RAILROAD MEDICARE ADVISORY

Latest Part B News for Railroad Medicare

February 2021
Volume 2021, Issue 2

What's Inside...

Continued >>

palmettogba.com/rr

The *Medicare Advisory* contains coverage, billing and other information for Railroad Medicare. 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 *Railroad 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 **https://www.PalmettoGBA.com/rr**.

A RRB-Contracted Specialty Medicare Administrative Contractor

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Therapy

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) on a variety of topics, such as psychiatry, preventive services, lumbar spinal fusion, 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.

eServices: COVID-19 Transition

In light of the COVID-19 pandemic, organizations are proactively transitioning employees across the health care industry back into the office.

Palmetto GBA is providing a quick reference eServices guide to assist with common issues you may experience if you have not logged into your eServices account in the past 30-60 days.

If you are not currently registered to use eServices, we have also included some resources to get you started.

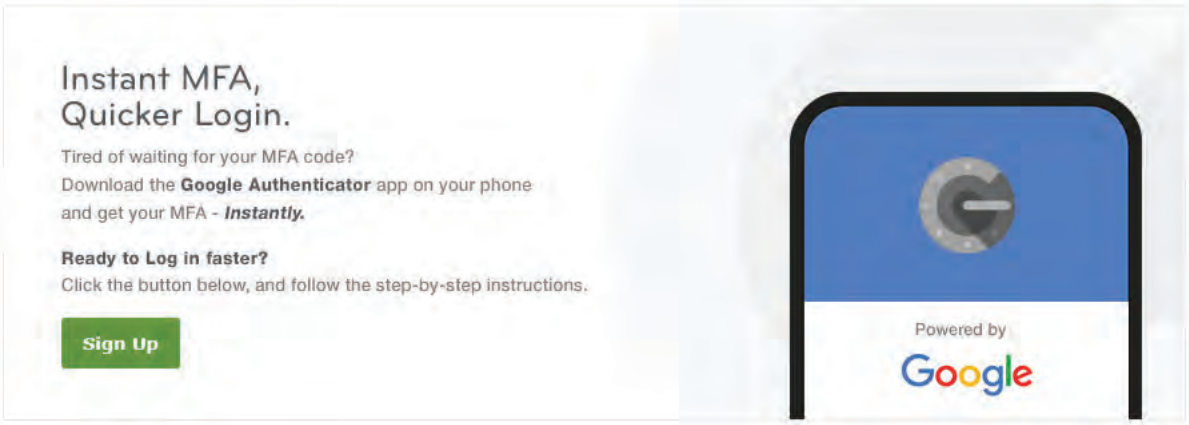
Railroad Medicare:
https://www.palmettogba.com/internet/PCIDN.nsf/R?OpenAgent&DID=BRKJM375&url=yes

Do You Have a Question Regarding eServices? We Can Help!

Palmetto GBA has dedicated representatives available to provide technical assistance and answer questions about our secure online portal — eServices. *Our Provider Contact Center (PCC) representatives* can be reached at 888-355-9165 (Monday – Friday, 8:30 a.m. to 4:30 p.m. ET for all time zones with the exception of PT, which receives services from 8 a.m. to 4 p.m.).

To connect with an eServices representative:
- Press 2 for EDI/eServices, then
- Press 1 for eServices inquiries

eServices and Google Authenticator



To enhance the security of Medicare information, the Centers for Medicare & Medicaid Services (CMS) requires the use of multi-factor authentication (MFA) each time you log in to eServices. We're excited to announce a new option to protect your account - Google Authenticator.

You now have three options to receive an MFA code:
- Email
- Text
- Google Authenticator

Are you new to eServices? Or maybe you already have an eServices account...no worries! In just a few quick steps, you can set up Google Authenticator. This two-step verification is available when initially registering for eServices or if you already have an existing eServices account.

Initial Registration
Upon initial registration to eServices, you must complete the fields on the MFA Setup screen.

The information entered on this screen will be saved in your profile. Select Authenticator Setup for Google Authenticator option.

After selecting the Authenticator Setup button, you'll see instructions for installing Google Authenticator. These steps are based on your device - iPhone or Android:
- iPhone users must access iTunes
- Android users must access Google Play

A successful installation prompts this screen showing your device is now linked. Select Submit to save the changes.

At your initial login to eServices, you are asked to choose your preferred method for receiving your MFA code.

Select the Use the app button to receive the MFA code via the Google Authenticator app.

Continued >>

After selecting Use the app, the verification code will appear in your Google Authenticator app. This code will renew every 30 seconds.

Enter the code in the available field and select the Submit button.

Existing Account
At your next login to eServices, you are asked to choose your preferred method for receiving your MFA code.

You must choose from the text or email options since you haven't set up the Google Authenticator option yet.

After verification, go to the My Account tab to change your account settings.

From the My Account tab, scroll down until you see the MFA Setup options.

The information entered on this screen will be saved in your profile. Select Authenticator Setup for Google Authenticator option.

After selecting the Authenticator Setup button, you'll see instructions for installing Google Authenticator. These steps are based on your device - iPhone or Android:

- iPhone users must access iTunes
- Android users must access Google Play

A successful installation prompts this screen showing your device is now linked. Select Submit to save the changes.

At your next login to eServices, you are again asked to choose your preferred method for receiving your MFA code. But not you'll notice you can also choose to receive your code with the Google Authenticator app.

Select the Use the app button to receive the MFA code via the Google Authenticator app.

After selecting Use the app, the verification code will appear in your Google Authenticator app. This code will renew every 30 seconds.

Enter the code in the available field and select the Submit button.

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

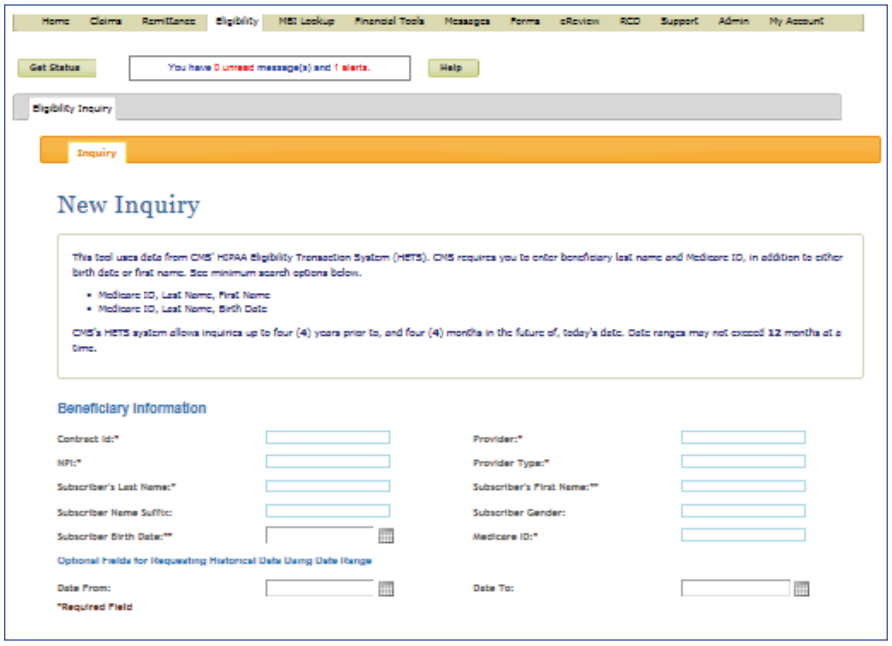
How to register to receive the Palmetto GBA Medicare Listserv: Go to http://tinyurl.com/PalmettoGBAListserv and select "Register Now." Complete and submit the online form. Be sure to select the specialties that interest you so information can be sent.

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 three days of your registration.

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 Medicare ID Number, in addition to either the birth date or first name. See options below:

- Medicare ID Number, Last Name, First Name, Birth Date
- Medicare ID Number, Last Name, Birth Date
- Medicare ID Number, 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.

Medicare Learning Network® (MLN)

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:
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index

- 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. 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.

ePass is Now Available in the Railroad Medicare Interactive Voice Response (IVR) Unit

Provider authentication by Provider Transaction Access Number (PTAN), National Provider Identifier (NPI) and Tax Identification Number (TIN) is required before the Palmetto GBA Interactive Voice Response (IVR) Unit is authorized to release Railroad Medicare claim status information, financial information, patient eligibility information, or to order a copy of a remittance advice.

An "ePass" is an eight-digit code you will be prompted to receive or enter each time you choose the IVR options for claims, finance, eligibility or duplicate remittance advice. When you choose option 2 to receive an ePass, you will be assigned an ePass code for the provider's PTAN/NPI/TIN combination you enter. You can then enter that ePass in the IVR for the remainder of the day in order to authenticate that provider. This eliminates the need to repeatedly enter the same PTAN, NPI and TIN into the IVR.

The goal of the ePass is to ease provider burden by eliminating the need to repeatedly authenticate the same provider each time you contact the IVR in a given day.

We hope this service will be effective and helpful to you. We encourage you to give us feedback about ePass through our website satisfaction survey. Your input helps us create new tools (like ePass) to make interacting with Railroad Medicare smooth and easy. To access the survey, access the "Topics" in the drop down menu at the top of this web page. The last item on the preview says "You Do Make a Difference," which is the link to the survey.

We look forward to hearing from you!

CMS Quarterly Provider Update

The Quarterly Provider Update is a comprehensive resource published by the Centers for Medicare & Medicaid Services (CMS) on the first business day of each quarter. It is a listing of all 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 and visit it often for this valuable information.

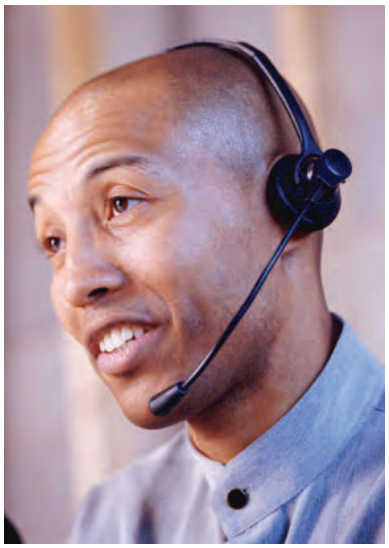
eServices Extends Administrator Unlock Feature Beyond 30 Days

Palmetto GBA has implemented new "Disable User" functionality in eServices that will disable a user that has been inactive for 30 days instead of terminating the User ID. Administrators will now be able to enable the user up to 120 days after 30 days of inactivity. If the user ID is not enabled within this time, the account will be terminated. We will send notification to providers through a series of periodic emails (up to the 120-day limit) to remind the user of their status and provide instructions to re-enable eServices IDs.

In short, provider administrators can now simply unlock users as well as other administrators. This is a significant change from past guidelines. Previously:

- Provider Administrators and users were required to login at least once every 30 days
    - Accounts in which users did not login past 30 days were deactivated/terminated
        - If the provider admin did not login, all user accounts associated with the provider admin were also deactivated/terminated
- This created additional work for administrators as they were required to create new accounts for deactivated/terminated users

The Provider Contact Center eServices Helpdesk is also able to assist if the provider administrator is unable to complete this task.



Provider Customer Service Center Training and Closure Dates

The Centers for Medicare & Medicaid Services (CMS) and the Railroad Retirement Board (RRB) have approved the RRB Specialty Medicare Administrative Contractor (RRB SMAC) to close up to eight hours per month for provider Customer Service Advocates (CSAs) training and/or staff development. The goal is to help CSAs improve the consistency and accuracy of their responses to provider questions; enhance their awareness and understanding of Medicare policies and issues; and facilitate CSAs' retention of the facts of their training by increasing its frequency.

When our CSAs participate in training and developmental sessions on Thursdays of each month, you may use our online provider portal called eServices. eServices provides claim status, duplicate remittances, patient eligibility and much more. Register now at https://www.PalmettoGBA.com/eServices. Please refer to the training schedule below for specific closure dates and times.

Date	Phones Closed
January 28, 2021	PCC closed for training / 1:30 to 4:30 PM ET
February 4, 2021	PCC closed for training / 2:30 to 4:30 PM ET
February 11, 2021	PCC closed for training / 2:30 to 4:30 PM ET
February 18, 2021	PCC closed for training / 2:30 to 4:30 PM ET
Febraury 25, 2021	PCC closed for training / 2:30 to 4:30 PM ET
May 31, 2021	Office closed / Memorial Day
July 5, 2021	Office closed / Independence Day
September 6, 2021	Office closed / Labor Day
November 25, 2021	Office closed / Thanksgiving Day
November 26, 2021	Office closed / Day After Thanksgiving
December 23, 2021	Office closed / Christmas Eve
December 24, 2021	Office closed / Christmas Day
December 31, 2021	Office closed / New Year's Day

Please note that we will attempt to provide advance notice of any changes to the above training schedule via the website, IVR features and automatic email notices.

If you have not already done so, we encourage you to sign up for automatic email notices of updates to our website. Subscribing to this listserv is the fastest way to find out about Medicare changes that may affect you. There is no charge for the service, and we will not share your email address with others. To register, go to Email Updates at https://www.palmettogba.com/registration.nsf/Push+Mail+Archive+Home?OpenForm.

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If you have questions, please call our Provider Contact Center at 888-355-9165 and select Option 5. Customer Service Advocates are available between the hours of 8:30 a.m. to 4:30 p.m. for all time zones, with the exception of PT, which receives service from 8 a.m. to 4 p.m. PT. Our eServices portal is available 24/7 with the exception of claims, remittance, and financial data, which is available from 8 a.m. to 7 p.m. Monday through Friday. You may access eServices 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 Medical Review Additional Documentation Request (ADR) letters and first level appeal Medicare Redetermination Notices (MRNs) 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.

Using MBIs in the IVR Now

The transition period during which you can use either a patient's Health Insurance Claim Number (HICN) or a Medicare Beneficiary Identifier (MBI) ended on December 31, 2019. All Railroad Medicare systems including our Interactive Voice Response (IVR) requires MBIs to obtain beneficiary and claims information.

Need help using MBIs in the IVR? Our IVR Conversion Tool can help! Use our IVR Conversion Tool (https://www.palmettogba.com/internet/PCIDN.nsf/R?OpenAgent&DID=BBBRUD68&url=yes) to quickly convert an MBI into the numbers/characters that are required by our IVR. This tool also converts your Provider Transaction Access Number (PTAN) and your patient's name.

As an alternative to the IVR, providers with an Electronic Data Interchange (EDI) enrollment agreement on file with Palmetto GBA Railroad Medicare and a claim in history can use Palmetto GBA's eServices online provider portal to check claim status and patient eligibility, to view and print remittance advice, and more. If you are already submitting claims electronically to Railroad Medicare, you do not have to submit a new EDI Enrollment Agreement. Register for eServices today at https://www.PalmettoGBA.com/eservices.

How Can I Tell if a Patient Has Railroad Medicare?

All Railroad Medicare beneficiaries have been mailed their new Railroad Medicare cards with their new Medicare Beneficiary Identifiers (MBIs). MBIs are "non-intelligent" numbers made up of 11 characters of numerals and capital letters. Unlike Railroad Medicare Health Insurance Claim Numbers (HICNs), which could be identified by their format (1-3 letters followed by 6 or 9 numbers), Railroad Medicare MBIs are indistinguishable from other MBIs. With MBIs you will not be able to tell if a patient is eligible for Railroad Medicare just by looking at the number.

The Medicare card of a person with Railroad Medicare will continue to be unique. The Railroad Retirement Board (RRB) will continue issuing Railroad Medicare cards with the RRB logo in the upper left corner, and 'Railroad Retirement Board' at the bottom, as shown here. Railroad Medicare cards will also have a QR code on the front lower right-hand corner of the cards, while Medicare cards will have a QR code on the back of the card. Make sure to ask your patients for their new cards and program your system to identify Railroad Medicare patients based on their cards, if possible.

If you verify your patient's eligibility electronically, CMS will return a message on the eligibility transaction response for a Fee-For-Service (FFS) Railroad Medicare MBI inquiry that will read "Railroad Retirement Medicare Beneficiary" in 271 Loop 2110C, Segment MSG.

If you verify a patient's eligibility using an MBI in the Palmetto GBA eServices online provider portal, the portal will return the "Railroad Retirement Medicare Beneficiary" message in the Additional Information field of the Eligibility sub-tab, as shown below.

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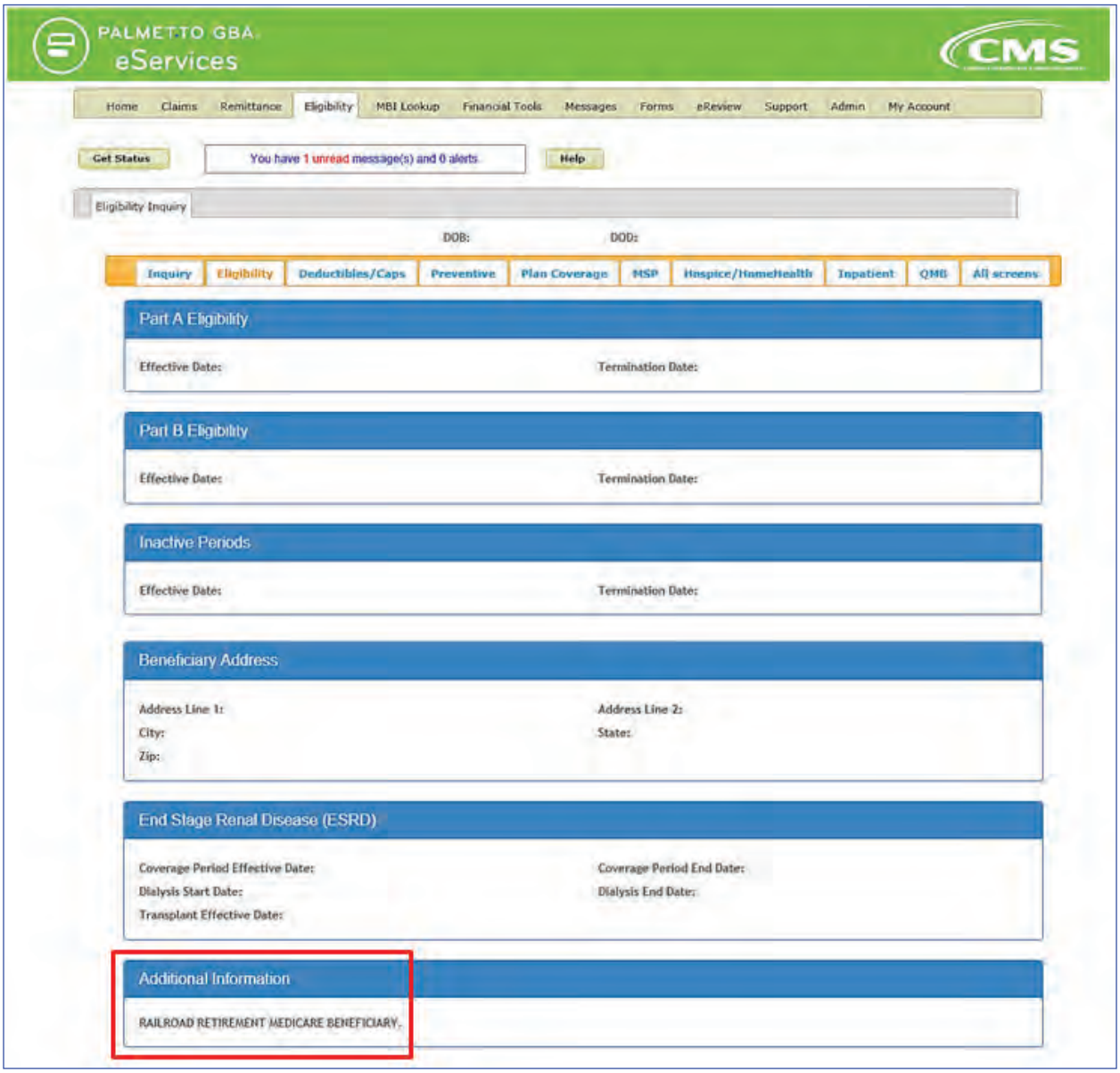

For more information on the new Medicare cards and using the new MBIs, see the following Medicare Learning Network (MLN) resources:

- MBI website: https://www.cms.gov/Medicare/New-Medicare-Card/index
- MLN SE18006 - New Medicare Beneficiary Identifier (MBI) Get It, Use It: https://tinyurl.com/SE18006

Help Us to Help You: Have Your Provider and Patient Information Ready When You Call Customer Service

Having the required provider and beneficiary authentication elements available when you call Customer Service will save you time and help us handle your inquiry more efficiently.

You will be asked for the following information about the provider:

- The provider's National Provider Identifier (NPI)
- The provider's Railroad Medicare Provider Transaction Access Number (PTAN)
- The provider's Tax Identification Number (TIN): last five digits

The Centers for Medicare & Medicaid Services (CMS) requires authentication of these provider elements whenever a request would involve the disclosure of personally-identifiable information (PII) or protected health information (PHI). If you are not able to provide the required elements, our Customer Service Advocates may ask you to obtain the information and call back.

Don't have your Railroad Medicare PTAN? Providers can use our PTAN Lookup and Request Tool to lookup their Railroad Medicare PTAN. If you are employed by a clearinghouse or third-party biller, you must contact the provider to obtain the Railroad Medicare PTAN. See our Using Railroad Medicare's Online PTAN Lookup and Request Tool article for details https://palmettogba.com/Palmetto/Providers.nsf/docsCat/Railroad%20Medicare~Resources~Provider%20Enrollment~Articles~Using%20Railroad%20Medicares%20Online%20PTAN%20Lookup%20and%20Request%20Tool?open&Expand=1

You will be asked to provide the following information about the beneficiary:

- The beneficiary's Medicare Beneficiary Identifier (MBI)
- The beneficiary's last name
- The beneficiary's first name or initial, and either
- The claim date(s) of service (for post-claim inquiries, such as reason for denial or rejection) or
- The beneficiary's date or birth (for pre-claim inquiries, such as entitlement requests/issues)

The CMS requires authentication of these beneficiary elements prior to disclosing PII or PHI about a Medicare beneficiary to an authenticated provider. All information must match. If you are not able to provide the required elements, our Customer Service Advocates may ask you to obtain the information and call back.

Don't have the patient's MBI? There are three ways you and your office staff can get MBIs:

1. Ask your patient
2. Use the MBI Look-up tool on the Palmetto GBA eServices portal or your local Medicare Administrative Contractor's portal
    - You can look up MBIs for your Medicare patients when they don't or can't give them. You must have your patient's first name, last name, date of birth and Social Security Number (SSN) to search. If a patient doesn't want to release their SSN to you, the patient will need to provide you with their MBI.
3. Check a remittance advice
    - If you previously saw a patient and got a claim payment decision based on a claim submission with a HICN before January 1, 2020, look at that remittance advice. We returned the MBI on every remittance

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advice when a provider submitted a claim with a valid and active HICN from October 1, 2018 through December 31, 2019.

Resource: MLN SE18006 — New Medicare Beneficiary Identifier (MBI) Get It, Use It at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE18006.pdf

Railroad Medicare's online "PTAN Lookup and Request Tool"

Providers can now obtain their existing Railroad Medicare Provider Transaction Access Number (PTAN) or request a new Railroad Medicare PTAN through our "PTAN Lookup and Request Tool" at http://www.PalmettoGBA.com/RR/PTAN.

Please review the following resources before using the PTAN Tool:

- Using Railroad Medicare's online "PTAN Lookup and Request Tool" https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Railroad%20Medicare~Resources~Provider%20Enrollment~Articles~AK7K447304?open
- Railroad Medicare PTAN Lookup and Request Tool FAQs https://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Railroad-Medicare~AXCNMG2662

Telehealth Expansion Benefit Enhancement Under the Pennsylvania Rural Health Model (PARHM) – Implementation

MLN Matters Number: MM11870 Revised
Related CR Release Date: December 22, 2020
Related CR Transmittal Number: R10533DEMO
Related Change Request (CR) Number: 11870
Effective Date: January 1, 2021
Implementation Date: January 4, 2021

Note: We revised this article due to a revised CR 11870, issued on December 22. The CR revision updated some denial edits. We added that information starting near the bottom of page 3 of this article. Also, we updated the CR release date, transmittal number, and the web address of the CR. All other information remains the same.

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Provider Types Affected

This MLN Matters Article is for rural acute care hospitals and Critical Access Hospitals (CAHs) submitting claims to Medicare Administrative Contractors (MACs) for telehealth services provided under the Pennsylvania Rural Health Model (PARHM) to Medicare beneficiaries.

Provider Action Needed

This article informs you about information related to the PARHM and the "Transformation Plans" for participating hospitals. CR 11870 expands the allowable telehealth services for Model-participant hospitals. Without this CR, some hospitals may fail to meet healthcare transformation goals set by the Model. Make sure your billing staffs are aware of these changes.

Background

The PARHM provides rural acute care hospitals and CAHs the opportunity to participate in hospital global budget payments for all inpatient and outpatient hospital services and CAH swing-bed services. The Centers for Medicare & Medicaid Services (CMS) reimburses participating rural hospitals according to an annual global budget, which is provided by the Commonwealth of Pennsylvania. CMS reimburses the participating rural hospitals on a biweekly basis, based on 1/26th of their global budget through the applicable MACs.

Pennsylvania provides CMS with annual global budgets for participating hospitals prior to the Performance Year (PY) (based on the Calendar Year (CY)). CMS will provide information to MACs of the participating rural hospitals and the Part A and B global budget payment amounts for hospital inpatient and outpatient services. Participating rural hospitals also submit claims to CMS, but no claim payments are made. This model is effective for claims with through or discharge dates on or after January 1, 2018. Beneficiaries and hospitals will be able to participate in other models, under the requirements of those models. Beneficiaries enrolled in a Medicare Advantage plan are excluded from this model.

As part of PARHM, participating rural hospitals must submit rural health transformation strategies called "Transformation Plans." These plans detail what healthcare delivery, coordination, and operations improvements the hospital plans to implement to reach the population health goals and financial benchmarks of the model.

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Many hospitals identified telehealth strategies in their Transformation plans. The model defines rural eligibility differently than the Metropolitan Statistical Area (MSA) method, and therefore only some participating rural hospitals in the model are currently able to use telehealth services. CR 11870 provides instruction to the MACs to implement a new Telehealth Benefit Enhancement. This will address this inequality and without it, some hospitals may fail at meeting healthcare transformation goals set by the PARHM.

For qualified PARHM participants, CMS is waiving the requirement that beneficiaries be located in a rural area and at a specified type of originating site in order to be eligible to receive telehealth services. This benefit enhancement allows payment of claims for telehealth services delivered by PARHM participants and Preferred Providers to beneficiaries in specified facilities or at their residence regardless of the geographic location of the beneficiary. An interactive telecommunications system is required as a condition of payment; however, CMS allows the use of asynchronous telehealth to deliver dermatology and ophthalmology services. These telehealth services are covered as of January 1, 2021, for PARHM participants.

Asynchronous telehealth includes the transmission of recorded health history (for example, retinal screening and digital images such as photos) through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time or live interaction. **Asynchronous telecommunications systems in single media format does not include:**

- Telephone calls
- Images transmitted via facsimile machines
- Text messages without visualization of the patient (electronic mail)

Photographs must be specific to the beneficiary's condition and adequate for rendering or confirming a diagnosis and treatment plan.

Payment will be permitted for telemedicine when asynchronous telehealth in single or multimedia formats is used as a substitute for an interactive telecommunications system for dermatology and ophthalmology services. Distant site practitioners will bill for these new services using new codes and the distant site practitioner must be a PARHM participant or Preferred Provider.

The codes for At-Home Synchronous Telehealth Services are:

- G9481: Remote E/M for a new patient (10 mins.) for CMMI demonstrations only
- G9482: Remote E/M for a new patient (20 mins.) for CMMI demonstrations only
- G9483: Remote E/M for a new patient (30 mins.) for CMMI demonstrations only
- G9484: Remote E/M for a new patient (45 mins.) for CMMI demonstrations only
- G9485: Remove E/M for a new patient (60 mins.) for CMMI demonstrations only
- G9486: Remote E/M for an established patient (10 mins.) for CMMI demonstrations only
- G9487: Remote E/M fir an established patient (15 mins.) for CMMI demonstrations only
- G9488: Remote E/M for an established patient (25 mins.) for CMMI demonstrations only
- G9489: Remote E/M for an established patient (40 mins.) for CMMI demonstrations only
- G0438: Annual wellness visit; first visit
- G0439: Annual wellness visit; subsequent visit(s)

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The codes for Asynchronous Telecommunication Services are:

- G9868: Receipt and analysis of remote, asynchronous images for dermatologic and/or ophthalmologic evaluation (15 minutes)
- G9869: Receipt and analysis of remote, asynchronous images for dermatologic and/or ophthalmologic evaluation (20 minutes)
- G9870: Receipt and analysis of remote, asynchronous images for dermatologic and/or ophthalmologic evaluation (25 minutes)

Where PARHM claims do not contain an aligned provider and the V4 modifier is appended, providers will see this denial messaging:

- Claims Adjustment Reason Code (CARC) 132: "Prearranged demonstration project adjustment"
- Remittance Advice Remark Code (RARC) N83: (No appeal rights. Adjudicative decision based on the provisions of a demonstration project.)
- Group Code CO: (Contractual Obligation)

When PARHM claims are denied because there is no aligned beneficiary, providers will see this denial messaging:

- CARC 96: "Non-covered charge(s)."
- RARC N83: (No appeal rights. Adjudicative decision based on the provisions of a demonstration project.)
- Group Code CO: (Contractual Obligation)

MACs will deny incoming PARHM claims if the Date of Service (DOS) on the claim is prior to January 1, 2021 using the following messages:

- CARC: 96- "Non-covered charge(s)."
- RARC: N83- (No appeal rights. Adjudicative decision based on the provisions of a demonstration project)
- Group Code: CO

MACs will deny PARHM claims when you elect this benefit enhancement for the DOS on the claim, the claim contains one of the appropriate HCPCS codes (that is, G0438, G0439, G9481, G9482, G9483, G9484, G9485, G9486, G9487, G9488, or G9489) and the POS is not (2). In this case, the MAC will use:

- CARC: 16 - (Claim/service lacks information or has submission/billing error(s))
- RARC: M77- (Missing/incomplete/invalid/inappropriate place of service)
- Group Code: CO

Additional Information

The official instruction, CR 11870, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10533DEMO.pdf.

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

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Document History

Date of Change	Description
December 22, 2020	We revised this article due to a revised CR 11870, issued on December 22. The CR revision updated some denial edits. We added that information starting near the bottom of page 3 of this article. Also, we updated the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
August 10, 2020	Initial article released.

Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 27.1, Effective April 1, 2021

MLN Matters Number: MM12110
Related CR Release Date: December 23, 2020
Related CR Transmittal Number: R10535CP
Related Change Request (CR) Number: 12110
Effective Date: April 1, 2021
Implementation Date: April 5, 2021

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

Provider Action Needed
CR 12110 provides the quarterly update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) edits. Please be sure your billing staffs know of the updates.

Background
CMS developed the NCCI to:
- Promote national correct coding methodologies
- Control improper coding that leads to inappropriate payment in Part B claims.

Version 27.1 will include all previous versions and updates from January 1, 1996, to the present.

In the past, NCCI was organized in two tables: Column 1/Column 2 Correct Coding Edits and Mutually Exclusive Code (MEC) Edits. To simplify the use of NCCI edit files (two tables), on April 1, 2012, CMS consolidated these two edit files into the Column One/Column Two Correct Coding edit file. Separate consolidations have occurred for the two practitioner NCCI edit files and the two NCCI edit files used for the Outpatient Code Editor (OCE). It will only be necessary to search the Column One/Column Two Correct Coding edit file for active or previously deleted edits. CMS no longer publishes a Mutually Exclusive edit file on its website for either practitioner or outpatient hospital services, since all active and deleted edits will appear in the single Column One/Column Two Correct Coding edit file on each website. The edits previously contained in the Mutually Exclusive edit file are NOT being deleted but are being moved to the Column One/Column Two Correct Coding edit file.

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

The coding policies developed are based on coding conventions defined in the American Medical Association's CPT manual, national and local policies and edits, coding guidelines developed by national societies, analysis of standard medical and surgical practice, and review of current coding practice.

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Additional Information

The official instruction, CR 12110, issued to your MAC regarding this change, is available at https://www.cms.gov/files/document/r10535cp.pdf.

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

Document History

Date of Change	Description
December 23, 2020	Initial article released.

Updating Calendar Year (CY) 2021 Medicare Diabetes Prevention Program (MDPP) Payment Rates

MLN Matters Number: MM12030
Related CR Release Date: December 23, 2020
Related CR Transmittal Number: R10528OTN
Related Change Request (CR) Number: CR 12030
Effective Date: January 1, 2021
Implementation Date: January 4, 2021

Provider Types Affected
This MLN Matters Article is for organizations enrolled as Medicare Diabetes Prevention Program (MDPP) suppliers billing Medicare Administrative Contractors (MACs) for MDPP services provided to Medicare beneficiaries.

Provider Action Needed
CR 12030 contains instructions for MACs and the Railroad Specialty MAC to update the MDPP Expanded Model payment rates for CY 2021. Make sure your billing staffs are aware of the update.

Background
The MDPP Expanded Model is an expansion of the CMS Diabetes Prevention Program (DPP) model test, which was tested from 2012-2015 under the authority of section 1115A(b) of the Social Security Act (the Act). In March 2016, the Secretary of HHS determined the DPP model test met the criteria for expansion in duration and scope under the authority of Section 1115A(c) of the Act.

Following this determination, CMS expanded the model nationwide through the CY 2017 and 2018 Medicare Physician Fee Schedule (MPFS) final rules.

MDPP suppliers began enrolling in Medicare on January 1, 2018 and began furnishing MDPP services and billing Medicare for MDPP services on April 1, 2018. The MDPP Expanded Model is intended to prevent Medicare beneficiaries with an indication of prediabetes from developing diabetes. Prevention of diabetes among this high-risk group of Medicare beneficiaries is expected to result in significant cost savings to the Medicare program.

We established the CY 2018 MDPP payment rates in the CY 2018 MPFS final rule. This rule also stipulates that the MDPP performance payments and bridge payment will be adjusted each calendar year by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th of the year preceding the update year. We calculate the percent change update based on the level of precision of the index as published by the Bureau of Labor Statistics and applied based on one decimal place of precision. Payment rates will be in effect each year from January 1st through December 31st.

CMS intends to calculate the payment rates for each calendar year, based on the CPI-U; and instruct the MACs and the Railroad Specialty MAC to update the MDPP payment rates each year.

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CR 12030 contains the MDPP Expanded Model payment rates for CY 2021. CMS calculates the CY 2021 MDPP payment rates for the 15 valid MDPP HCPCS G-codes based on the payment rates shown in the following table. These rates are in effect for dates of service January 1, 2021 through December 31, 2021.

Table: MDPP Expanded Model HCPCS G-Codes CY 2021

HCPCS G-Code	Long Descriptor	2021 Payment Amount
G9873	First Medicare Diabetes Prevention Program (MDPP) core session was attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	$26
G9874	Four total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	$52
G9875	Nine total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	$95
G9876	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	$15
G9877	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.	$15

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HCPCS G-Code	Long Descriptor	2021 Payment Amount
G9878	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	$63
G9879	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.	$63
G9880	The MDPP beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight in months 1-12 of the MDPP services period under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 5% weight loss from baseline as measured by an in-person weight measurement at a core session or core maintenance session.	$169
G9881	The MDPP beneficiary achieved at least 9% weight loss (WL) from his/her baseline weight in months 1-24 under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 9% weight loss from baseline as measured by an in-person weight measurement at a core session, core maintenance session, or ongoing maintenance session.	$26
G9882	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 13-15 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 13-15.	$52

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HCPCS G-Code	Long Descriptor	2021 Payment Amount
G9883	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 16-18 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 16-18.	$52
G9884	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 19-21 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 19-21.	$53
G9885	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 22-24 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 22-24.	$53
G9890	Bridge Payment: A one-time payment for the first Medicare Diabetes Prevention Program (MDPP) core session, core maintenance session, or ongoing maintenance session furnished by an MDPP supplier to an MDPP beneficiary during months 1-24 of the MDPP Expanded Model (EM) who has previously received MDPP services from a different MDPP supplier under the MDPP Expanded Model. A supplier may only receive one bridge payment per MDPP beneficiary.	$27
G9891	MDPP session reported as a line-item on a claim for a payable MDPP Expanded Model (EM) HCPCS code for a session furnished by the billing supplier under the MDPP Expanded Model and counting toward achievement of the attendance performance goal for the payable MDPP Expanded Model HCPCS code.(This code is for reporting purposes only).	$0

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Additional Information

The official instruction, CR 12030, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10528otn.pdf.

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

Document History

Date of Change	Description
December 23, 2020	Initial article released.

Billing for Home Infusion Therapy Services on or After January 1, 2021

MLN Matters Number: MM11880 Revised
Related CR Release Date: December 31, 2020
Related CR Transmittal Number: R10547BP, R10547CP
Related Change Request (CR) Number: 11880
Effective Date: January 1, 2021
Implementation Date: January 4, 2021

Note: We revised this article to reflect a revised CR 11880 issued on December 31. In the article, we added two codes (J1559 JB and J7799 JB) as we show in red print in Table 3.2 on page 7. Also, we revised the CR release date, transmittal numbers, and the web addresses of the transmittals. All other information remains the same.

Provider Type Affected
This MLN Matters Article is intended for qualified Home Infusion Therapy (HIT) suppliers who bill Part B Medicare Administrative Contractors (A/B MACs) for professional HIT services provided to Medicare beneficiaries.

Provider Action Needed
This article provides guidance to providers and suppliers about claims processing systems changes necessary to implement Section 5012(d) of the 21st Century Cures Act. These changes are effective on and after January 1, 2021. Make sure that your billing staff is aware of these changes.

Background
Effective January 1, 2021, Section 5012(d) of the 21st Century Cures Act (Pub. L 114-255) amended sections 1861(s)(2) and 1861(iii) of the Social Security Act (the Act), requiring the Secretary to establish a new Medicare HIT services benefit. The Medicare HIT services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified HIT supplier (suppliers must have specialty code D6).

Section 1861(iii)(3)(C) of the Act defines a "home infusion drug" as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. In the CY 2020 HH PPS final rule with comment period (84 FR 60618), the Centers for Medicare & Medicaid Services (CMS) stated that this means that "home infusion drugs" are defined as parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit, pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

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Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. CMS finalized the definition of "infusion drug administration calendar day" in regulation as the day on which HIT services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel (42 CFR 486.505).

Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the Physician Fee Schedule (PFS) (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting. This statutory provision limits the single payment amount so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. CMS retained the three current payment categories, with the associated J-codes as outlined in section 1834(u)(7)(C) of the Act, to utilize an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, as required by section 1834(u)(1)(A)(ii) of the Act. The payment amount for each of these three categories is different, though each category has its associated single payment amount. The single payment amount (per category) would thereby reflect variations in nursing utilization, complexity of drug administration, and patient acuity, as determined by the different categories based on therapy type. CMS set the amount equivalent to 5 hours of infusion in a physician's office. Each payment category amount would be in accordance with the six infusion CPT codes identified in section 1834(u)(7)(D) of the Act

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections the single payment amount will increase by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10 year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

Section 1834(u)(1)(C) of the Act allows the Secretary discretion to adjust the single payment amount to reflect outlier situations and other factors as the Secretary determines appropriate, in a budget neutral manner. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for HIT services.

In accordance with section 1834(u)(1)(B)(i) of the Act, we are using the Geographic Adjustment Factor (GAF) to wage adjust the home infusion therapy services payment. In order to make the application of the GAF budget neutral we are going to apply a budget-neutrality factor. Additionally, in CY 2022, we will adjust the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10 year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

Finally, Medicare is increasing the payment amounts for each of the three payment categories for the initial infusion therapy service visit by the relative payment for a new patient rate over an existing patient rate using

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the physician evaluation and management (E/M) payment amounts for a given year. Overall, this adjustment would be budget-neutral, resulting in a small decrease to the payment amounts for any subsequent infusion therapy service visits.

In the event that multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, a single payment would be made that is equal to the highest payment category.

The G-codes are:

- G0068: Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes Short Descriptor: Adm IV infusion drug in home
- G0069: Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes Short Descriptor: Adm SQ infusion drug in home
- G0070: Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm of IV chemo drug in home
- G0088: Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm IV drug 1st home visit
- G0089: Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm SubQ drug 1st home visit
- G0090: Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm IV chemo 1st home visit

NOTE: The G-code payment rates are being added to the PFS fee schedule incorporating the required annual and geographic wage adjustments. The G codes will appear on the PFS as
status "X."

A qualified HIT supplier is only required to enroll in Medicare as a Part B supplier and is not required to enroll as a DME supplier, therefore, the G-codes will be billed through the A/B MACs and the Multi-Carrier System (MCS) for Medicare Part B claims. DME suppliers, also enrolled as qualified HIT suppliers, would continue to submit DME claims through the DME MACs; however, they would also be required to submit HIT service claims (G-codes) to the A/B MACs for processing. The qualified HIT supplier will submit all HIT service claims on the 837P/CMS-1500 professional and supplier claims form to the A/B MACs. DME suppliers, concurrently enrolled as qualified HIT suppliers, will need to submit one claim for the DME, supplies, and drug on the 837P/CMS-1500 professional and supplier claims form to the DME MAC and a separate 837P/CMS-1500 professional and supplier claims form for the professional HIT services to the A/B MAC. Similarly, home health agencies, concurrently enrolled as qualified HIT suppliers, will need to continue submitting a standard 837/CMS-1450

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institutional claims form for the professional home health services to the A/B MAC (HHH) and a separate 837P/CMS-1500 professional and supplier claims form for the professional HIT services to the A/B MAC.

Because the HIT services are contingent upon a home infusion drug J-code being billed, the appropriate drug associated with the visit must be billed with the visit or no more than 30 days prior to the visit. To identify and process claims for the items and services furnished under the home infusion therapy benefit, a Common Working File (CWF) edit will be implemented for the submitted G-code claims. The claims processing system will recycle the G-code claim for the professional services associated with the administration of the home infusion drug until a claim containing the J-code for the infusion drug is received in the CWF. The professional visit G-code claim will recycle three times (with a 30-day look back period) for a total of 15 business days. After 15 business days, if no J-code claim is found in claims history, the G-code claim will be denied.

Suppliers must ensure that the appropriate drug associated with the visit is billed with no more than 30 days prior to the visit. In the event that multiple visits occur on the same date of service, suppliers must only bill for one visit and should report the highest paying visit with the applicable drug. Claims reporting multiple visits on the same line item date of service will be returned as unprocessable.
Suppliers should report visit length in 15-minute increments (15 minutes = 1 unit). See Table 1 for guidance on billing time increments.

Billing for Home Infusion Therapy Services on or After January 1, 2021
Table 1 shows the time increments providers should report visit length in 15-minute increments (15 minutes = 1 unit). See the table below for the rounding of units:

Table 1: Time Increments

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

Home infusion therapy suppliers will use a new G-code to differentiate the first visit from all subsequent visits. Home infusion therapy suppliers may only bill the new G-code to indicate an initial visit for a new patient who had previously received their last home infusion therapy service visit more than 60 days prior to the new initial home infusion therapy service visit. If any of the home infusion therapy G-codes is found in the claims history within 60-days prior to the date of service for an initial visit, then the initial visit claim will be rejected. Table 2 below shows the use of the G-codes established for the home infusion therapy services benefit, and reflects the therapy type and complexity of the drug administration per category.

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Table 2: Payment Categories for Home Infusion Therapy Professional Services (G-Codes)

	Category 1	Category 2	Category 3
Description G-Code	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain intravenous infusion drugs	Subcutaneous immunotherapy and other certain Subcutaneous infusion drugs	Chemotherapy and other certain highly complex intravenous drugs
Initial Visit	G0088	G0089	G0090
Subsequent Visit	G0068	G0069	G0070

Home infusion drugs are assigned to three payment categories, as determined by the HCPCS J-code:

- Payment category 1 includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, chelation drugs.
- Payment category 2 includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs.
- Payment category 3 includes certain chemotherapy drugs and other certain highly complex intravenous drugs.

CMS has established a single payment amount for each of the three categories for professional services furnished for each infusion drug administration calendar day. Each payment category will be paid at amounts in accordance with infusion codes and units for such codes under the physician fee schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category. The payment amounts are equal to 5 hours of infusion therapy in a physician's office. Tables 3.1, 3.2, and 3.3 below provide a list of J-codes associated with the home infusion drugs that fall within each category.

Tables 3.1, 3.2, and 3.3: Payment Categories for Home Infusion Drugs (J-Codes)
Table 3.1 – Category 1

J-Code	Description
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg

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J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, Treprostinil, 1 mg

Table 3.2 – Category 2

J-Code	Description
J1555 JB	Injection, immune globulin (cuvitru), 100 mg
J1558 JB	Injection, immune globulin (xembify), 100mg
J1559 JB	Injection, immune globulin (hizentra), 100mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g. liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
J7799 JB	This NOC code may be used to identify the subcutaneous immune globulin (cutaquig)

Table 3.3 – Category 3

J-Code	Description
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

The payment category may be determined by the DME MAC for any new home infusion drug additions to the Local Coverage Determination (LCD) for External Infusion Pumps as identified by the following not-otherwise-classified (NOC) codes:

J7799 - Not otherwise classified drugs, other than inhalation drugs, administered through DME
J7999 - Compounded drug, not otherwise classified.

Note that qualified home infusion suppliers must have a specialty code of D6, effective for claim lines for HIT services on or after January 1, 2021. Claims lines from specialties other than D6 will be denied with the following messages:

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- Claim Adjustment Reason Code (CARC) 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- Remittance Advice Remarks Code (RARC) N256 - Missing/incomplete/invalid billing provider/supplier name.
- Group Code: CO

Also, note that Medicare will only pay for one of the G-codes listed per line item date of service. If more than one G-code line item is billed for the same day, it will be denied using the following messages:
- CARC 97 - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N111 - No appeal right except duplicate claim/service issue. This service was included in a claim that has been previously billed and adjudicated.
- Group Code CO

If G-codes are billed for a date of service on or after January 1, 2021, and there is not a timely billed DME claim with one of the allowable drug J-codes as noted above (and after the G-code is recycled up to three times for a minimum of up to 15 days, MACs will deny the G-code with the following messages:
- CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N657 - This should be billed with the appropriate code for these services.
- Group Code - CO (Contractual Obligation)

If more than one claim line is billed with one of the G-codes within a 60-day period, subsequent lines will be denied with the following messages:
- CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N640 - Exceeds number/frequency approved/allowed within time period.
- Group Code - CO (Contractual Obligation)

Additional Information
The official instructions, CR11880, issued to your MAC regarding this change are available at https://www.cms.gov/files/document/r10547bp.pdf and https://www.cms.gov/files/document/r10547cp.pdf.

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Additional instruction, CR 11750, issued to your MAC regarding the new supplier specialty code for home infusion therapy services is in two transmittals. The first updates the Medicare Claims Processing Manual and it is available at https://www.cms.gov/files/document/r10124cp.pdf. The second updates the Medicare Financial Management Manual and it is at https://www.cms.gov/files/document/r10124fm.pdf.

MACs will post the HIT fees on their websites as soon as possible.

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

Document History

Date of Change	Description
December 31, 2020	We revised this article to reflect a revised CR 11880 issued on December 31. In the article, we added two codes (J1559 JB and J7799 JB) as we show in red print in Table 3.2 on page 7. Also, we revised the CR release date, transmittal numbers, and the web addresses of the transmittals. All other information remains the same.
November 13, 2020	We revised this article to reflect a revised CR 11880 issued on November 13. In the article, we added statements related to the status indicator for the G codes on the Physician Fee Schedule and noting that MACs will post the HIT fees on their websites as soon as possible. Also, we revised the CR release date, transmittal numbers, and the web addresses of the transmittals. All other information remains the same.
August 7, 2020	Initial article released.

January 2021 Update of the Ambulatory Surgical Center (ASC) Payment System

MLN Matters Number: MM12129
Related CR Release Date: December 31, 2020
Related CR Transmittal Number: R10546CP
Related Change Request (CR) Number: 12129
Effective Date: January 1, 2021
Implementation Date: January 4, 2021

Provider Types Affected
This MLN Matters Article is intended for physicians, other providers, and suppliers submitting claims to Medicare contractors (A/B Medicare Administrative Contractors (A/B MACs)) for services to Medicare beneficiaries.

Provider Action Needed
This article describes changes to and billing instructions for various payment policies implemented in the January 2021 Ambulatory Surgical Center (ASC) payment system update. CR 12129 also includes updates to HCPCS. Make sure that your billing staffs are aware of these changes.

Background
CR 12129 includes Calendar Year (CY) 2021 payment rates for separately payable procedures/services, drugs and biologicals, including descriptors for newly created CPT and Level II HCPCS codes. CMS will issue a January 2021 ASC Fee Schedule (ASCFS) File, January 2021 ASC Payment Indicator (ASC PI) File, a January 2021 ASC Drug File, and a January 2021 ASC Code Pair file in conjunction with CR 12129.

Following are the key points of CR 12129:

1. New Device Pass-Through Categories
Section 1833(t)(6)(B) of the Social Security Act (the Act) requires that, under the Outpatient Prospective Payment System (OPPS), categories of devices be eligible for transitional pass-through payments for at least 2 but not more than 3 years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that CMS create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices. This policy was implemented in the 2008 revised ASC payment system. Therefore, additional payments may be made to the ASC for covered ancillary services, including certain implantable devices with pass-through status under the OPPS. Three new device pass-through categories are established as of January 1, 2021. Table 1 of CR 12129 describes these categories for HCPCS codes C1825, C1052, and C1062.

a. Device Offset from Payment:
Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices in the OPPS an amount that reflects the device portion of the Ambulatory Payment Classification (APC) payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-

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through payments for the applicable pass-through device. This policy was implemented in the 2008 revised ASC payment system.

We determined that there are device offset amounts associated with each of the new device pass-through categories effective January 1, 2021, that are included in Table 1. There are also device offset amount changes associated with existing device pass-through HCPCS C1839, C1748, and C1982.

We determined the device offset amounts for OPPS APC 5491 Level 1 Intraocular Procedures and OPPS APC 5492 Level 2 Intraocular Procedures that are associated with the costs of the device category described by HCPCS code C1839 (Iris prosthesis). The device in the category described by HCPCS code C1839 should always be billed by ASCs with one of the following CPT codes:

- CPT code 0616T – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens, which is assigned to OPPS APC 5491 for CY 2021
- CPT code 0617T – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens, which is assigned to OPPS APC 5492 for CY 2021
- CPT code 0618T – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens, which is assigned to OPPS APC 5492 for CY 2021

We determined the device offset amount for OPPS APC 5465 (Level 5 Neurostimulator and Related Procedures) that is associated with the cost of the device category described by HCPCS code C1825 (Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)). The device in the category described by HCPCS code C1825 should be billed by ASCs with the following CPT code:

- CPT code 0266T (Implt/rpl crtd sns dev total), which is assigned to OPPS APC 5465 for CY 2021

We determined the device offset amounts for OPPS APC 5302 (Level 2 Upper Gastrointestinal (GI) Procedures) and OPPS APC 5312 (Level 2 Lower GI Procedures) that are associated with the cost of the device category described by HCPCS code C1052 (Hemostatic agent, gastrointestinal, topical). The device in the category described by HCPCS code C1052 should always be billed by ASCs with one of the following CPT codes:

- CPT code 43227 (Esophagoscopy control bleed), which is assigned to OPPS APC 5302 for CY 2021
- CPT code 43255 (Egd control bleeding any), which is assigned to OPPS APC 5302 for CY 2021
- CPT code 44366 (Small bowl endoscopy), which is assigned to OPPS APC 5302 for CY 2021
- CPT code 44378 (Small bowel endoscopy), which is assigned to OPPS APC 5302 for CY 2021
- CPT code 44391 (Colonoscopy for bleeding), which is assigned to OPPS APC 5312 for CY 2021
- CPT code 45334 (Sigmoidoscopy for bleeding), which is assigned to OPPS APC 5312 for CY 2021
- CPT code 45382 (Colonoscopy w/control bleed), which is assigned to OPPS APC 5312 for CY 2021

We determined the device offset amount for OPPS APC 5114 (Level 4 Musculoskeletal Procedures) that is associated with the cost of the device category described by HCPCS code C1062 (Intravertebral body fracture augmentation with implant (e.g., metal, polymer). The device in the category described by HCPCS code C1062 should always be billed with one of the following CPT codes:

- CPT code 22513 (Perq vertebral augmentation), which is assigned to OPPS APC 5114 for CY 2021
- CPT code 22514 (Perq vertebral augmentation), which is assigned to OPPS APC 5114 for CY 2021

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On July 1, 2020, we determined that an offset would apply to HCPCS code C1748 (Endoscope, single-use, (i.e. disposable), Upper GI, imaging/illumination device (insertable)) because OPPS APC 5303 (Level 3 Upper GI Procedures) and OPPS APC 5331 (Complex GI Procedures) already contain costs associated with the device described by HCPCS code C1748. HCPCS code C1748 should always be billed with the CPT codes listed below. The device offset is a deduction from pass-through payments for HCPCS code C1748. After further review, we determined that the costs associated with HCPCS code C1748 are not already reflected in OPPS APCs 5303 or 5331. Therefore, CMS is not applying a device offset to HCPCS code C1748. This determination to not apply the device offset from payment will be retroactive to July 1, 2020. Your MAC will reprocess affected claims.

- CPT code 43260 (Ercp w/specimen collection), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43261 (Endo cholangiopancreatograph), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43262 (Endo cholangiopancreatograph), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43263 (Ercp sphincter pressure meas), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43264 (Ercp remove duct calculi), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43265 (Ercp lithotripsy calculi), which is assigned to OPPS APC 5331 for CY 2021
- CPT code 43274 (Ercp duct stent placement), which is assigned to OPPS APC 5331 for CY 2021
- CPT code 43275 (Ercp removed forgn body duct), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43276 (Ercp stent exchange w/dilate), which is assigned to OPPS APC 5331 for CY 2021
- CPT code 43277 (Ercp ea duct/ampulla dilate), which is assigned to OPPS APC 5303 for CY 2021
- CPT code 43278 (Ercp lesion ablate w/dilate), which is assigned to OPPS APC 5303 for CY 2021

We determined the device offset amount for APC 2025 (Cath, pressure, valve-occlu) that is associated with the cost of the device category described by HCPCS code C1982 (Cath, pressure, valve-occlu). The device in the category described by HCPCS code C1982 may be billed with the following CPT code:

- CPT code 37242 (Vasc embolize/occlude artery), which is assigned to APC 5193 for CY 2021

2. Device Pass-Through Payments

Per Transmittal 1325, which we issued on December 7, 2007, ASC pass-through device pricing is based on acquisition cost or invoice. Provider education regarding ASC pass-through device pricing, as well as billing guidance associated with MAC processing of pass-through device claims, will be posted to MAC websites.

3. New HCPCS Code Describing the Administration of Subretinal Therapies Requiring Vitrectomy

CMS is establishing a new HCPCS code C9770, to describe a vitrectomy, mechanical, pars plana approach, with subretinal injection of a pharmacologic or biologic agent. Table 2 of CR 12129 lists this HCPCS, short descriptor, long descriptor, and ASC PI.

4. New HCPCS Code Describing Nasal Endoscopy with Cryoablation of Nasal Tissue(s) and/or Nerve(s)

CMS is establishing HCPCS code C9771 to describe the technology associated with nasal endoscopy with cryoablation of nasal tissues and/or nerves. Table 3 of CR 12129 (https://www.cms.gov/files/document/R10546CP.pdf/#page=15) lists this HCPCS, short descriptor, long descriptor, and ASC PI.

5. New HCPCS Codes Describing Peripheral Intravascular Lithotripsy (IVL) Procedures

For the January 2021 update, we are establishing 4 additional new HCPCS codes to describe the technology associated with the IVL procedure, which has integrated lithotripsy emitters and is designed to enhance percutaneous transluminal angioplasty by enabling delivery of the calcium disrupting capability of lithotripsy

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prior to full balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive vascular deposit (stenosis) prior to low-pressure balloon dilation of the stenosis and facilitates the passage of blood and is used for the treatment of Peripheral Artery Disease (PAD). Specifically, we are establishing HCPCS codes C9772, C9773, C9774, and C9775 to describe the surgical procedures utilizing IVL. Table 4 of CR 12129 (https://www.cms.gov/files/document/R10546CP.pdf/#page=16) lists these HCPCS, short descriptors, long descriptors, and ASC PIs.

6. Removal of Selected National Coverage Determinations (NCDs) Effective January 1, 2021

As stated in the CY 2021 Physician Fee Schedule (PFS) final rule with comment period, effective January 1, 2021, CMS removed certain NCDs. Table 5 of CR 12129 lists the NCD name and manual citation.

As a result of this change, the coverage determinations for the procedures, services, and items associated with the NCDs listed above will be made by the local MAC. Also, we revised the ASC PIs for the codes listed in Table 6 of CR 12129 from ASC PI = "Y5" (Non-Surgical Procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made.) to the ASC PIs listed below.

7. Existing HCPCS Codes for Certain Drugs and Biologicals That Will Start to Receive Separate Payment

There is one existing HCPCS code for certain drugs and biologicals in the ASC setting that will start to receive separate payment beginning on January 1, 2021. We list this code (J9198) in Table 7 of CR 12129.

8. Newly Established HCPCS Codes for Drug and Biologicals Effective January 1, 2021

Fifteen (15) new HCPCS codes have been created for reporting drugs and biologicals in the ASC payment effective January 1, 2021. Table 8 of CR 12129 lists these HCPCS codes. The HCPCS codes listed in the "old HCPCS codes" column of Table 8, are deleted effective January 1, 2021.

9. Retroactive Correction for HCPCS J1097 Effective October 1, 2020

Effective October 2020, HCPCS J1097 (Phenylep ketorolac opth soln), brand name Omidria, became separately payable in the ASC payment system. A payment rate wasn't available to MACs as part of the October release in the ASC payment system. Consequently, ASCs that may have submitted claims for this drug, may not have been paid correctly.

Retroactively, HCPCS J1097 is separately payable for ASC claims with dates of service beginning October 1, 2020.

Suppliers who think they may have previously received an incorrect payment or incorrect disposition associated with this correction for J1097, for claims beginning October 1, 2020, may request their MAC adjust the previously processed claims.

10. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2021, payment for nonpass-through drugs and biologicals continues to be made at a single rate of ASP + 6 percent, which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. In addition, in CY 2021, a single payment of ASP + 6 percent continues to be made for OPPS pass-through drugs, and biologicals to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items. Payments for drugs and biologicals based on ASPs will be updated on a quarterly basis as later quarter ASP submissions become available. Updated payment rates effective January

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1, 2021, are in the January 2021 update of ASC Addendum BB at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.

a. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates
Some drugs and biologicals with payment rates based on the ASP methodology may have their payment rates corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payment rates will be accessible on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Restated-Payment-Rates.html.

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

11. Skin Substitute Procedure Edits
Payment for skin substitute products that don't qualify for hospital OPPS pass-through status are packaged into the OPPS payment for the associated skin substitute application procedure. This policy is also implemented in the ASC payment system.

Skin substitute products are divided into two groups:

1) High-cost skin substitute products
2) Low-cost skin substitute products for packaging purposes

High-cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by CPT codes 15271-15278. Low-cost skin substitute products should only be used in combination with the performance of one of the skin application procedures described by HCPCS code C5271-C5278. All OPPS pass-through skin substitute products (ASC PI=K2) should be billed in combination with one of the skin application procedures described by CPT code 15271-15278.

Note: The final rule skin substitute table incorrectly assigned Q4222 (Progenamatrix, per sq cm) to the low-cost group when it should have been assigned to the high-cost group for January. This correction is currently reflected in all relevant January ASC payment files and tables.

Table 9 of CR 12129 (https://www.cms.gov/files/document/R10546CP.pdf/#page=19) lists the skin substitute products and their assignment as either a high-cost or a low-cost skin substitute product, when applicable.

Note: ASCs shouldn't separately bill for packaged skin substitutes (ASC PI=N1) since packaged codes aren't reportable under the ASC payment system.

12. Coverage Determinations
Assignment of an HCPCS code and payment rate under the ASC payment system to a drug, device, procedure, or service doesn't 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's excluded from payment.

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Additional Information

The official instruction, CR 12129, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/R10546CP.pdf.

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

Document History

Date of Change	Description
January 5, 2021	Initial article released.

Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: MM12080
Related CR Release Date: December 18, 2020
Related CR Transmittal Number: R10523CP
Related Change Request (CR) Number: 12080
Effective Date: January 1, 2021
Implementation Date: January 4,

Provider Type Affected
This MLN Matters Article is for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for laboratory services for Medicare beneficiaries.

Provider Action Needed
Related CR 12080 provides instructions for the Calendar Year (CY) 2021 Clinical Laboratory Fee Schedule (CLFS), mapping for new codes for clinical laboratory tests, and updates for laboratory costs subject to the reasonable charge payment. Make sure your billing staffs are aware of these updates.

Background
The CY 2021 updates are as follows:

Advanced Diagnostic Laboratory Tests (ADLTs)
Refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests for further information on these tests.

- **Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests —DELAYED**
- Section 1834A of the Social Security Act (the Act), as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019, through June 30, 2019.
- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, the revisions are as follows:
  - The next data reporting period of January 1, 2022, through March 31, 2022, will be based on the original data collection period of January 1, 2019, through June 9.
  - After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).

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The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that is, through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15% for CYs 2022 through 2024.

COVID-19 Policy Updates

Payment for High Throughput Technologies

On October 15, 2020, CMS issued ruling CMS-2020-1-R2 which amends CMS Ruling 2020-1-R, which articulated CMS's policy concerning the designation and payment of certain CDLTs related to COVID-19 under the Medicare Part B CLFS.

CMS Ruling 2020-1-R defined certain highly sophisticated equipment called "high throughput technology." It also established a payment amount for molecular genomic CDLTs making use of high throughput technologies for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID-19 and that are administered during the ongoing emergency period defined in paragraph (1)(B) of Section 1135(g) of the Act.

CMS Ruling 2020-2-R amends CMS Ruling 2020-1-R by modifying the payment amount established in that Ruling for such CDLT based on a re-evaluation of the resources necessary for the timely administration of these tests. The ruling:

- Establishes a revised payment amount for HCPCS codes U0003 and U0004 of $75 per procedure (previously was $100)
- Sets a new add-on payment amount of $25 for HCPCS code U0005 which is to be used to indicate that the
  - corresponding CDLT (U0003 or U0004) that makes use of high throughput technology for the detection of SARS–CoV–2 or diagnosis of the virus that causes COVID-19 is completed within 2 calendar days of the specimen being collected, and
  - the laboratory completed a majority of these CDLTs (for all patients during the prior calendar month) in 2 calendar days or less from when the specimen was collected.

For more information on this policy update, please refer to
https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf.

Clinical Laboratory Fee Schedule Update to Fees

In accordance with Section 1833(h)(2)(A)(i) of the Act, the annual update to the local clinical laboratory fees for CY 2021 is 0.20%. Beginning January 1, 2021, this update applies only to pap smear tests. For a pap smear test, Section 1833(h)(7) of the Act requires payment to be the lesser of the local fee or the National Limitation Amount, but not less than a national minimum payment amount. However, for pap smear tests, payment may also not exceed the actual charge. The CY 2021 national minimum payment amount is $15.15 (This value reflects the CY 2020 national minimum payment with a 0.2% increase or $15.12 times 1.0020). The affected codes for the national minimum payment amount are: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, Q0111, Q0115, and P3000.

The annual update to payments made on a reasonable charge basis for all other laboratory services for CY 2021 is 0.6% (See 42 CFR 405.509(b)(1)). The Part B deductible and coinsurance do not apply for services paid under the CLFS.

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Access to Data File
You'll have Internet access to the CY 2021 CLFS data file at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. It will be available in multiple formats including Excel, text, and comma delimited.

Public Comments and Final Payment Determinations
On June 22, 2020, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2019 codes and new CY 2021 CPT codes. Notice of the meeting was published in the **Federal Register** on May 4, 2020. Many attendees, including individuals representing laboratories, manufacturers, and medical societies made recommendations to CMS. We posted a summary of the meeting and the tentative payment determinations at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html. We accepted additional written comments from the public until October 21, 2020. We also posted a summary of the public comments and the rationale for the final payment determinations at the same CMS web site identified in the previous sentence.

Pricing Information
The CY 2021 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees have been established in accordance with Section 1833(h)(4)(B) of the Act.
We update the fees for clinical laboratory travel codes P9603 and P9604 on an annual basis. You may bill the clinical laboratory travel codes only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there is a revision to the standard mileage rate for CY 2021, CMS will issue a separate instruction on the clinical laboratory travel fees.

The CY 2021 CLFS may also include codes that have a "QW" modifier to both identify codes and determine payment for tests performed by a laboratory having only a CLIA certificate of waiver. Code will be listed if applicable.

Mapping Information
CY 2021 CLFS Mapping Information
1. New code 0141U is to be gapfilled
2. New code 0142U is to be gapfilled
3. New code 0151U is to be gapfilled
4. New code 0202U is priced at the same rate as code 87633
5. New code 0140U is to be gapfilled
6. New code 0152U is to be gapfilled
7. New code 0210U is priced at the same rate as code [0065U PLUS (0065U TIMES 0.03)]
8. New code U0001 is to be gapfilled
9. New code U0002 is to be gapfilled
10. New code U0003 is to be gapfilled
11. New code U0004 is to be gapfilled
12. New code 87635 is to be gapfilled
13. New code 86328 is to be gapfilled
14. New code 86769 is to be gapfilled
15. New code 0181U is priced at the same rate as code 81403

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16. New code 0182U is priced at the same rate as code 81405
17. New code 0183U is priced at the same rate as code 81403
18. New code 0184U is priced at the same rate as code 81403
19. New code 0185U is priced at the same rate as code 81403
20. New code 0186U is priced at the same rate as code 81403
21. New code 0187U is priced at the same rate as code 81404
22. New code 0188U is priced at the same rate as code 81404
23. New code 0189U is priced at the same rate as code 81404
24. New code 0190U is priced at the same rate as code 81404
25. New code 0191U is priced at the same rate as code 81404
26. New code 0192U is priced at the same rate as code 81404
27. New code 0193U is priced at the same rate as code 81406
28. New code 0194U is priced at the same rate as code 81403
29. New code 0196U is priced at the same rate as code 81403
30. New code 0197U is priced at the same rate as code 81403
31. New code 0198U is priced at the same rate as code 81406
32. New code 0199U is priced at the same rate as code 81404
33. New code 0200U is priced at the same rate as code 81404
34. New code 0201U is priced at the same rate as code 81403
35. New code 0221U is to be gapfilled
36. New code 0222U is to be gapfilled
37. New code 0180U is to be gapfilled
38. New code 0143U is to be gapfilled
39. New code 0144U is to be gapfilled
40. New code 0145U is priced at the same rate as code G0480
41. New code 0146U is priced at the same rate as code G0480
42. New code 0147U is priced at the same rate as code G0480
43. New code 0148U is priced at the same rate as code G0480
44. New code 0149U is priced at the same rate as code G0480
45. New code 0150U is priced at the same rate as code G0480
46. New code 80179 is priced at the same rate as code 80299
47. New code 80151 is priced at the same rate as code 80299
48. New code 80143 is priced at the same rate as code 80299
49. New code 82077 is priced at the same rate as code 83520
50. New code 80161 is priced at the same rate as code 80299
51. New code 80167 is priced at the same rate as code 80299
52. New code 80181 is priced at the same rate as code 80299
53. New code 80189 is priced at the same rate as code 80187
54. New code 80193 is priced at the same rate as code 80230
55. New code 80204 is priced at the same rate as code 80230
56. New code 80210 is priced at the same rate as code 80199
57. New code 0219U is to be gapfilled
58. New code 81513 is priced at the same rate as code 87631
59. New code 81514 is priced at the same rate as code 87506
60. New code 81546 is priced at the same rate as code 81545

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61. New code 0208U is to be gapfilled
62. New code 0014M is priced at the same rate as code 0003M*0.35
63. New code 0166U is priced at the same rate as code 0003M
64. New code 0139U is to be gapfilled
65. New code 0170U is priced at the same rate as code 0090U
66. New code 81554 -NEW-This code was approved as an ADLT
67. New code 0164U is to be gapfilled
68. New code 0168U is priced at the same rate as code 81420
69. New code 0174U is to be gapfilled
70. New code 0015M is to be gapfilled
71. New code 0016M is to be gapfilled
72. New code 0163U is to be gapfilled
73. Reconsidered code 81307 is priced at the same rate as code 81317
74. Reconsidered code 0071U is priced at the same rate as code 81238
75. Reconsidered code 0101U is to be gapfilled
76. Reconsidered code 0102U is to be gapfilled
77. Reconsidered code 0103U is to be gapfilled
78. Reconsidered code 0129U is to be gapfilled
79. New code 81168 is priced at the same rate as code 81315
80. New code 81278 is priced at the same rate as code 81315
81. New code 81191 is priced at the same rate as code 81315
82. New code 81192 is priced at the same rate as code 81315
83. New code 81193 is priced at the same rate as code 81315
84. New code 0209U is to be gapfilled
85. New code 81194 is priced at the same rate as code 81315 TIMES 2.5
86. New code 0153U is to be gapfilled
87. New code 0155U is priced at the same rate as code 81309
88. New code 0177U is priced at the same rate as code 81310
89. New code 0157U is to be gapfilled
90. New code 0158U is to be gapfilled
91. New code 0159U is to be gapfilled
92. New code 0160U is to be gapfilled
93. New code 0161U is to be gapfilled
94. New code 0162U is to be gapfilled
95. New code 81279 is priced at the same rate as code 81403
96. New code 81338 is priced at the same rate as code 81402
97. New code 81339 is priced at the same rate as code 81403
98. New code 81347 is priced at the same rate as code 81120
99. New code 81348 is priced at the same rate as code 81233
100. New code 81357 is priced at the same rate as code 81120
101. New code 81360 is priced at the same rate as code 81120
102. New code 0171U is to be gapfilled
103. New code 81351 is priced at the same rate as code 81298
104. New code 81353 is priced at the same rate as code 81299
105. New code 81352 is priced at the same rate as code 81334

Continued >>

106. New code 0154U is priced at the same rate as code 81309 PLUS 81315
107. New code 0156U is to be gapfilled
108. New code 0179U is to be gapfilled
109. New code 0195U is priced at the same rate as code 81215
110. New code 0169U is priced at the same rate as code 0034U
111. New code 0165U is to be gapfilled
112. New code 0167U is priced at the same rate as code 84703
113. New code 0178U is to be gapfilled
114. New code 81419 is priced at the same rate as code 81443
115. New code 0173U is to be gapfilled
116. New code 0175U is to be gapfilled
117. New code 0203U is priced at the same rate as code 0011M
118. New code 0204U is priced at the same rate as code 81455
119. New code 0205U is priced at the same rate as code 81330
120. New code 0211U is priced at the same rate as code 0019U PLUS 0036U
121. New code 0212U is to be gapfilled
122. New code 0213U is to be gapfilled
123. New code 0214U is to be gapfilled
124. New code 0215U is to be gapfilled
125. New code 0216U is to be gapfilled
126. New code 0217U is to be gapfilled
127. New code 0218U is priced at the same rate as code 81408 PLUS 81161
128. New code 0176U is priced at the same rate as code 86828
129. New code 0206U is to be gapfilled
130. New code 0207U is to be gapfilled
131. New code 0220U is to be gapfilled
132. New code 82681 is priced at the same rate as code 82670
133. New Code U0002QW is priced at the same rate as code U0002
134. New Code 87635QW is priced at the same rate as code 87635
135. New Code 87426QW is priced at the same rate as code 87426
136. Existing code 0006U is deleted
137. Existing code 0124U is deleted
138. Existing code 0125U is deleted
139. Existing code 0126U is deleted
140. Existing code 0127U is deleted
141. Existing code 0128U is deleted
142. Existing code 87450 is deleted

Laboratory Costs Subject to Reasonable Charge Payment in CY 2020

Hospital outpatient claims are paid under a reasonable charge basis (See Section 1842(b)(3) of the Act). In accordance with 42 CFR 405.502 through 42 CFR 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index (CPI) for the 12-month period ending June 30 of each year as set forth in 42 CFR 405.509(b)(1). The CPI update for CY 2021 is **0.60%**.

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Manual instructions for determining the reasonable charge payment are in Chapter 23, Sections 80 through 80.8 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf. If there is not sufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

Services described by HCPCS codes in the following list are performed for independent dialysis facility patients. Chapter 8, Section 60.3 of the Medicare Claims Processing Manual, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf, instructs that the reasonable charge basis applies. However, when these services are performed for hospital-based renal dialysis facility patients, payment is made on a reasonable cost basis. Also, when these services are performed for hospital outpatients, payment is made under the hospital Outpatient Prospective Payment System (OPPS).

Laboratory Costs Subject to Reasonable Charge Payment in CY 2021

Code Category	Codes
Blood Products	P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033 P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9044 P9050 P9051 P9052 P9053 P9054 P9055 P9056 P9057 P9058 P9059 P9060 P9070 P9071 P9073 P9100 Also, payment for the following codes should be applied to the blood deductible as instructed in Publication 100-01, Medicare General Information, Eligibility and Entitlement Manual, Chapter 3, Section 20.5 through 20.5.4: P9010 P9016 P9021 P9022 P9038 P9039 P9040 P9051 P9054 P9056 P9057 P9058 NOTE: Biologic products not paid on a cost or prospective payment basis are paid based on Section 1842(o) of the Act. The payment limits based on Section 1842(o), including the payment limits for codes P9041, P9045, P9046, and P9047, should be obtained from the Medicare Part B drug pricing files.
Transfusion Medicine	86850 86860 86870 86880 86885 86886 86890 86891 86900 86901 86902 86904 86905 86906 86920 86921 86922 86923 86927 86930 86931 86932 86945 86950 86960 86965 86970 86971 86972 86975 86976 86977 86978 86985
Reproductive Medicine Procedures	89250 89251 89253 89254 89255 89257 89258 89259 89260 89261 89264 89268 89272 89280 89281 89290 89291 89335 89337 89342 89343 89344 89346 89352 89353 89354 89356

New Codes Effective October 6, 2020

The listed new codes are on the national HCPCS file with an effective date of October 6, 2020, and do not need to be manually added to the HCPCS files by the MACs. These new codes are contractor-priced (where applicable) until they are nationally priced and undergoes the CLFS annual payment determination process in accordance with the Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

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- Code: 87636
  - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
  - Short Descriptor: SARSCOV2 & INF A&B AMP PRB
  - Type of Service (TOS): 5
- Code: 87637
  - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
  - Short Descriptor: SARSCOV2&INF A&B&RSV AMP PRB
  - TOS: 5
- Code: 87811
  - Long Descriptor: Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Streptococcus, group B severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
  - Short Descriptor: SARS-COV-2 COVID19 W/OPTIC
  - TOS: 5

Proprietary Laboratory Analysis (PLAs)

The listed new codes have been added to the national HCPCS file with an effective date of October 6, 2020, and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July 2021 as they were received after the 2020 public meeting. MACs only price PLA codes for laboratories within their jurisdiction.

- Code: 0240U
  - Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
  - Short Descriptor: NFCT DS VIR RESP RNA 3 TRGT
  - Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (SARS-CoV-2 u targets only), Cepheid
  - TOS: 5
- Code: 0241U
  - Long Descriptor: Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
  - Short Descriptor: NFCT DS VIR RESP RNA 4 TRGT
  - Laboratory Name: Xpert® Xpress SARS-CoV-2/Flu/RSV (all targets), Cepheid
  - TOS: 5

New Codes Effective November 10, 2020

The listed new code will be added to the national HCPCS file with an effective date of November 10, 2020, and does not need to be manually added to the HCPCS files by the MACs. However, the new code is contractor-

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priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 87428
  - Long Descriptor: Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARSCoV-2 [COVID-19]) and influenza virus types A and B
  - Short Descriptor: SARSCOV & INF VIR A&B AG IA
  - TOS: 5

New Codes Effective January 1, 2021

Per the above discussion in the COVID-19 Policy Updates section, Payment for High Throughput Technologies, we added the listed new code to the national HCPCS file with an effective date of January 1, 2021, and doesn't need to be manually added to the HCPCS files by the MACs. Such tests, as identified by U0005, in accordance with CMS Ruling CMS-2020-02-R, shall be paid at the rate of $25.

This new code is:

- Code: U0005
  - Long Descriptor: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (List separately in addition to either HCPCS code U0003 or U0004) as described by CMS-2020-01-R2.
  - Short Descriptor: Infec agen detec ampli probe
  - Type of Service: 5

Proprietary Laboratory Analysis (PLAs)

New Codes Effective January 1, 2021

PLAs: The following new codes have been added to the national HCPCS file with an effective date of January 1, 2021. These new codes are contractor-priced until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in June or July of 2021, as they were received after the 2020 public meeting. MACs will only price PLA codes for laboratories within their jurisdiction.

- CPT Code; 0227U
  - Long Descriptor: Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
  - Short Descriptor: RX ASY PRSMV 30+RX/METABLT
  - Laboratory: Comprehensive Screen, Aspenti Health
- CPT Code: 0228U
  - Long Descriptor: Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
  - Short Descriptor: ONC PRST8 MA MOLEC PRFL ALG
  - Laboratory: PanGIA Prostate, Genetics Institute of America, Entopsis, LLC

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- CPT Code: 0229U
  - Long Descriptor: BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
  - Short Descriptor: BCAT1 PROMOTER MTHYLTN ALYS
  - Laboratory: Colvera®,Clinical Genomics Pathology Inc
- CPT Code: 0230U
  - Long Descriptor: AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: AR FULL SEQUENCE ANALYSIS
  - Laboratory: Genomic Unity® AR Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0231U
  - Long Descriptor: CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, Short Tandem Repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: CACNA1A FULL GENE ANALYSIS
  - Laboratory: Genomic Unity® CACNA1A Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0232U
  - Long Descriptor: CSTB (cystatin B) (eg, progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, Short Tandem Repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: CSTB FULL GENE ANALYSIS
  - Laboratory: Genomic Unity® CSTB Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0233U
  - Long Descriptor: FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: FXN GENE ANALYSIS
  - Laboratory: Genomic Unity® FXN Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0234U
  - Long Descriptor: MECP2 (methyl CpG binding protein 2) (eg, Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: MECP2 FULL GENE ANALYSIS
  - Laboratory: Genomic Unity® MECP2 Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0235U
  - Long Descriptor: PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: PTEN FULL GENE ANALYSIS
  - Laboratory: Genomic Unity® PTEN Analysis, Variantyx Inc, Variantyx Inc

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- CPT Code: 0236U
  - Long Descriptor: SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
  - Short Descriptor: SMN1&SMN2 FULL GENE ANALYSIS
  - Laboratory: Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0237U
  - Long Descriptor: Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: CAR ION CHNLPTHY GEN SEQ PNL
  - Laboratory: Genomic Unity® Cardiac Ion Channelopathies Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0238U
  - Long Descriptor: Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
  - Short Descriptor: ONC LNCH SYN GEN DNA SEQ ALY
  - Laboratory: Genomic Unity® Lynch Syndrome Analysis, Variantyx Inc, Variantyx Inc
- CPT Code: 0239U
  - Long Descriptor: Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations
  - Short Descriptor: TRGT GEN SEQ ALYS PNL 311+
  - Laboratory: FoundationOne® Liquid CDx, FOUNDATION MEDICINE, INC, FOUNDATION MEDICINE, INC

Additional Information

The official instruction, CR 12080, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10523CP.pdf.

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

Document History

Date of Change	Description
December 18, 2020	Initial article released.

Addition of the QW Modifier to Healthcare Common Procedure Coding System (HCPCS) Codes 87811 and 87428

MLN Matters Number: MM12093
Related CR Release Date: December 23, 2020
Related CR Transmittal Number: R10529OTN
Related Change Request (CR) Number: 12093
Effective Date: October 6, 2020
Implementation Date: April 5, 2021

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

Provider Action Needed
This article informs you of the addition of the QW modifier to the following CMS HCPCS codes:

- 87811 [Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])] and code
- 87428 [Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B].

Make sure your billing staffs are aware of these changes.

Background
The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

We discussed HCPCS code 87811 in MLN Matters article MM12080 (https://www.cms.gov/files/document/mm12080.pdf) with an effective date of October 6, 2020. We discussed HCPCS code 87428 in the same article with an effective date of November 10, 2020.

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. During public health emergencies declared under Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, the FDA is able to issue Emergency Use Authorizations (EUAs) when certain criteria are met that allows for the use and distribution of potentially life-saving medical products to diagnose, treat, or prevent the disease, which can include diagnostic tests. Currently, there is no FDA-approved or cleared test to diagnose or detect COVID-19. The FDA has issued several In Vitro Diagnostic EUAs for SAR-CoV-2 and COVID-19.

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The FDA doesn't categorize tests authorized under an EUA. The settings in which an EUA- authorized test may be used are described in the Letter of Authorization. As discussed in the Guidance for Industry and Other Stakeholders: Emergency Use Authorization of Medical Products and Related Authorities, when the FDA authorizes tests for use at the point of care (including SARS-CoV-2 point of care test systems) under an EUA, such tests are deemed to be CLIA waived tests. For the duration of the emergency declaration, you can perform such tests in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The tests listed on the FDA's In Vitro Diagnostic EUAs website authorized by the FDA for use at point of care under an EUA can be used by facilities having a current CLIA certificate of waiver. To be recognized as a test that can be performed in a facility having a CLIA certificate of waiver, the modifier QW must be added.

As of December 2, 2020, the FDA issued 2 individual EUAs for antigen detection by immunoassay with direct optical (that is, visual) observation for SARS-CoV-2 that are authorized for use at the Point of Care setting, that is, in patient care settings operating under a CLIA Certificate of Waiver. The HCPCS code 87811QW describes the testing performed by these 2 EUA antigen detection by immunoassay with direct optical observation SARS-CoV-2 tests.

The FDA issued one individual EUA for infectious agent antigen detection by immunoassay technique, qualitative or semiquantitative for SARS-CoV-2 and influenza virus types A and B that is authorized for use at the POC setting. The HCPCS code 87428QW describes this EUA test.

CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

- The use of code 87811QW for claims submitted by facilities with a valid, current CLIA certificate of waiver is permitted with dates of service on or after October 6, 2020.
- The use of code 87428QW for claims submitted by facilities with a valid, current CLIA certificate of waiver is permitted with dates of service on or after November 10, 2020.

MACs won't search their files to either retract payment for claims already paid or to retroactively pay claims. However, your MAC will adjust claims that you bring to their attention.

Additional Information

The official instruction, CR 12093, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/R10529OTN.pdf.

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

Document History

Date of Change	Description
December 23, 2020	Initial article released.

2021 Annual Update to the Therapy Code List

MLN Matters Number: MM12126
Related CR Release Date: December 31, 2020
Related CR Transmittal Number: R10542CP
Related Change Request (CR) Number: 12126
Effective Date: January 1, 2021
Implementation Date: January 4, 2021

Provider Types Affected
This MLN Matters Article is for physicians, therapists, providers, and suppliers billing Medicare Administrative Contractors (MACs) for therapy services provided to Medicare beneficiaries.

Provider Action Needed
This article informs you of updates to the list of codes that sometimes or always describe therapy services. The additions, changes, and deletions to the therapy code list reflect those made in the Calendar Year (CY) 2021 CPT and Level II HCPCS. Make sure your billing staffs are aware of these updates.

Background
Section 1834(k)(5) of the Social Security Act (the Act) requires that all claims for outpatient rehabilitation therapy services and all Comprehensive Outpatient Rehabilitation Facility (CORF) services use a uniform coding system. The CY 2021 CPT and Level II HCPCS are the coding systems you use for reporting these services. You'll find the therapy code listing at
http://www.cms.gov/Medicare/Billing/TherapyServices/index.html.

CMS discussed the policies implemented in this notification in CY 2021 Medicare Physician Fee Schedule (MPFS) rulemaking. CR 12126 updates the therapy code list and associated policies for CY 2021. CMS designated all these HCPCS/CPT codes as "sometimes therapy," to permit physicians and certain Non-Physician Practitioners (NPPs), including nurse practitioners, physician assistants, and clinical nurse specialists, to render these services outside a therapy plan of care when appropriate.

Further, these HCPCS/CPT codes are considered communication technology-based (CTB) services so other NPPs can render these services, such as psychologists and social workers, in addition to therapists (physical therapists, occupational therapists, and speech-language pathologists) whether in private practice or those that are facility-based. Also, these codes for CTB services replace codes for similar services that CMS included in CR 11791. For the five codes below (2 HCPCS and 3 CPT codes), CY 2021 rulemaking made these codes permanent, meaning they are no longer restricted by the effectiveness timeline of the Public Health Emergency (PHE) for COVID-19. The HCPCS codes and long descriptors include:

- **HCPCS code G2250** - Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment. HCPCS code G2250 replaced HCPCS code G2010.

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- **HCPCS code G2251** - Brief communication technology-based service, e.g., virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available. HCPCS code G2251 replaced HCPCS code G2012.

The CPT Editorial Panel for CY 2020 created CPT codes 98970, 98971, and 98972. During MPFS rulemaking for CY 2021, CMS decided to use these codes in place of G2061, G2062, and G2063, since their descriptors were similar. The CPT codes and their long descriptors are:

- **CPT 98970** - Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes. CPT code 98970 replaced HCPCS code G2061.
- **CPT 98971** - Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes. CPT code 98971 replaced HCPCS code G2062.
- **CPT 98972** - Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes. CPT code 98970 replaced HCPCS code G2063.

CR 11971 added the CPT codes for telephone assessment as "sometimes therapy" codes effective for the duration of the PHE for COVID-19. As with the other CTB services noted above, therapists in private practice and therapists who work for institutional providers may furnish these services. The CPT codes and their long descriptors are:

- **CPT 98966** - Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.
- **CPT 98967** - Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.
- **CPT 98968** - Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion.

We are removing the following HCPCS codes from the therapy code list, effective for dates of service on and after January 1, 2021:

- G2010
- G2012
- G2061
- G2062
- G2063

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Additional Information

The official instruction, CR 12126, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10542cp.pdf.

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

Document History

Date of Change	Description
December 31, 2020	Initial article released.

MLN Connects™

MLN Connects 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™ for December 23, 2020
https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-12-23-mlnc

MLN Connects™ for January 7, 2021
https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-01-07-mlnc

MLN Connects™ for January 14, 2021
https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-01-14-mlnc

MLN Connects™ for January 21, 2021
https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-01-21-mlnc

Special Edition – Friday, December 18, 2020
Monitoring for Hospital Price Transparency
Hospital Price Transparency requirements go into effect January 1, 2021. CMS plans to audit a sample of hospitals for compliance starting in January, in addition to investigating complaints that are submitted to CMS (https://www.cms.gov/hospital-price-transparency/contact-us) and reviewing analyses of non-compliance, and hospitals may face civil monetary penalties for noncompliance.

Is your institution prepared to comply with the requirements of the Hospital Price Transparency Final Rule (https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf)? Effective January 1, 2021, each hospital operating in the United States is required to provide publicly accessible standard charge information online about the items and services they provide in 2 ways:

- Comprehensive machine-readable file with all items and services
- Display of 300 shoppable services in a consumer-friendly format

In the final rule, CMS outlined a monitoring and enforcement plan to ensure compliance with the requirements. We finalized a policy that CMS monitoring activities may include, but would not be limited to, the following, as appropriate:

- Evaluation of complaints made by individuals or entities to CMS
- Review of individuals' or entities' analysis of noncompliance
- Audit of hospital websites

If we conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, we may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s)
- Request a Corrective Action Plan (CAP) if noncompliance constitutes a material violation of one or more requirements

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- Impose a civil monetary penalty not in excess of $300 per day and publicize the penalty on a CMS website if the hospital fails to respond to our request to submit a CAP or comply with the requirements of a CAP

See 45 CFR part 180 Subpart C- Monitoring and Penalties for Noncompliance (https://www.ecfr.gov/cgi-bin/text-idx?SID=7489fc7c77b5dc2b5aa746eb0f5bcca9&mc=true&node=20191127y1.36).

Visit the Hospital Price Transparency (https://www.cms.gov/hospital-price-transparency) website for additional information and resources to help hospitals prepare for compliance, including:

- FAQs (PDF): https://www.cms.gov/hospital-price-transparency
- 8 Steps to a Machine-Readable File (PDF): https://www.cms.gov/files/document/steps-machine-readable-file.pdf
- 10 Steps to a Consumer-Friendly Display (PDF): https://www.cms.gov/files/document/steps-making-public-standard-charges-shoppable-services.pdf
- Quick Reference Checklists (PDF): https://www.cms.gov/files/document/hospital-price-transparency-final-rule-quick-reference-checklists.pdf

Special Edition – Friday, December 18, 2020
COVID-19: Add-on Payment for New Treatments

CMS issued an Interim Final Rule with Comment Period (https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency), which established the New COVID-19 Treatments Add-on Payment (NCTAP) under the Medicare Inpatient Prospective Payment System (IPPS), effective from November 2, 2020, until the end of the Public Health Emergency (PHE) for COVID-19. To mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the COVID-19 PHE, the Medicare program will provide an enhanced payment for eligible inpatient cases that involve use of certain new products with current Food and Drug Administration approval or emergency use authorization to treat COVID-19. Visit the NCTAP (https://www.cms.gov/medicare/covid-19/covid-19-treatments-add-payment-nctap) webpage for more information.

Special Edition – Tuesday, December 22, 2020
COVID-19 Vaccine Codes: Updated Effective Date for Moderna

On December 18, 2020, the U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for the Moderna COVID19 Vaccine (https://www.fda.gov/media/144636/download) for the prevention of COVID-19 for individuals 18 years of age and older. Review Moderna's Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (https://www.fda.gov/media/144637/download) regarding the limitations of authorized use.

During the COVID-19 Public Health Emergency (PHE), Medicare will cover and pay for the administration of the vaccine (when furnished consistent with the EUA). Review our updated payment and HCPCS Level I CPT code structure (https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies) for specific COVID-19 vaccine information. Only bill for the vaccine administration codes when you submit claims to Medicare; don't include the vaccine product codes when the vaccines are free.

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Related links:

- CMS COVID-19 Provider Toolkit: https://www.cms.gov/covidvax-provider
- CMS COVID-19 FAQs: https://www.cms.gov/covidvax-provider
- CDC COVID-19 Vaccination Communication Toolkit for medical centers, clinics, and clinicians: https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- FDA COVID-19 Vaccines webpage: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Special Edition – Monday, December 28, 2020

Medicare FFS Claims: 2% Payment Adjustment (Sequestration) Suspended Through March

The Coronavirus Aid, Relief, and Economic Security (CARES) Act suspended the payment adjustment percentage of 2% applied to all Medicare Fee-For-Service (FFS) claims from May 1 through December 31. The Consolidated Appropriations Act, 2021, signed into law on December 27, extends the suspension period to March 31, 2021.

Special Edition – Thursday, January 7, 2021: Physician Fee Schedule Update

On December 27, the Consolidated Appropriations Act, 2021 modified the Calendar Year (CY) 2021 Medicare Physician Fee Schedule (MPFS):

- Provided a 3.75% increase in MPFS payments for CY 2021
- Suspended the 2% payment adjustment (sequestration) through March 31, 2021
- Reinstated the 1.0 floor on the work Geographic Practice Cost Index through CY 2023
- Delayed implementation of the inherent complexity add-on code for evaluation and management services (G2211) until CY 2024

CMS has recalculated the MPFS payment rates and conversion factor to reflect these changes. The revised MPFS conversion factor for CY 2021 is 34.8931. The revised payment rates are available in the Downloads section of the CY 2021 Physician Fee Schedule final rule (CMS-1734-F) webpage at https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1734-f.

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.

https://www.cms.gov/MLNGenInfo

Railroad Medicare Customer Information and Outreach

Important Telephone Numbers

Provider Contact Center
888-355-9165

Interactive Voice Response (IVR) System
877-288-7600

Telephone Reopenings
888-355-9165

Electronic Data Interchange (EDI)
Technical Support
888-355-9165

Beneficiary Contact Center
800-833-4455
TTY 877-566-3572

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Attention: Billing Manager