CR) #: CR 9552
Related CR Release Date: September 16, 2016
Effective Date: December 19, 2016
Related CR Transmittal #: R676PI
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 reassignor 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
Influenza Vaccine Payment Allowances - Annual Update for 2016-2017 Season

MLN Matters® Number: MM9758
Related Change Request (CR) #: CR 9758
Related CR Release Date: September 9, 2016
Effective Date: August 1, 2016
Related CR Transmittal #: R3611CP
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.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html. Make sure that your billing staffs are aware that the payment allowances are being updated.

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

Continued >>
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 webpage (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html) 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


Global Surgery Calculator Self-Service Tool

This tool will allow you to calculate both 10 and 90 day global surgery periods. You can also look up your 2016 procedure code global days requirement by using this tool. Just enter the procedure code in the tool and the global surgery indicator information will appear. Access the Global Surgery Calculator tool under Forms/Tools on the home page.

Global Surgery Calculator

Method 1: To determine when the global period ends for a major surgical procedure with a global period, please enter the date of surgery. A date picker box will then help guide you through the rest of the process.

**Enter the Date**

- 90 Days
- 10 Days

[Calculate]

Method 2: You can look up your 2016 procedure code global days requirement by using this tool. Enter your procedure code. Alternatively, you can go straight to our Medicare Physicians Fee Schedule Tool and lookup your code there.

**Enter your Procedure Code**

[Lookup]
2016-2017 Influenza (Flu) Resources for Health Care Professionals

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

Continued >>
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.

**CPT Codes:**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Effective Dates</th>
<th>Payment Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>90630</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90653</td>
<td>8/1/2016 – 7/31/2017</td>
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<td>90662</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90672</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90673</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90685</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90686</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90687</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>90688</td>
<td>8/1/2016– 7/31/2017</td>
<td>Pending</td>
</tr>
</tbody>
</table>

**HCPCS Codes:**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Effective Dates</th>
<th>Payment Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2035</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>Q2036</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>Q2037</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>Q2038</td>
<td>8/1/2016 – 7/31/2017</td>
<td>Pending</td>
</tr>
<tr>
<td>Q2039</td>
<td>8/1/2016– 7/31/2017</td>
<td>Flu Vaccine Adult – Not Otherwise Classified: Payment allowance is to be determined by the local claims processing contractor.</td>
</tr>
</tbody>
</table>

The above pricing, and any required updates, will be available at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html).

**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/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html](https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html)

Continued >>

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2. Other CMS Resources

- MLN Preventive Services Educational Products webpage - https://www.cms.gov/Medicare/Prevention/PreventionGenInfo/ProviderResources.html
- Prevention General Information - 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
  - Food and Drug Administration - http://www.fda.gov
  - Immunization Action Coalition - http://www.immunize.org
  - Indian Health Services - http://www.ihs.gov
  - National Alliance for Hispanic Health - http://www.hispanichealth.org
  - National Foundation For Infectious Diseases - http://www.nfid.org/influenza
  - National Vaccine Program - http://www.hhs.gov/nvpo
  - World Health Organization - http://www.who.int/en

Beneficiary Information

For information to share with your Medicare patients, please visit http://www.medicare.gov.
October Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule

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

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, managed care organizations, and other interested parties shortly after the release of the above PUF.
**Additional Information**


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**Denial Resolution Tool**

The Palmetto GBA Denial Resolution tool, located on the home page under Forms/Tools, includes resources for resolving the top claim rejections and denial reasons. Save time and resources by looking here before you pick up the phone.

- Access denial reasons in plain language
- Scroll through the titles to locate your procedure
- Use the Palmetto GBA search engine to search by remark code

<table>
<thead>
<tr>
<th>Anesthesia Services: Bundling Denials</th>
<th>09/01/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficiary Eligibility Denials</td>
<td>09/01/2015</td>
</tr>
<tr>
<td>C-Reactive Protein Testing: Medical Necessity Denials</td>
<td>09/01/2015</td>
</tr>
<tr>
<td>CERT Order Denials</td>
<td>09/01/2015</td>
</tr>
<tr>
<td>CERT Signature Denials</td>
<td>09/01/2015</td>
</tr>
<tr>
<td>Chest X-ray or EKG: Duplicate Denials</td>
<td>09/01/2015</td>
</tr>
<tr>
<td>Chiropractic Manipulative Treatment: Duplicate Denials</td>
<td>09/01/2015</td>
</tr>
</tbody>
</table>
Educational Events Now Available…Don’t Miss this Wonderful Opportunity!

Join the Provider Outreach and Education event listed below to learn about the Medicare program.

<table>
<thead>
<tr>
<th>Event Title</th>
<th>Date/Time</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locating Local Coverage Determinations, Coverage Articles and Self-Administered Drug Exclusion Lists Webcast</td>
<td>September 29, 2016 10 a.m. ET</td>
<td><a href="http://tinyurl.com/j6ggdne">http://tinyurl.com/j6ggdne</a></td>
</tr>
<tr>
<td>Ask the Contractor Teleconference</td>
<td>November 10, 2016, 10:00 am ET</td>
<td>Teleconference number: 866-745-0425 Passcode: 87679707</td>
</tr>
</tbody>
</table>
Healthcare Provider Taxonomy Codes October 2016 Code Set Update

MLN Matters® Number: MM9659
Related Change Request (CR) #: CR 9659
Related CR Release Date: August 26, 2016
Effective Date: October 1, 2016
Implementation Date: January 3, 2017, except some MACs may implement on October 1, 2016
Related CR Transmittal #: R3597CP

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 and Hospice MACs and Durable Medical Equipment MACs, for services provided to Medicare beneficiaries.

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.

Continued >>
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**


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**eServices Eligibility**

eServices, by Palmetto GBA, allows you to search for patient eligibility, which is a functionality of HETS. HETS requires you to enter beneficiary last name and HICN, in addition to either the birth date or first name. See options below:

- HICN, Last Name, First Name, Birth Date
- HICN, Last Name, Birth Date
- HICN, Last Name, First Name

For more information about eServices and the many services it offers, please visit our website at [http://www.PalmettoGBA.com/eServices](http://www.PalmettoGBA.com/eServices).
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)

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.

Continued >>

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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**

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**Review and Print Electronic Remittances – via eRemits**

Palmetto GBA is pleased to offer eRemits through our eServices, a free, web-based, provider self-service tool. You can view or print remittances, which are available for approximately one year. In addition, eServices will let you store remittances and utilize search features to find specific information on the notices. eRemits are available to be accessed every day between the hours of 8 a.m. and 7 p.m. ET.

To use eServices, you must have an Electronic Data Interchange (EDI) Agreement on file with Palmetto GBA. If you are already submitting claims electronically, you do not have to submit a new EDI Enrollment Agreement. For more information on EDI, please visit our website at [www.PalmettoGBA.com/EDI](http://www.PalmettoGBA.com/EDI).
Affordable Care Act - Operating Rules - Requirements for Phase II and Phase III Compliance for Batch Processing

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**

Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2016 Update

MLN Matters® Number: MM9749 Revised
Related Change Request (CR) #: CR 9749
Related CR Release Date: August 24, 2016
Effective Date: January 1, 2016
Related CR Transmittal #: R3595CP
Implementation Date: October 3, 2016

Note: This article was revised on August 24, 2016, due to a revised Change Request (CR). The transmittal number, CR release date and link to the CR also changed. All other information remains unchanged.

Provider Types Affected
This MLN Matters® Article is intended for physicians, provider and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries and subject to the Medicare Physician Fee Schedule (MPFS).

Provider Action Needed
This article is based on CR 9749, which informs you that payment files were issued to MACs based upon the Calendar Year (CY) MPFS Final Rule. This change request amends those payment files. Make sure that your billing staffs are aware of these changes.

Background
Section 1848(c)(4) of the Social Security Act authorizes the Secretary to establish ancillary policies necessary to implement relative values for physicians’ services. Unless otherwise stated, the changes included in the October update to the 2016 MPFSDB are effective for dates of service on and after January 1, 2016.

The key changes for the October update are the following:

<table>
<thead>
<tr>
<th>CPT/HCPCS Code</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0436</td>
<td>Procedure Status = I (Effective for services on or after 10-1-2016.)</td>
</tr>
<tr>
<td>G0437</td>
<td>Procedure Status = I (Effective for services on or after 10-1-2016.)</td>
</tr>
<tr>
<td>44799</td>
<td>Procedure Status = C; Global Surgery Days = YYY</td>
</tr>
<tr>
<td>32666</td>
<td>Bilateral Indicator = 1</td>
</tr>
</tbody>
</table>

The HCPCS codes listed below have been added to the MPFSDB effective for dates of service on and after October 1, 2016. All of these new codes were communicated through other instructions. Please consult those instructions for the description and other information.

Continued >>
<table>
<thead>
<tr>
<th>Code</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0490</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9679</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9680</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9681</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9682</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9683</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9684</td>
<td>Procedure Status = X; there are no RVUs; all policy indicators = concept does not apply</td>
</tr>
<tr>
<td>G9685</td>
<td>Procedure Status = A; RVUs = Work 3.86, Non-Facility 1.55, Facility 1.55, MP 0.29</td>
</tr>
<tr>
<td>G9686</td>
<td>Procedure Status = A; RVUs = Work 1.50, Non-Facility 0.61, Facility 0.61, MP 0.10</td>
</tr>
</tbody>
</table>

The following payment policy indicators apply to G9685 and G9686: Multiple Surgery = 0, Bilateral Surgery = 0, Assistant at Surgery = 0, Co-Surgeons = 0, Team Surgeons = 0, PC/TC = 0, Physician Supervision of Diagnostic Procedures = 09, and Diagnostic Imaging Family = 99. The Global Surgery Days = XXX.

New code G0498, listed below, has been added to the MPFSDB effective for dates of service on and after January 1, 2016. The Procedure Status is C and there are no RVUs. The following payment policy indicators apply to G0498: Multiple Surgery = 0, Bilateral Surgery = 0, Assistant at Surgery = 0, Co-Surgeons = 0, Team Surgeons = 0, PC/TC = 5, Physician Supervision of Diagnostic Procedures = 09, and Diagnostic Imaging Family = 99. The Global Surgery Days = YYY.

<table>
<thead>
<tr>
<th>Code</th>
<th>Short Descriptor</th>
<th>Long Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0498</td>
<td>Chemo extend iv infus w/pump</td>
<td>Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/other outpatient setting using office/other outpatient setting pump/supplies, with continuation of the infusion in the community setting (e.g., home, domiciliary, rest home or assisted living) using a portable pump provided by the office/other outpatient setting, includes follow up office/other outpatient visit at the conclusion of the infusion</td>
</tr>
</tbody>
</table>

Additional Information

Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 24, 2016</td>
<td>Note: The article was revised due to a revised Change Request (CR), The transmittal number, CR release date and link to the CR also changed.</td>
</tr>
<tr>
<td>August 19, 2016</td>
<td>Initial article released</td>
</tr>
</tbody>
</table>

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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
Coding Revisions to National Coverage Determination (NCDs)

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

Continued >>
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
Ambulance Staffing Requirements

MLN Matters® Number: MM9761
Revised Related Change Request (CR) #: CR 9761
Related CR Release Date: September 12, 2016
Effective Date: January 1, 2016
Related CR Transmittal #: R226BP
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.

Continued >>
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

Continued >>
• 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, “Ambulance,” Section 20.1.4 for payment of paramedic intercept services at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c15.pdf.
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

Document History

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 13, 2016</td>
<td>The article was revised due to a revised 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.</td>
</tr>
<tr>
<td>September 10, 2016</td>
<td>Initial article released</td>
</tr>
</tbody>
</table>

Medicare Physician Fees Lookup Tool

Use the Medicare Physician Fee Lookup Tool, located on our home page. The Physician Fee Schedule tool saves our customers time and money by providing a ‘one stop shop’! Customers can locate fees for the 2013 through 2016 throughout the United States. The tool can search up to five codes and each code shows the allowance, all of the indicator rules such as the Global Surgery modifiers and Multiple Surgery rules. This tool helps customers research more than a fee; they can determine if the wrong modifier was appended to a service, or if the service was subject to multiple surgery rules. The fees and indicator files are downloadable and customers can easily save the data to their systems for future use.

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

MLN Matters® Number: MM9773
Related Change Request (CR) #: CR 9773
Related CR Release Date: August 26, 2016
Effective Date: October 1, 2016
Related CR Transmittal #: R3601CP
Implementation Date: October 3, 2016

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 1 – New Separately Payable Procedure Code Effective October 1, 2016

<table>
<thead>
<tr>
<th>HCPCS Code</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

Continued >>
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.

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.

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.

<table>
<thead>
<tr>
<th>HCPCS Code</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, 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>

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

Continued >>

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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.

4. 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

Global Surgery Denial Tool
If the procedure code was denied with remittance message CO-B15/CO-97 (claim/service denied/reduced because this procedure/service is not paid separately OR payment is included in the allowance for another service/procedure), then use the following worksheet to see what, if any, corrections you can make to your claim. Just answer a few questions, and the tool will provide you with information to help you with your service. Access the Global Surgery Denial tool under Forms/Tools on the home page.
Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template

MLN Matters® Number: SE1620
Revised Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation 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 at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

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.

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Quick User Guide

Fee-For-Service Data Collection System:
Clinical Laboratory Fee Schedule Data Reporting Template
TABLE OF CONTENTS

OVERVIEW......................................................................................... 1
NAVIGATING THE TEMPLATE......................................................... 1
TEMPLATE CONSTRAINTS.............................................................. 2
FIELD DEFINITIONS........................................................................ 3
TEMPLATE REQUIREMENTS........................................................... 3
LIST OF FIGURES

Figure 1 – The CLFS template view using Notepad....... 3
Figure 2 – The CLFS template view using MS Excel...... 3
1 OVERVIEW

Section 1834A of the Social Security Act (the Act), added by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), significantly changes how Medicare payment rates are set for clinical diagnostic laboratory tests (CDLTs) paid under the Medicare Clinical Laboratory Fee schedule (CLFS). In general, the Centers for Medicare & Medicaid Services (CMS) will establish Medicare payment rates for CDLTs on the Clinical Laboratory Fee Schedule (CLFS) based on the weighted median of the rates that private payors pay for the test during a specified data collection period. Applicable laboratories must collect applicable information (that is, private payor rates and associated volume for covered tests identified by HCPCS codes) for the period beginning January 1, 2016, through June 30, 2016. Applicable laboratories must report their data to CMS beginning January 1, 2017, through March 31, 2017. CMS will use this data to calculate payment rates for the calendar year 2018 CLFS update.

The CLFS data reporting template provides the required data fields for reporting applicable information for the CLFS private payor rate-based system. “Comma Separated Value” (.csv) is the available format for data submission through a file upload process. Alternatively, data may be submitted through an online interface. Data must be reported to CMS through the Fee-For-Service Data Collection System (FFSDCS) CLFS System at https://portal.cms.gov. For detailed guidance on data collection and reporting, refer to Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System.

NOTE: The requirements under Section 1834A of the Act and the data reported on this form are exempt from the requirements of the Paperwork Reduction Act (Chapter 35 of Title 44, United States Code).

2 NAVIGATING THE TEMPLATE

- The template file is named “CLFS-Lab Data-Collection-Final.csv”. You can access it in the Downloads section on the Clinical Laboratory Fee Schedule web page.
- The CLFS .csv template may be opened using a text editor, such as Notepad or a spreadsheet application such as MS Excel.

Quick User Guide Version 1.1/September 13, 2016
The template opened with Notepad:

![Figure 1 – The CLFS template view using Notepad](image)

The template opened with MS Excel:

![Figure 2 – The CLFS template view using MS Excel](image)

### 3 TEMPLATE CONSTRAINTS

- The template may be populated through system generated content or manually via an online interface
- Do not manipulate the Header Row (Row 1)
- Report data in the order specified by the template
- A comma must separate each value
- The CLFS System will not recognize any formatting or manipulation in Excel
- The CLFS System will validate data fields as defined by “Field Definition” in Table 1

Quick User Guide Version 1.1/September 13, 2016
4 FIELD DEFINITIONS

You must enter properly formatted data through the provided template.

Table 1: Field Definitions for CLFS Template

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Definition</th>
<th>Value Values</th>
<th>Required Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS Code</td>
<td>Standardized coding system used to represent medical procedures performed on a patient or non-physician services.</td>
<td>5 alphanumeric characters are accepted.</td>
<td>Yes</td>
</tr>
<tr>
<td>Payment Rate</td>
<td>Each unique private payor rate for each test.</td>
<td>Only numeric values are accepted. Values include numeric characters with 2 decimal places. Formatted as XXXXX.XX.</td>
<td>Yes</td>
</tr>
<tr>
<td>Volume</td>
<td>Number of lab tests paid at each unique private payor rate.</td>
<td>Only positive numeric values including 0 are accepted. Values include numeric characters, no decimal places. Formatted as XXXXX.</td>
<td>Yes</td>
</tr>
<tr>
<td>National Provider Identifier</td>
<td>A unique 10-digit identification number required by HIPAA for all health care transactions by providers in the United States.</td>
<td>10 numeric digits are accepted.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

5 TEMPLATE REQUIREMENTS

1. Do not add additional columns to the template.
2. Do not add, remove, or otherwise change columns or column headings within the template.
3. Do not submit blank rows between data entries. You must submit all data in contiguous rows.
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: 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.

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 and will become effective on January 1, 2017.

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.

Additional Information
Overview of the Skilled Nursing Facility Value-Based Purchasing Program

MLN Matters® Number: SE1621
Related Change Request (CR) #: N/A
Related CR Release Date: N/A
Effective Date: N/A
Related CR Transmittal #: N/A
Implementation Date: N/A

Provider Types Affected
This article is intended for physicians, clinical staff, and administrators of Skilled Nursing Facilities (SNFs) submitting claims under the SNF Prospective Payment System (PPS) to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries during a SNF stay.

What You Need to Know
The Centers for Medicare & Medicaid Services (CMS) SNF Value-Based Purchasing (VBP) Program is one of many VBP programs that aims to reward quality and improve health care. Beginning October 1, 2018, SNFs will have an opportunity to receive incentive payments based on performance on the specified quality measure.

Background
The Protecting Access to Medicare Act (PAMA) of 2014, enacted into law on April 1, 2014, authorized the SNF VBP program. PAMA requires CMS to adopt a VBP payment adjustment for SNFs beginning October 1, 2018. By law, the SNF VBP Program is limited to a single readmission measure at a time.

PAMA requires CMS, among other things, to:
• Furnish value-based incentive payments to SNFs for services beginning October 1, 2018.
• Develop a methodology for assessing performance scores.
• Adopt performance standards on a quality measure that include achievement and improvement.
• Rank SNFs based on their performance from low to high. The highest ranked facilities will receive the highest payments, and the lowest ranked 40 percent of facilities will receive payments that are less than what they otherwise would have received without the Program.

CMS will withhold 2 percent of SNF Medicare payments starting October 1, 2018, to fund the incentive payment pool and will then redistribute 50-70 percent of the withheld payments back to SNFs through the SNF VBP Program.

Readmissions Measures
Skilled Nursing Facility 30-Day All Cause Readmission Measure (SNFRM)
In the Fiscal Year (FY) 2016 SNF Prospective Payment System (PPS) final rule, CMS adopted the SNFRM as the first measure for the SNF VBP Program. The measure is defined as the risk-standardized rate of all-cause, unplanned hospital readmissions of Medicare beneficiaries within 30 days of discharge from their prior hospitalization. Hospital readmissions are identified through Medicare hospital claims (not SNF claims) so no readmission data is collected from SNFs and there are no additional reporting requirements for the measure.

Continued >>
This measure is endorsed by the National Quality Forum.

Readmissions to a hospital within the 30-day window are counted regardless of whether the beneficiary is readmitted directly from the SNF or after discharge from the SNF as long as the beneficiary was admitted to the SNF within 1 day of discharge from a hospital stay. The measure excludes planned readmissions because they do not indicate poor quality of care. The measure is risk-adjusted based on patient demographics, principal diagnosis from the prior hospitalization, comorbidities, and other health status variables that affect probability of readmission.

Other exclusions include patients who were hospitalized for medical treatment of cancer, do not have Medicare Part A coverage for the full 30-day window, and do not have Part A coverage for the 12 months preceding the prior hospital discharge. Additional exclusions include SNF stays with:

• An intervening post-acute care admission within the 30-day window,
• Patient discharge from the SNF against medical advice,
• Principal diagnosis in prior hospitalization was for rehabilitation, fitting of prosthetics, or adjustment of devices,
• Prior hospitalization for pregnancy, and
• Other reasons documented in the measure’s technical specifications.

**Skilled Nursing Facility 30-Day Potentially Preventable Readmission (SNFPPR) Measure**

On July 29, 2016, CMS adopted the SNFPPR measure for future use in the SNF VBP Program. The SNFPPR measure assesses the risk-standardized rate of unplanned, Potentially Preventable Readmissions (PPRs) for Medicare Fee-For-Service SNF patients within 30 days of discharge from a prior hospitalization.

Potentially preventable hospital readmissions for post-acute care are defined using the existing evidence, empirical analysis, and technical expert panel input. However, the key difference between the SNFRM and SNFPPR measures is that the SNFPPR focuses on potentially preventable readmissions rather than all-cause readmissions. As required by the Program’s statute, CMS will replace the SNFRM with the SNFPPR as soon as practicable.

**Performance Scoring**

CMS has adopted these scoring methodologies to measure SNF performance that includes levels of achievement and improvement:

• Achievement scoring compares a SNF’s performance rate in a performance period against all SNFs’ performance during the baseline period
• Improvement scoring compares a SNF’s performance during the performance period against its own prior performance during the baseline period

For FY 2019 of the SNF VBP Program, achievement scoring will compare SNFs’ 2017 performance to the performance of all facilities during Calendar Year (CY) 2015. Improvement scoring methodology will compare a SNFs’ 2017 performance to its own prior performance during CY 2015. For more information about the SNF VBP Program’s scoring methodology, refer to the FY 2017 SNF PPS final rule ([https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18113.pdf](https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18113.pdf)).
Quality Feedback Reports
On October 1, 2016, SNFs will begin receiving quarterly confidential feedback reports about their performance in the SNF VBP Program via the Certification and Survey Provider Enhanced Reporting (CASPER) system.

Additional Information

If you have additional questions, please email them to: SNFVBPinquiries@cms.hhs.gov.

A list of current system-related claims payment issues is available on our website. These issues were reported to the Centers for Medicare & Medicaid Services (CMS) and/or the Multi-Carrier System (MCS). Please check often for updates before contacting the provider contact center. The issues are identified by stand alone articles and will be updated as needed.

Be sure to sign-up to receive updates using the “Article Update Notification” feature.
MLN Matters® Number: MM9748
Related Change Request (CR) #: CR 9748
Related CR Release Date: September 16, 2016
Effective Date: October 18, 2016
Related CR Transmittal #: R101GI, R227BP and R3612CP
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.

Continued >>
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:

eServices: Claim Status
To check on a particular claim status, please enter the HICN and other required beneficiary information, as well as the date(s) of service. Should you not know the exact date of service, you are able to enter a span or range of up to 45 days. Please keep in mind, retrieving claims older than six months takes a little longer than something more current. Claims older than three years may not be searchable. For more information about eServices and the many services it offers, please visit our website at http://www.PalmettoGBA.com/eServices.
Interactive Tools

These guides provide instruction on how to complete or interpret the following forms. They are available on the home page, under Forms/Tools.

Remittance Advice

EDI Agreement

EDI Application

EDI Provider Authorization

CMS 1500 Claim Form

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Medical Director’s Desk

Medical Affairs publishes Medicare Local Coverage Determination (LCDs) and medically related articles in this special section of the Medicare Advisory. We encourage you to help us maintain accurate LCDs. Please review LCDs and address your comments and concerns to your Carrier Advisory Committee specialty representative or contact the Medical Affairs Department.

Medical articles are published in the Medicare Advisory to provide education and alert Medicare providers of billing/coding issues. Remember, physicians and non-physician practitioners (NPPs) who bill Medicare are responsible for accurate service coding. Errors may result in overpayment requests or Recovery Auditor (RA) referrals. If you purchase a new device or need to submit claims for a new procedure, please review applicable service codes and descriptions in the current CPT and HCPCS manuals. If you question the recommended service procedures received from other sources such as manufacturers, send your inquiry and the device description to the Medical Affairs Department.

To contact the Medical Affairs Department:

e-mail: B.Policy@PalmettoGBA.com
Mail: Part B Medical Affairs, AG-300
     Palmetto GBA
     PO Box 100190
     Columbia, SC 29202-3190

Continued >>
### Part B Local Coverage Determinations

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Response to Comments</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>Oral Maxillofacial Prosthesis L33468 Rev #3</td>
<td>The comment period began on 06/13/16 and ended on 07/29/16. No comments were received from the provider community. The notice period begins on 09/01/16 and the LCD becomes final on 10/17/16.</td>
<td>10/17/16</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Policy Title</th>
<th>LCD Revisions</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>Special Electroencephalography L33447 Rev #6</td>
<td>Under <strong>CPT/HCPCS Codes Group 1: Codes</strong> deleted 95812, 95813, 95816, 95819, 95822 and 95827.</td>
<td>9/26/16</td>
</tr>
<tr>
<td>Chemodenervation L33458 Rev #9</td>
<td>Under <strong>CPT/HCPCS Codes Group 1: Paragraph</strong> in the second sentence deleted CPT codes 64611 and 64617. The verbiage was corrected to now read “Use CPT codes 95873 and 95874 in addition to the code for the primary procedure CPT codes 64612, 64615, 64616, 64642, 64643, 64644, 64645, 64646, and 64647” effective on or after October 01, 2015.</td>
<td>9/01/16</td>
</tr>
<tr>
<td>Chemodenervation L33458 Rev #10</td>
<td>Under <strong>Coverage Indications, Limitations and/or Medical Necessity</strong> bullet 3 revised the verbiage to read “Chemodenervation of extremity muscles in the management of dystonias, cerebral palsy, upper and lower limb spasticity (see <strong>Note:</strong>) and multiple sclerosis”. Under <strong>Note:</strong> added the verbiage “Onabotulinumtoxin A (Botox®) is the only botulinum toxin that is FDA approved for lower limb spasticity in adults” to the end of the sentence. Under <strong>ICD-10 Codes that Support Medical Necessity Group 7: Codes</strong> added ICD-10 Codes G83.81 and G83.82.</td>
<td>9/29/16</td>
</tr>
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</table>

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<thead>
<tr>
<th>Article Title</th>
<th>Articles</th>
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<table>
<thead>
<tr>
<th>billing and coding instructions for Lemtrada® (alemtuzumab) when used in the treatment of relapsing multiple sclerosis A55310 New</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under Article Text added the verbiage Lemtrada® is indicated in the treatment of patients with relapsing forms of multiple sclerosis. The dosage of Lemtrada® when used for this indication is 12mg/day infused for 5 consecutive days, then 12mg/day infused for 3 days at one interval one year from the first course of treatment.</td>
</tr>
</tbody>
</table>

To submit a claim for Lemtrada® in Part B of A (hospital outpatient) on a UB-04 claim form, the following information must appear on the form:

**Diagnosis-(Box 66)**
- ICD-9 340 Multiple Sclerosis (for claims with DOS from 11/14/2014 to 9/30/2015)
- ICD-10 G35 Multiple Sclerosis (for claims with DOS from 10/01/2015 forward)

**HCPCS drug code-(Field 44)**
- C9399 Unclassified drugs or biologics (DOS from 11/14/2014 to 9/30/2015)
- Q9979 Injection, alemtuzumab 1mg (DOS from 10/01/2015 to 12/31/2015)
- J0202 Injection, alemtuzumab 1mg (DOS 1/1/2016 forward)

**Narrative (Remarks) in (Field 80) (or electronic equivalent)**
- NDC- 58468-0200-1 or 58468-0200-01 Single use vial 12mg/1.2 ml (10mg/ml)
- Name of Drug (trade and generic)
- Dose of drug administered
- Route of administration

To submit a claim for Lemtrada® in Part B on a CMS-1500 claim form, the following information must appear on the form:

**Diagnosis-(Box 21)**
- ICD-9 340 Multiple Sclerosis (for claims with DOS from 11/14/2014 to 9/30/2015)
- ICD-10 G35 Multiple Sclerosis (for claims with DOS from 10/01/2015 forward)

**HCPCS drug code- (Box 24D)**
- J3490 Unclassified drugs or J3590 unclassified biologics (DOS from 11/14/2014 to 9/30/2015)
- Q9979 Injection, alemtuzumab 1mg (DOS from 10/01/2015 to 12/31/2015)
- J0202 Injection, alemtuzumab 1mg (DOS 1/1/2016 forward)

**Narrative- (Box 19) (or electronic equivalent)**
- NDC- 58468-0200-1 or 58468-0200-01 Single use vial 12mg/1.2 ml (10mg/ml)
- Name of Drug (trade and generic)
- Dose of drug administered
- Route of administration

**Note:** This drug is supplied in a single use vial that contains 12 mg of alemtuzumab. Per FDA labeling, the dose of this drug is 12 mg per day, therefore claims reflecting administered dosages other than 12 mg per DOS or claims reporting wastage or product NDC numbers other than those listed above will be rejected.

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<table>
<thead>
<tr>
<th>Policy Title</th>
<th>Response to Comments</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>Response to Comments for the Colonoscopy/Sigmoidoscopy/Proctosigmoidoscopy&lt;br&gt;L34454&lt;br&gt;NEW</td>
<td>The comment period for the Colonoscopy/Sigmoidoscopy/Proctosigmoidoscopy Local Coverage Determination (LCD) L34454 began on 06/13/16 and ended on 07/29/16. No comments were received from the provider community. This LCD will begin the notice period on 08/18/16 and will become effective on 10/03/16.</td>
<td>8/18/16</td>
</tr>
<tr>
<td>Response to comments for Ophthalmic Angiography&lt;br&gt;(Fluorescein and Indocyanine Green)&lt;br&gt;L34426&lt;br&gt;Rev #5</td>
<td>The Comment Period for Ophthalmic Angiography (Fluorescein and Indocyanine Green) local coverage determination (LCD) L34426 began on 06/13/16 and ended on 07/29/16. Comments were received from the provider community. Comment 1: Certain translations of ICD-9 codes covered in the retired ICD-9 version of the LCD (L31557) are not included as covered in the current LCD. Response 1: Specifically, for coverage under CPT 92240, ICD-10 diagnosis codes H30.109, H30.119, H30.129, H30.139, H30.60, H35.60, H35.719, H35.729, and H35.739 make laterality reference to “unspecified eye”. These codes were not included in the LCD because correct coding procedures dictate that claims be coded to the highest level of specificity possible. CMS directives regarding ICD-10 coding support contractors in their decision not to cover ICD-10 diagnosis codes relating to unspecified anatomical structures in LCDs. Palmetto GBA will not add the ICD-10 codes for “unspecified eye” to this LCD. Comment 2: For CPT 92240, H35.053 the code for bilateral eyes, was omitted while H35.051 and H35.052 are listed as covered. Response 2: H35.053 as a covered ICD-10 diagnosis for CPT 92240 was previously added to the current LCD in response to a previous reconsideration request from the same provider. No further action is required. Comment 3: For CPT 92240, H35.32 is not covered but the equivalent was covered in the retired version of the LCD but not included in the current LCD. Response 3: H35.32 is listed as a covered diagnosis for CPT 92240 under Group 2 Codes. This code was previously added to the current LCD in response to a previous reconsideration request from the same provider. No further action is required. Comment 4: For CPT 92235 coverage for all appropriate translations of ICD-9 diagnoses 362.03, 362.04, 362.05 and 362.06 are not included among the covered diagnoses.</td>
<td>9/08/16</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Date</th>
<th>Response</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/08/16</td>
<td>Response 4:</td>
<td>These codes were previously added to the current LCD in response to a previous reconsideration request from the same provider. No further action is required. Only the following translations that were requested for addition in the prior reconsideration request were not added to the current list of covered diagnoses: E08.311, E09.311, E10.311, E11.311, E13.311, E08.319, E09.319, E10.319, E11.319 and E13.319. These codes all contain the description “unspecified diabetic retinopathy”. All other diagnosis codes for the same conditions with either nonproliferative diabetic retinopathy or proliferative diabetic retinopathy, graded as either mild, moderate or severe in their description are listed as covered diagnoses in the current LCD, there is no need to include these non-specific code for the same reason outlined in section A of this response.</td>
</tr>
<tr>
<td></td>
<td>Comment 5:</td>
<td>Under <strong>Group 3: ICD-10 Codes that DO NOT Support Medical Necessity</strong> there is a conflict between the codes listed in this section and the covered codes in <strong>Group 1: ICD-10 Codes</strong> for Fluorescein Angiography. The list of non-covered codes in Group 3 should only apply to CPT 92240 Indocyanine Green Angiography.</td>
</tr>
<tr>
<td></td>
<td>Response 5:</td>
<td>Palmetto GBA agrees with the commenter in this regard and will remove Group 3 from the LCD. It is adequate to list only covered diagnosis codes for each procedure in the LCD. All diagnosis codes not listed for a given CPT code should be assumed to be non-covered.</td>
</tr>
<tr>
<td>10/10/16</td>
<td>The comment period for the White Cell Colony Stimulating Factors Local Coverage Determination (LCD) L36598 began on 02/08/16 and ended on 03/24/16. The following comments were received from the provider community:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comment 1:</td>
<td>The comment referred to the FDA label requirements for the timing of Neulasta® administration. The FDA label includes the following statement: “Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.”</td>
</tr>
<tr>
<td></td>
<td>Response 1:</td>
<td>With the advent of dose dense chemotherapy cycles for various malignancies including breast cancer, it is not possible to administer the drug within this time frame when employing a 14-day chemotherapy cycle. While it is possible to administer Neulasta® 24 hours after the conclusion of the dose dense cytotoxic chemotherapy administration, such an administration would be less than 14 days before the next cycle of dose dense chemotherapy would be scheduled. There is sufficient current peer reviewed medical literature to suggest that it is safe and effective to administer Neulasta® at an interval which is less than 14 days prior to the next cycle when employing dose dense chemotherapy regimens, therefore the policy will be revised to allow an exception to the 14 day rule when a dose dense chemotherapy cycle is prescribed.</td>
</tr>
</tbody>
</table>
Response to Comments for the White Cell Colony Stimulating Factors L36598 NEW continued

Comment 2:
The issue was also raised concerning the need for adherence to the requirement that Neulasta® not be administered less 24 hours after the conclusion of a cytotoxic chemotherapy dose.
Response 2:
With the introduction of the Neulasta® Onpro™, a drug delivery system that is placed on the patient at the conclusion of the chemotherapy administration and is programmed to deliver the dose of the drug 27 hours after placement of the device, the need for a return visit the following day, which is the source of most of the concern regarding compliance, has effectively been eliminated.

Comment 3:
The manufacturer of Neulasta® and Neupogen® commented that the indication listed in the LCD as a covered “off label” indication: “Hemopoetic Syndrome of Acute Radiation”, is now officially part of the FDA product labeling and asked that this indication be acknowledged appropriately in the LCD.
Response 3:
This change was made.

Comment 4:
The manufacturer of Neulasta® and Neupogen® also suggested that several diagnosis codes be added as covered diagnoses for Neulasta® and Neupogen®.
Response 4:
Of these diagnoses Palmetto GBA agrees to add for Neupogen® diagnosis codes related to chronic myeloid leukemia as Neupogen® is used in the process of preparation for transplant in that condition. Also added are the diagnosis codes for myeloid sarcoma, acute monoblastic/monocytic leukemia, and acute erythroid leukemia as they are part of the AML spectrum for which Neupogen® has a label indication. For Neulasta®, the diagnosis codes for other drug induced pancytopenia and other drug induced agranulocytosis will be added as UpToDate® gives both of these off label indications a Grade 1C recommendation. The other requested codes were determined to be too non-specific to accurately reflect label and approved off-label indications as primary diagnosis codes.

This LCD will begin the notice period on 08/25/16 and will become effective on 10/10/16.

<table>
<thead>
<tr>
<th>Policy Title</th>
<th>LCD Revisions</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy/ Sigmoidoscopy/ Proctosigmoidoscopy L34454 Rev #8</td>
<td>Under Associated Contract Numbers added the contractor numbers for Part B as the Part A LCD was made an A/B MAC LCD.</td>
<td>10/03/16</td>
</tr>
<tr>
<td>Ophthalmic Angiography (Fluorescein and Indocyanine Green) L34426 Rev #5</td>
<td>Under ICD-10 Codes that DO NOT Support Medical Necessity deleted the Group 1: Paragraph and all Group 1: Codes due to comments received.</td>
<td>10/24/16</td>
</tr>
</tbody>
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Once in a Lifetime Abdominal Aortic Aneurysm (AAA) Screening A55071 Rev #1

Under *Article Text, Covered ICD-10 Codes-Group 1: Paragraph and Covered ICD-10 Codes Group 1: Codes* added the ICD-10 code Z87.891.

9/26/16

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Once in a Lifetime Abdominal Aortic Aneurysm (AAA) Screening A55071 Rev #2

Under *Covered ICD-10 Codes-Group 1: Paragraph* added ICD-10 code F17.210 to the statement indicated with two asterisks as it was inadvertently omitted.

9/26/16

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Billing and Coding of Drug and Biological Infusions A55297 NEW

This coverage article is effective for dates of service on and after October 10, 2016 for Medicare Parts A and B and replaces all prior articles on this specific subject.

The CPT® 2016 Professional Edition, page 651 contains the following information and direction for CPT® codes to be used for the administration of chemotherapy:

“Chemotherapy administration codes 96401-96549 apply to parenteral administration of non-radiounucleide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of non-cancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as certain monoclonal antibody agents, and other biologic response modifiers. The highly complex infusion of chemotherapy or other drug or biologic agents requires physician or other qualified health care professional work and/or clinical staff monitoring well beyond that of therapeutic drug agents (96360-96379) because the incidence of severe adverse patient reactions are typically greater. These services can be provided by any physician or other qualified health care professional. Chemotherapy services are typically highly complex and require direct supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intraservice supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring. Examples are frequent changes in the infusion rate, prolonged presence of the nurse administering the solution for patient monitoring and infusion adjustments, and frequent conferring with the physician or other qualified health care professional about these issues. When performed to facilitate the infusion or injection, preparation of chemotherapy agent(s), highly complex agent(s), or other highly complex drugs is included in the administration service and is not reported separately. To report infusions that do not require this level of complexity, see 96360-96379. Codes 96401-96402, 96409-96425, 96521-96523 are not intended to be reported by the individual physician or other qualified health care professional in the facility setting.”

“The term ‘chemotherapy’ in 96401-96549 includes other highly complex drugs or highly complex biologic agents.”

Medicare has determined under Title XVIII of the Social Security Act, Section 1861(t) that reimbursement may be provided for these drugs when they are administered incident to a physician’s service and determined to be medically reasonable and necessary. Such determination of reasonable and necessary is determined by the Medicare Administrative Contractor. The documentation in the patient’s medical record must support that the drug(s) is (are) medically reasonable and necessary for the specific clinical circumstances under which the drug(s) is (are) administered.

Continued >>
**Billing and Coding of Drug and Biological Infusions**  
**NEW continued**

As stated in the CMS Internet Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 12, §30.5 Payment for Codes for Chemotherapy Administration and Non Chemotherapy Injections and Infusions, Part D- Chemotherapy Administration: “A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.”

The lists below are not all-inclusive and will continue to be revised as new information becomes available.

**Intramuscular and Subcutaneous Injections**
Administration of the following drugs in their subcutaneous or intramuscular forms should NOT be billed using a chemotherapy administration code (CPT® 96401-96549). Instead, these should be billed using CPT® code 96372 [therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular].

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canakinumab (Ilaris®)</td>
<td>J0638</td>
</tr>
<tr>
<td>Certolizumab pegol (Cimzia®)</td>
<td>J0717</td>
</tr>
<tr>
<td>Denosumab (Prolia® / Xgeva®)</td>
<td>J0897</td>
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<tr>
<td>Mepolizumab (Nucala®)</td>
<td>J3590</td>
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<tr>
<td>Omalizumab (Xolair®)</td>
<td>J2357</td>
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<tr>
<td>Rilonacept (Arcalyst®)</td>
<td>J2793</td>
</tr>
<tr>
<td>Tocilizumab (Actemra®)</td>
<td>J3262</td>
</tr>
<tr>
<td>Ustekinumab (Stelera®)</td>
<td>J3357</td>
</tr>
</tbody>
</table>

The intralesional administration of talimogene laherparepvec (Imlygic®) should be billed using HCPCS code J9999 (OPPS: C9399) with an intralesional injection CPT® code 96405 or 96406; whichever is appropriate.

When gonadotropin releasing hormone (GnRH) and analogs (including but not limited to J9217) are used in the treatment of cancer, the administration of these drugs may be billed ONLY with CPT® 96402 – chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.

This article notifies providers that the use of only one chemotherapy drug administration code is appropriate for these compounds: CPT® 96402. This code, and no other chemotherapy administration code, should be used for the administration of GnRH and its analogs and only when used for anticancer treatments.

**Infusions Non-Chemotherapy**
Palmetto GBA has received inquiries about the use of a chemotherapy administration code for an infusion (or push) of the following drugs. The administration of any of the drugs listed below should NOT be billed using a chemotherapy administration code. Instead, these should be billed with an appropriate from the range of CPT® codes 96365-96379 (infusion for therapy, prophylaxis, or diagnosis).
Billing and Coding of Drug and Biological Infusions

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>decitabine (Dacogen®)</td>
<td>J0894</td>
</tr>
<tr>
<td>eculizumab (Soliris®)</td>
<td>J1300</td>
</tr>
<tr>
<td>golimumab (Simponi Aria®)</td>
<td>J1602</td>
</tr>
<tr>
<td>tocilizumab (Actemra®)</td>
<td>J3262</td>
</tr>
<tr>
<td>vedolizumab (Entyvio®)</td>
<td>J3380</td>
</tr>
</tbody>
</table>

**Infusions Chemotherapy**

The HCPCS Level II establishes “Chemotherapy Drugs” as those in the range of codes J9000-J9999. Infusions of drugs with assigned HCPCS codes in this range are accepted as appropriately billed using the chemotherapy administration codes (CPT® 96401-96549).

Additionally, because of the documented increased frequency of infusion reactions and/or other reasons for which increased administration practice expense is incurred, Palmetto GBA agrees with the use of an appropriate chemotherapy (CPT® 96401-96549) administration code for an infusion (or push) of the following drugs.

<table>
<thead>
<tr>
<th>Generic Name (Trade Name)</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>alemtuzumab 1 mg (Lemtrada™)</td>
<td>J0202</td>
</tr>
<tr>
<td>daratumumab (Darzalex™)</td>
<td>J3590</td>
</tr>
<tr>
<td>elotuzumab (Empliciti™)</td>
<td>J3590</td>
</tr>
<tr>
<td>irinotecan liposome (Onivyde®)</td>
<td>J3490</td>
</tr>
<tr>
<td>nectatumumab (Portrazza™)</td>
<td>J3590</td>
</tr>
<tr>
<td>trabectedin (Yondelis®)</td>
<td>J3490</td>
</tr>
<tr>
<td>infliximab, biosimilar 10 mg* (InflectraTM)</td>
<td>Q5102-ZB**</td>
</tr>
<tr>
<td>infliximab, 10mg (Remicade®)</td>
<td>J1745</td>
</tr>
<tr>
<td>teniposide, 50mg (Vumon®)</td>
<td>Q2017</td>
</tr>
<tr>
<td>Doxorubicin hydrochloride, liposomal, NOS (Doxil®)</td>
<td>Q2050</td>
</tr>
<tr>
<td>Pembrolizumab 1mg (Keytruda®)</td>
<td>J9271</td>
</tr>
</tbody>
</table>

*Note that infliximab-dyyb (infliximab biosimilar, InflectraTM, Q5102-ZB effective on or after dates of service 4/05/16 but processed 7/01/16 and after) must be billed with the ZB modifier which distinguishes it from Remicade®.

Palmetto GBA also reminds providers that when a patient has to return for a significant, separately identifiable infusion or injection on the same day or the administration of the infusion or injection requires two IV lines per protocol, these circumstances are to be billed using the -59 modifier per CMS Internet Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 12, Section 30.5 E.

Coverage of any drug considered to be a chemotherapy agent without its own specific “J” code is limited to FDA approved on-label indications. The indication for what the drug is being used for must be indicated in box 19 of the CMS-1500 Claim Form or the electronic equivalent for Part B or in the remarks field (Field Locator 80) of the CMS-1450 (UB-04) Claim Form or the electronic equivalent for Part A.

**Prolonged Drug and Biological Infusions Using an External Pump** (currently applies to Yondelis®)

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Continued >>

CPT codes, descriptors and other data only are copyright 2015 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS apply. Current Dental Terminology, fourth edition (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. ©2015 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.
Medicare pays for drugs and biological agents, which are not usually self-administered by the patient and are furnished “incident to” physicians’ services rendered to patients while in the physician’s office or the hospital outpatient department.

Recently, a chemotherapy drug which requires a prolonged administration via an infusion pump (24 hr infusion) has been FDA approved. When administering a drug(s) which requires a significantly extended infusion, a hospital outpatient department or physician office may in some situations:

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

In this case, bill Palmetto GBA for the drug or biological, the administration, and the external infusion pump. Additional information is available in MLN Matters® Special Edition Article # 1609.

One CPT® code that is intended for this purpose is:
- 96416 Initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump.

However, the practice expense for 96416, though inclusive of all other expenses for provision of a prolonged chemotherapy infusion (other than the drug itself), does not include the expense specific to the pump (since 96416 is intended for the situation where the pump has previously been implanted or is otherwise provided). Therefore, for billing the service to include the expense of the provision of the pump, providers SHOULD NOT SUBMIT THE CODE 96416 OR ANOTHER PUMP CODE, but should instead submit this service using the code:
- 96549 Unlisted chemotherapy procedure

Include the words: “96416 plus pump” in the CMS-1500 claim form box 19 or the electronic equivalent for Part B or in the remarks field (Field Locator 80) of the CMS-1450 (UB-04) Claim Form or the electronic equivalent for Part A. This submission of 96549 with these words added to the claim will then be paid by this contractor at a rate equal to the 96416 plus an additional amount for the pump (until such time as there exists from CPT® or CMS an all inclusive code for this combined service).

**Patients supplying their own drugs**

The Medicare Program provides limited benefits for outpatient drugs. The program covers drugs that are furnished under the “incident to” benefit (section 1861(s)(2)(A) or (B) of the Social Security Act), for an FDA approved drug or biological which is furnished by a physician’s practice or hospital (respectively), provided that the drug is not usually self-administered by the patient, and is reasonable and necessary for the diagnosis or treatment of the illness or injury according to accepted standards of medical practice. The physician practice or hospital must incur a cost for the drug or biological which is then administered by the physician or by auxiliary personnel employed by the practice or hospital and under the physician’s personal supervision.
Per the “incident to” guidelines explained above and in the CMS Internet-Only Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, 50.3 providers are NOT allowed to instruct patients to purchase a drug themselves and bring it to the provider’s office for administration. Claims that are billed with the chemotherapy administration codes 96401-96549 that do not have an associated drug in claim history, will deny. When the administration claim is processing, an allowed claim for the drug must be present, either on a prior claim or on the same claim as the administration.

For other regulations related to the billing of chemotherapy administration, refer to the CMS Internet-Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 12, §30.5.

### Retired Articles

<p>| FDA Approved Indications for Keytruda® (Pembrolizumab) A53795 | New FDA approved indication for patients with recurrent or metastatic head and neck squamous cell cancer as of 08/05/16 were not included in this article. This article is being retired as it is being incorporated into the Billing and Coding of Drug and Biological Infusions A55297 article. 8/5/16 |
| Empliciti™ (elotuzumab) Coding and Billing Guidelines and Indications A54955 | This article is being retired 10/09/16 as it is being incorporated into the Billing and Coding of Drug and Biological Infusions A55297 article. 10/9/16 |
| Darzalex™ (daratumumab) Coding and Billing Guidelines and Indications A54956 | This article is being retired 10/09/16 as it is being incorporated into the Billing and Coding of Drug and Biological Infusions A55297 article. 10/9/16 |</p>
<table>
<thead>
<tr>
<th>Policy Title</th>
<th>LCD Revision</th>
</tr>
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<tbody>
<tr>
<td>Infectious Disease Molecular Diagnostic Testing L33433</td>
<td>Reconsideration Request: Added the following codes to Group 9 as a covered diagnosis codes to allow coverage per the Preventive Services guidelines. Z11.3 – Encounter for screening for infections with a predominantly sexual mode of transmission Z72.89, Z72.51, Z72.52, Z72.53 - high risk heter, homo bisexual behavior, Z34.00, Z34.01, Z34.02, Z34.03- encounter for pregnancy, Z34.80, Z34.81, Z34.82, Z34.83-encounter for supervision of other normal pregnancy, Z34.90, Z34.91, Z34.92, Z34.93-encounter for supervision of normal pregnancy, O09.90, O09.91, O09.92, and O09.93-high risk pregnancy</td>
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</table>

Infectious Disease Molecular Diagnostic Testing L33433

ICD-10-CM Code Changes

GROUP #1
M25541 Added
M25542 Added

GROUP #3
H53041 Added
H53042 Added
H53043 Added
M25541 Added
M25542 Added
N508 DELETED
N50811 Added
N50812 Added
R827 DELETED
R8271 Added
R8279 Added

GROUP #4
D47Z2 Added
R312 DELETED
R3121 Added
R3129 Added

GROUP #7
N508 DELETED
N50811 Added
N50812 Added
N5082 Added
N5089 Added

GROUP #8
R312 DELETED

GROUP #9
M25541 Added
M25542 Added
N508 DELETED
N50811 Added
N50812 Added
N5082 Added
N5089 Added

Effective Date: 09/22/2016

Continued >>
<table>
<thead>
<tr>
<th>Article Title</th>
<th>Article Revision</th>
<th>Effective Date</th>
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<tr>
<td>MolDX: ConfirmMDX Epigenetic Molecular Assay</td>
<td>ICD-10-CM Code Changes</td>
<td>10/01/2016</td>
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<tr>
<td>L35632</td>
<td>R97.2 was deleted from Group 1</td>
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<tr>
<td></td>
<td>N40.0 descriptor was changed in Group 1 from Enlarged prostate without lower urinary tract symptoms to Benign prostatic hyperplasia without lower urinary tract</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N40.1 descriptor was changed in Group 1 from Enlarged prostate with lower urinary tract symptoms to Benign prostatic hyperplasia with lower urinary tract</td>
<td></td>
</tr>
<tr>
<td>MolDX Biomarkers in Cardiovascular Risk Assessment</td>
<td>ICD-10-CM Code Changes</td>
<td>10/01/2016</td>
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<tr>
<td>L36129</td>
<td>E780 DELETED</td>
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<td></td>
<td>E7800 ADDED</td>
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<td></td>
<td>E7801 ADDED</td>
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<tr>
<td>MolDX: Breast Cancer Assay: Prosigna</td>
<td>This LCD version was created as a result of DL36125 being released to a Final LCD.</td>
<td>10/17/2016</td>
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<tr>
<td>L36125</td>
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<tr>
<td>MolDX- CDD: ProMark Risk Score</td>
<td>This LCD version was created as a result of DL36665 being released to a Final LCD.</td>
<td>10/10/2016</td>
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<tr>
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<tr>
<td>GlycoMark Testing for Glycemic Control</td>
<td>This LCD version was created as a result of DL36761 being released to a Final LCD.</td>
<td>10/17/2016</td>
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<td>L36761</td>
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<tr>
<td>Article Title Article Revision Effective Date</td>
<td></td>
<td></td>
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<tr>
<td>MolDX: bioTheranostics Cancer TYPE ID® Update</td>
<td>ICD-10 codes update: deleted D49.5, added D49.511 and D49.512</td>
<td>10/01/2016</td>
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<td>A53101/M00027</td>
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<tr>
<td>MolDX: Corus® CAD Test Coding and Billing Guidelines</td>
<td>ICD-10 code updates: Added E78.00-Pure hypercholesterolemia, unspecified and E78.01-familial hypercholesterolemia to Group 3. Deleted - E78.0 - Pure hypercholesterolemia</td>
<td>10/01/2016</td>
</tr>
<tr>
<td>A53102/M00009</td>
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</tbody>
</table>

Continued >>
| MolDX: Progenesis® PCA3 Assay Coverage Update A53107/M00013 | ICD-10 codes update: Deleted R31.2 and R97.2; Added R31.21, R31.29, and R97.20 | 10/01/2016 |
| MolDX: ResponseDX Tissue of Origin® Coding and Billing Guidelines A53108/M00034 | ICD-10 codes update: deleted D49.5, added D49.511 and D49.512 | 10/01/2016 |
CMS e-News

e-News contains a week’s worth of Medicare-related messages instead of many different messages being sent to you throughout the week. This notification process ensures planned, coordinated messages are delivered timely about Medicare-related topics.

MLN Connects™ Provider eNews

MLN Connects™ Provider eNews for September 1, 2016

MLN Connects™ Provider eNews for September 8, 2016

MLN Connects™ Provider eNews for September 15, 2016

MLN Connects™ Provider eNews for September 22, 2016

Receive ADRs Electronically: Go Green via eServices

Providers can now opt to receive Additional Documentation Requests (ADRs) through eServices. If your claim is selected for review, you can receive your request as it is generated – instead of by mail (which decreases the amount of time you have to respond).

This new process is free, secure and easy to use. Our messaging function in eServices will send an inbox message to let users know that an ‘eLetter’ is now available. This new process delivers the electronic document as a link within the secure message once you sign into eServices.

For more information about eServices and the many services it offers, please visit our website at www.PalmettoGBA.com/eServices.
CMS Offers FREE Medicare Training for Providers

CMS Web Training
The Centers for Medicare & Medicaid Services (CMS) has launched a series of education and training programs designed to leverage emerging Internet and satellite technologies to offer just-in-time training to Medicare providers and suppliers throughout the United States. Many of these programs include free, downloadable computer/Web based training courses. These courses are also available on CD-ROM.

http://www.cms.gov/MLNGenInfo

Palmetto GBA Medicare Customer Information and Outreach

Important Telephone Numbers

Provider Contact Center
(855) 696-0705 (Toll-Free)

Electronic Data Interchange (EDI) Technical Support
(855) 696-0705

Medicare Beneficiary Call Center
1-800-MEDICARE (1-800-633-4227)
TTY 1-877-486-2048

Training Available
To request a Medicare Education meeting/seminar at no cost to you, complete and fax the form located on the

http://www.PalmettoGBA.com/Medicare

Important Sources For You

• http://www.cms.gov
• http://www.cms.gov/MLNGenInfo
• http://www.cms.gov/CMSforms/CMSforms/list.asp

Attention: Billing Manager