January 2024
Volume 2024, Issue 1

RAILROAD MEDICARE ADVISORY

Latest Part B News for Railroad Medicare

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

PALMETTO GBA®
A CELERIAN GROUP COMPANY

Laboratory

CMS MLN Information

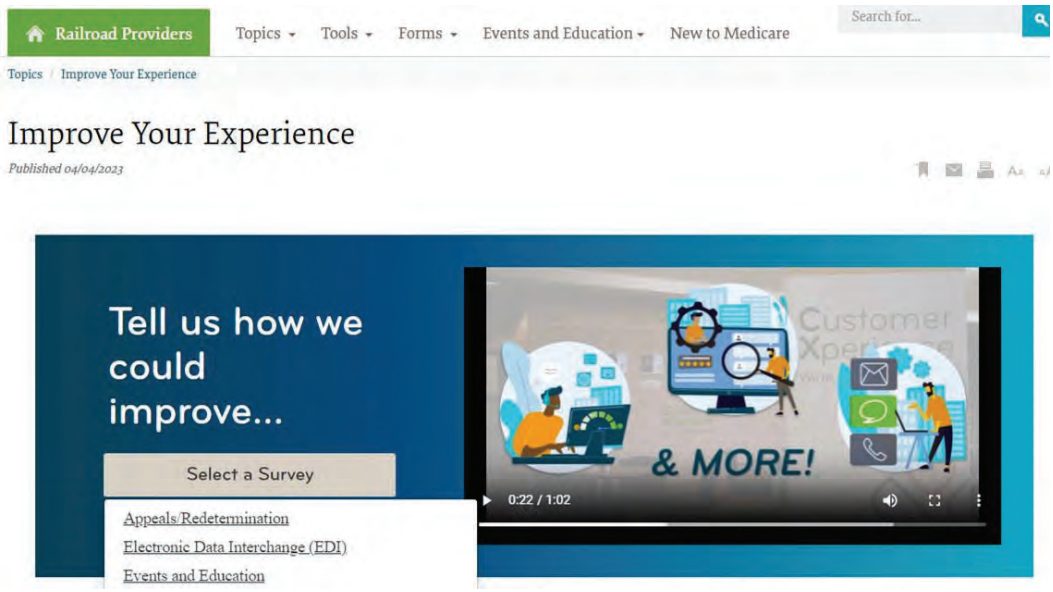
Self-Service Tools

Help Us Improve Your Experience

How can Palmetto GBA serve you better? Let us know how we're doing by completing our MAC Customer Experience (MCE) survey. Visit our new Improve Your Experience topic page to find links to the various MAC Customer Experience surveys and information about the enhancements we have made in response to your feedback.

When completing an MCE survey, please be sure to add details about your experience so we know exactly what you liked or what we could do better. We encourage you to leave your contact information so we can reach out to you if we have questions about your feedback.

https://www.palmettogba.com/RR/Survey



Need to speak with Railroad Medicare?

Call our Provider Contact Center toll-free 888-355-9165 at for Customer Service inquiries, technical support for EDI and the eServices portal, Provider Enrollment inquiries, and to request a Telephone Reopening.

Railroad Medicare representatives are available to handle provider inquiries Monday through Friday, from 8:30 a.m. to 4:30 p.m. for all time zones with the exception of Pacific Time (PT) which receives service from 8 a.m. to 4 p.m. PT. The PCC will be unavailable during weekly training and holidays.

When you call the toll-free 888-355-9165 line, the system provides the following selections:

Press 1 for Claim Status, Eligibility or a Duplicate Remittance Advice
Please note: Claim status, beneficiary eligibility and duplicate remittance advice should be requested through our Interactive Voice Response (IVR) unit at 1-877-288-7600 or through our secure internet portal, eServices, at https://www.onlineproviderservices.com/ecx_improvev2/.

Press 2 for Technical Support Regarding EDI or eServices, then
- Press 1 for eServices inquiries
- Press 2 for EFT
- Press 0 for technical assistance with electronic billing, Electronic Remittance Advice (ERA) or other EDI issues

Press 3 for Provider Enrollment

Press 4 for Telephone Reopening, then
- Press 1 for the explanation of a denied claim
- Press 0 to request a Telephone Reopening to correct minor errors or omissions

Press 5 for Customer Service
- Press 0 to speak to a Customer Service Advocate

Press 6 for Our Mailing Address and Hours of Operation

Press 9 to repeat this menu

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://www.palmettogba.com/palmetto/rr.nsf/DID/AK7K447304.

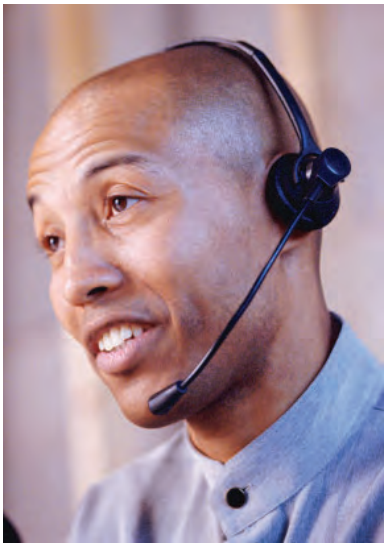
You will be asked to provide the following information about the beneficiary:

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



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.

December 21, 2023	PCC closed for training / 2:30 to 4:30 p.m. ET
December 25, 2023	Office closed / Christmas Eve
December 26, 2023	Office closed / Christmas Day
January 1, 2024	Office closed / New Year's Day
January 11, 2024	PCC closed for training / 1:30 to 4:30 p.m. ET
January 15, 2024	Office closed / Martin Luther King Jr. Day
January 18, 2024	PCC closed for training / 2:30 to 4:30 p.m. ET
January 25, 2024	PCC closed for training / 2:30 to 4:30 p.m. ET
May 27, 2024	Office closed / Memorial Day
July 4, 2024	Office closed / Independence Day
September 2, 2024	Office closed / Labor Day
November 28, 2024	Office closed / Thanksgiving Day
November 29, 2024	Office closed / Day After Thanksgiving
December 24, 2024	Office closed / Christmas Eve
December 25, 2024	Office closed / Christmas 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 the email update 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/palmetto/rr.nsf/M/Registration.

How Can I Tell if a Patient Has Railroad Medicare?

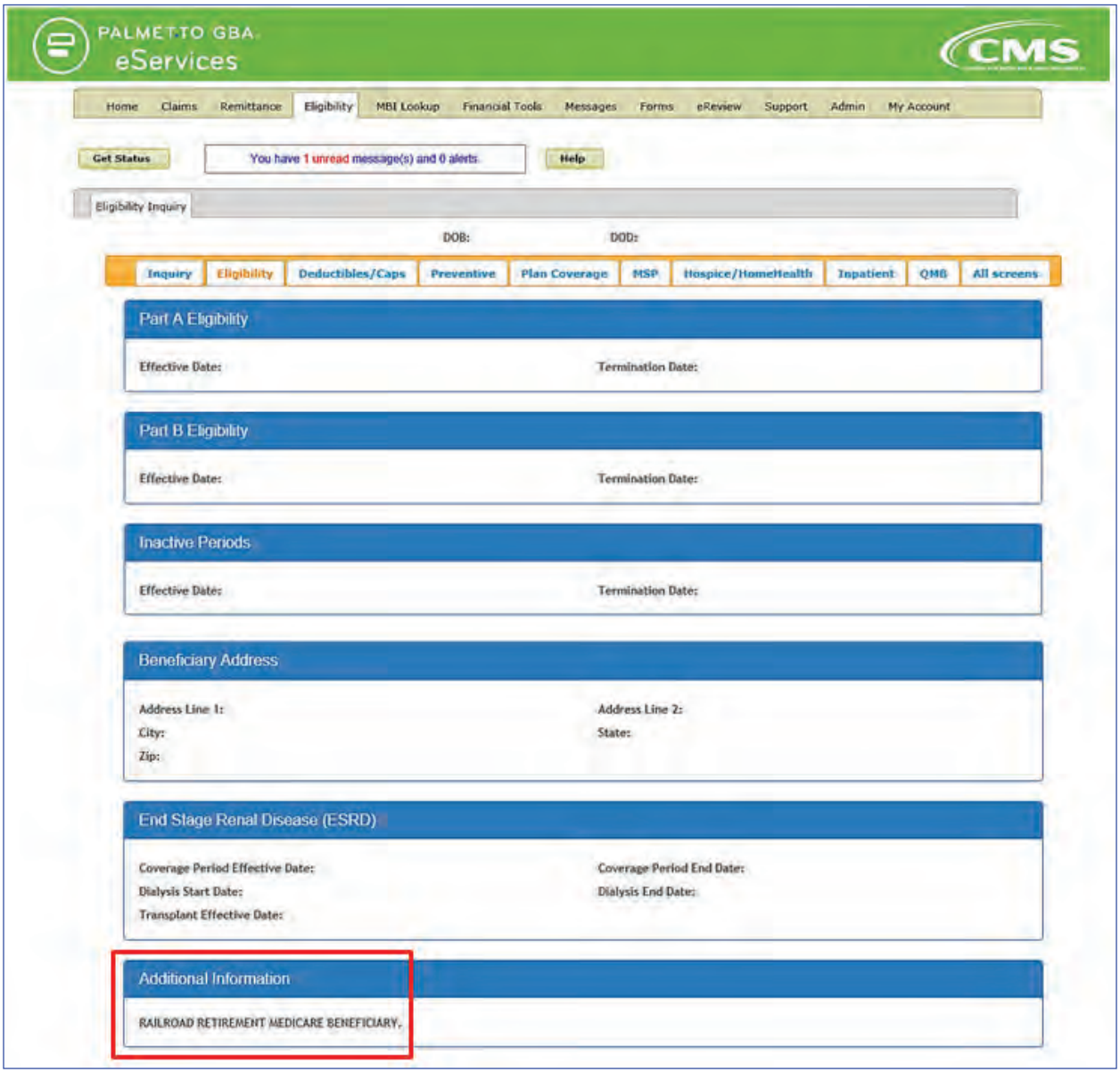
Railroad Medicare beneficiaries historically have had unique Medicare numbers, which made them easily distinguishable from Social Security Medicare patients. With today's Medicare Beneficiary Identifiers (MBIs), the you can't tell the difference by the MBI. Instead, the difference lies in the design of the Medicare card.

The Medicare card of a person with Railroad Medicare is unique. The Railroad Retirement Board (RRB) issues 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 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.

Continued >>



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

- MBI website: https://www.cms.gov/Medicare/New-Medicare-Card/index

Educational Events Where You Can Ask Questions and Get Answers from Palmetto GBA

Don’t Miss this Wonderful Opportunity!

If you are in search of an opportunity to interact with and get answers to your Medicare billing, coverage and documentation questions from Palmetto GBA’s Provider Outreach and Education (POE) department, please see these educational offerings which have a question and answer session:

Railroad Medicare: Behavioral Health Initiative Services - Psychotherapy for Crisis Webcast

What: Railroad Medicare: Behavioral Health Initiative Services - Psychotherapy for Crisis Webcast
Date: Tuesday, January 30, 2024
Time: 1 p.m. ET
Duration: 1 hour
Audience Link:
https://events.teams.microsoft.com/event/ae1dd467-d5ad-4859-86a1-e740cc877d88@d560165e-85d7-436f-a978-c588cf12ebe1
CEUs will be offered for this event!

Please join Railroad Medicare’s Part B Provider Outreach and Education Team on January 30, 2024, at 1 p.m. ET as we provide information on recently approved Medicare Behavioral Health Initiative Service - Psychotherapy for Crisis, as outlined in the Consolidated Appropriations Act 2023.

During this informative session we will explore the Consolidated Appropriations Act 2023 and identify each of its new behavioral health initiatives.

Then, we will provide you with details regarding Medicare’s coverage guidelines and billing requirements specifically for Psychotherapy for Crisis Services.

Following the content of this webcast, we will shine a spotlight on resources related to the topic of this session and give you the opportunity to ask questions about the information covered during this event.

Please note that this webcast was developed by CGS Administrators, LLC (CGS), Palmetto GBA Jurisdiction J (JJ), Jurisdiction M (JM), & the Railroad Retirement Board Specialty Medicare Administrative Contractor (RRB SMAC), Part B, Outreach & Education departments. Therefore, this webcast will be of interest to Part B providers, staff, and billing companies that may provide or may consider providing these new behavioral health services. (This session may end early if all content is presented, and questions have been addressed.)

If you do not have a NPI or PTAN to register for this event, please enter ‘N/A’ into this registration field.

Palmetto GBA Educational Webinars will be Transitioning to the Cvent Platform

Palmetto GBA is excited to announce that our online education events will soon be exclusively on the Cvent platform.

Cvent is a national company that offers a multitude of event resources. As we transition to Cvent, you may see a blend of current and past events on our old ON24 platform until November 27, 2023.

Registration through Cvent will have a new look but the information required to register for webinars will be the same.

There are many benefits to you with this change to Cvent. The Cvent platform will provide the same look and feel for all events, allow for increased engagement, and after an initial registration is complete, your next registration will auto populate text fields making future event registration quick and easy. Cvent also allows us to create a new library of recorded webinars available. Many of the ON24 webinars will be rerecorded and placed into our new library to supply the most current and updated information.

More information on using and attending Cvent webinars is forthcoming.

Stop by our website often for updates and register for our email updates to stay in the know at https://www.palmettogba.com/palmetto/rr.nsf/M/Registration.

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12397	**Date: December 7, 2023**
	Change Request 13468

SUBJECT: Payment of Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide clarification to the A/B MACs regarding the Medicare guidance/policy as described in Chapter 12, section 30.5 of the Medicare Claims Processing Manual that relates to the complex administration of CPT codes 96401-96549.

EFFECTIVE DATE: December 21, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 21, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 12397	Date: December 6, 2023	Change Request: 13468

SUBJECT: Payment of Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

EFFECTIVE DATE: December 21, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: December 21, 2023

I. GENERAL INFORMATION

A. Background: The purpose of this change request (CR) is to provide clarification to the A/B MACs regarding the Medicare guidance/policy as described in Chapter 12, section 30.5 of the Medicare Claims Processing Manual that relates to the complex administration of CPT codes 96401-96549. As stated in Section 30.5.D of Chapter 12 of the Medicare Claims Processing Manual, "Chemotherapy administration codes [CPT codes 96401-96549] apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers." The manual provides examples (but not an exhaustive list) of monoclonal antibody drugs.

B. Policy: The A/B MACs shall not make claim adjustments or edits to claims for CPT codes 96401-96549 based solely on the specific drug or agent being administered. Claims for CPT codes 96401-96549 that involve administration of monoclonal, complex biological, and rheumatological therapies, shall be paid as complex administration, so long as all elements of these codes that are required for appropriate billing are met, using Medicare guidance/policy (such as described in Chapter 12, section 30.5 of the Medicare Claims Processing Manual). We intend to provide further clarificaiton regarding this policy with future rulemaking.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13468.1	Contractors shall not make claim adjustments or edits to claims for CPT codes 96401-96549 based solely on the specific drug or agent being administered. Claims for CPT codes 96401-96549 that involve administration of monoclonal, complex biological, and rheumatological therapies, shall be paid as complex administration, so long as all elements of these codes that are required for appropriate billing are met,	X	X							

	using Medicare guidance/policy (such as described in Chapter 12, section 30.5 of the Medicare Claims Processing Manual).									

III. PROVIDER EDUCATION TABLE

13468.2	CR as Provider Education: Contractors shall post this entire instruction, or a direct link to this instruction, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the entire instruction must be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement it with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

DMEPOS Fee Schedule: CY 2024 Update

Related CR Release Date: December 7, 2023
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13463
Related Change Request (CR) Number: CR 13463 https://www.cms.gov/files/document/r12398CP.pdf
Related CR Transmittal Number: R12398CP
Related CR Title: Calendar Year 2024 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

Affected Providers

- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for DMEPOS provided to Medicare patients

Action Needed

Make sure your billing staff knows about:

- CY 2024 fee schedule amounts for new and existing codes
- Payment policy changes

Background

CMS pays for certain DMEPOS products and surgical dressings on a fee schedule basis per Sections 1834(a), (h), and (i) of the Social Security Act (the Act) https://www.ssa.gov/OP_Home/ssact/title18/1834.htm. 42 CFR 414.102 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-C/section-414.102 requires payment on a fee schedule for parenteral and enteral nutrition (PEN), splints, casts, and intraocular lenses (IOLs) inserted in a physician's office. Effective January 1, 2024, the DMEPOS fee schedule file will include national payment amounts for lymphedema compression treatment items.

The DMEPOS and PEN fee schedule files contain HCPCS codes subject to fee schedule adjustments for these items under the DMEPOS Competitive Bidding Program (CBP), as well as codes that aren't subject to the CBP or fee schedule adjustments.

1. The Consolidated Appropriations Act, 2023

Section 4139 of the Consolidated Appropriations Act (CAA), 2023 https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf#page=1468 requires the fee schedule amounts for items and services provided in non-rural contiguous non-competitive bidding areas (CBAs) be based on a blend of 75% of the adjusted fee schedule amounts and 25% of the unadjusted fee schedule amounts for claims with dates of service for the remainder of the COVID-19 public health emergency (PHE) or December 31, 2023, whichever was later.

The COVID-19 PHE ended at the end of the day on May 11, 2023. Starting January 1, 2024, the fee schedule amounts for items and services you provide in non-rural contiguous non-CBAs is based on 100% of the fee schedule amounts adjusted with regulations at 42 CFR 414.210(g)

Continued >>

https://www.cms.gov/medicare/payment/fee-schedules/dmepos-fee-schedule/dmepos-laws-regulations. Details are in the 2024 Home Health Prospective Payment System (HH PPS) final rule https://www.cms.gov/medicare/medicare-fee-service-payment/homehealthpps/home-health-prospective-payment-system/cms-1780-f.

Starting January 1, 2024, there's a gap period in the DMEPOS CBP. All Medicare Round 2021 DMEPOS CBP contracts for off-the-shelf (OTS) back braces and OTS knee braces expire on December 31, 2023.

During the gap period, payment for items and services we included in the CBP are equal to 80% of the lesser of the supplier's charge or the fee schedule amount for the item. We base the fee schedules for items and services you provide in former CBAs on the single payment amounts (SPAs) in effect in the CBA on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban consumers (CPI-U) for the 12-month period on the date after the contract periods ended. We increase the fee schedule amounts once every 12 months on the anniversary date of the first day after the contract period ended with the CPI-U.

- For items awarded contracts in Round 2021, for CY 2024, we adjust the fee schedule amounts for items you provide in areas that were CBAs as of December 31, 2023, based on the SPAs for each specific CBA, increased by the projected percentage change in the CPI-U of 2.9% for the 12-month period ending January 1, 2024
- For items of the CBP included in Round 2021, where contracts weren't awarded, the 2023 adjusted fee schedule amounts are increased by the projected CPI-U of 2.9% for CY 2024

A former CBA ZIP Code file contains the CBA ZIP Codes we used in pricing a claim for an item you provided in a CBA. We update the file quarterly as necessary. Starting January 1, 2024, the former CBA ZIP Code file will contain the ZIP Codes for the CBAs included in Round 2021.

More information is available on the gap period https://www.cms.gov/medicare/payment/fee-schedules/dmepos-competitive-bidding.

2. DMEPOS Rural ZIP Codes

The DMEPOS Rural ZIP Code file contains the ZIP Codes of rural areas. ZIP Codes for non-continental Metropolitan Statistical Areas (MSAs) aren't in the DMEPOS Rural ZIP Code file, which we update quarterly, as necessary. 42 CFR 414.202 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-D/section-414.202 defines a rural area as a geographical area represented by a postal ZIP Code where at least 50% of the total geographical area of the ZIP Code is estimated to be outside any MSA. A rural area also includes any ZIP Code within an MSA that's excluded from a CBA established for that MSA.

3. KE Modifier

The January 2024 DMEPOS fee schedule files will continue to incorporate fee schedule amounts for certain codes billed with modifier KE for rural and non-contiguous, non-CBAs.

Starting January 1, 2024, we'll populate the non-rural fees for these KE codes with zeros on the fee schedule file since KE isn't a valid option for areas without blended fees.

Continued >>

CR 6270 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1630CP.pdf provides background information on the KE modifier. Suppliers should append the KE modifier to the HCPCS code for the accessory for patients residing in rural or non-contiguous, non-CBAs where accessories included in the Initial Round One CBP in 2008 were provided for use with base equipment that wasn't included in the 2008 CBP (for example, manual wheelchairs where the KU modifier doesn't apply, canes, and aspirators).

4. DMEPOS Fee Schedule Files

We're providing updates to the following files:

- DMEPOS fee schedule file for 2024
- DMEPOS Rural ZIP Code file for Quarter 1, 2024
- DMEPOS PEN fee schedule file for 2024
- Former CBA fee schedule file
- Former CBA National Mail Order diabetic testing supply fee schedule
- Former CBA ZIP Code

These updates will be available as Public Use Files (PUFs) https://www.cms.gov/medicare/payment/fee-schedules/dmepos/dmepos-fee-schedule for State Medicaid Agencies, managed care organizations, and other interested parties.

5. Codes Added

New DMEPOS codes we're adding to the HCPCS file, effective January 1, 2024, are:

- A4287
- A4457
- A4468
- A4540
- A4541
- A4542
- A7023
- E0492
- E0493
- E0530
- E0678
- E0679
- E0680
- E0681
- E0682
- E0732
- E0733
- E0734
- E0735
- E1301
- E2001
- E2398
- E3000
- L3161

Continued >>

- L5615
- L5926
- K1007
- L8701
- L8702

6. Migration of Temporary HCPCS Codes

Attachment B in CR 13463 https://www.cms.gov/files/document/r12398CP.pdf has new codes on the DMEPOS fee schedule file effective January 1, 2024. These new codes are permanent codes established as part of the First Biannual (B1) 2023 Non-Drug and Non-Biological Items and Services HCPCS Coding Cycle for supplies and other products to replace temporary HCPCS Level II code (K code) that became effective January 1, 2020, through 2022. The fee schedule amounts for the new permanent codes are the corresponding fee schedule amounts for the temporary K codes. We'll delete the corresponding temporary K codes for the supplies and other products from the fee schedule file effective January 1, 2024.

7. New HCPCS and Fee Schedule Amounts for Lymphedema Compression Treatment Items

The CY 2024 HH PPS final rule establishes a new benefit category for standard and custom fitted compression garments and additional lymphedema compression treatment items under Medicare Part B. The lymphedema compression treatment items benefit category includes standard and custom fitted compression garments and additional lymphedema compression treatment items used to serve a medical purpose, that are for the treatment of lymphedema, prescribed by an authorized practitioner for items they provide starting January 1, 2024.

The Medicare payment for lymphedema compression treatment items is equal to 80% of the lesser of the supplier's charge for the item or the national payment amount.

The national payment amount for the item is 120% of the average of Medicaid payment amounts. Where Medicaid state plan payment amounts aren't available for an item, the Medicare national payment amount for the item is the average of average internet retail prices and payment the TRICARE insurance program uses. If TRICARE payment amounts aren't available for the item, the Medicare national payment amount uses the average internet retail prices.

The following general categories of lymphedema compression treatment items are included in the new benefit:
- Standard daytime gradient compression garments
- Custom daytime gradient compression garments
- Nighttime gradient compression garments
- Gradient compression wraps
- Accessories (for example, zippers, linings, padding or fillers, etc.) necessary for the effective use of a gradient compression garment or wrap
- Compression bandaging systems and supplies

HCPCS codes for lymphedema compression treatment items are included in the HCPCS file https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/alpha-numeric.

Starting January 1, 2024, national payment amounts for lymphedema compression treatment items are on the DMEPOS fee schedule file for the following new HCPCS codes:

Continued >>

- A6520
- A6521
- A6522
- A6523
- A6524
- A6525
- A6526
- A6527
- A6528
- A6529
- A6530
- A6533
- A6534
- A6535
- A6536
- A6537
- A6538
- A6539
- A6540
- A6541
- A6552
- A6553
- A6554
- A6555
- A6556
- A6557
- A6558
- A6562
- A6563
- A6564
- A6565
- A6566
- A6567
- A6568
- A6569
- A6570
- A6571
- A6572
- A6573
- A6574
- A6575
- A6576
- A6577
- A6578
- A6579

Continued >>

- A6580
- A6581
- A6582
- A6583
- A6585
- A6586
- A6587
- A6588
- A6589
- A6594
- A6595
- A6596
- A6597
- A6598
- A6599
- A6600
- A6601
- A6602
- A6603
- A6604
- A6605
- A6606
- A6607
- A6608
- A6610

DME MACs will make payment for covered claims for items described by HCPCS codes A6559-A6561 on an individual, claim-by-claim basis until we have data to develop national payment amounts.

On the fee schedule file, a new payment category indicator of LC will identify lymphedema compression treatment items. The LC indicator will be added to the record layout for the DMEPOS fee schedule in Section 60.1 of the Medicare Claims Processing Manual, Chapter 23, as part of this update. The relevant Manual text is part of CR 13463 https://www.cms.gov/files/document/r12398CP.pdf.

Additional claims processing instructions are available in MLN Matters Article MM13286 https://www.cms.gov/files/document/mm13286-lymphedema-compression-treatment-items-implementation.pdf.

8. New and Deleted Fee Schedule Amounts

As part of this update, we added fee schedules amounts to the DMEPOS fee schedule file for new and revised HCPCS codes effective January 1, 2024.

We're deleting the listing of A6545 without a modifier from the DMEPOS fee schedule file as part of this update as there are no payment amounts associated with this listing.

Continued >>

We revised the administrative fields for the following codes, showing they fall under the orthotic benefit category effective January 1, 2024:

- K1007
- L8701
- L8702

We'll make payment for covered devices described by these codes on an individual basis until we establish national fees through the HCPCS public meeting process.

We included the 'KU' modifier when billed with wheelchair code E2398 in the January 2024 file for billing when you provide these items in connection with a Group 3 power wheelchair, complex rehabilitative manual wheelchair (identified by HCPCS codes K0005, E1161, E1231, E1232, E1233, and E1234), and certain manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008.

For gap-filling purposes, the deflation factors for 2024 by payment category are:

- 0.359 for Oxygen
- 0.361 for Capped Rental
- 0.362 for Prosthetics and Orthotics
- 0.460 for Surgical Dressings
- 0.500 for Parental and Enteral Nutrition (PEN)
- 0.765 for Splints and Casts
- 0.752 for Intraocular Lenses (IOL)

9. 2024 Fees Update Factor of 2.6%

For CY 2024, we apply an update factor of 2.6% to certain DMEPOS fee schedule amounts that aren't adjusted using information from CBPs.

We update certain DMEPOS fee schedule amounts for 2023 by the percentage increase in the CPI-U for the 12-month period ending June 30, 2023, adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business Multi-Factor Productivity (MFP). Starting with the November 18, 2021, release of productivity data, The Bureau of Labor Statistics replaced the term MFP with Total Factor Productivity (TFP).

For CY 2024, the TFP adjustment is 0.4% and the CPI-U increase is 3%. We reduce the 3% increase in the CPI-U by the 0.4% increase in the TFP, resulting in a net increase of 2.6%.

10. Therapeutic Shoe Modification Codes

We annually adjust the fee schedule amounts for shoe modification codes, A5503 through A5507, to show the most current allowed service data. We do this in a way that prevents a net increase in expenditures when substituting these items for therapeutic shoe insert codes A5512, A5513, and A5514.

To establish the fee schedule amounts for the shoe modification codes, the base fees for codes A5512 and A5513 were weighted based on the approximated total allowed services for each code for items provided during the second quarter of CY 2004. For 2024, we're updating the weighted average insert fees used to establish the fee schedule amounts for the shoe modification codes with the most current allowed service data

Continued >>

for each insert code. The base fees for A5512, A5513, and A5514 will be weighted based on the approximated total allowed services for each code for items provided during CY 2022. We revised the fee schedule amounts for A5503 through A5507 to show this change, effective January 1, 2024.

11. Diabetic Testing Supplies

We're not updating the fee schedule for non-mail order Diabetic Testing Supplies (DTS) (without the KL modifier) for codes A4233, A4234, A4235, A4236, A4253, A4256, A4258, and A4259. We adjusted the fee schedule amounts for these codes in CY 2013 so they're equal to the SPAs for mail order DTS established in implementing the national mail-order CBP. CRs 8204 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2661CP.pdf and 8325 https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2709CP.pdf contain initial program instructions on these fees, or you can visit the National Mail-Order Recompete DTS SPAs website https://www.dmecompetitivebid.com/cbic/cbic.nsf/DocsCat/Home.

We'll update the non-mail order DTS amounts on the fee schedule each time the SPAs are updated. This can happen no less often than every time we recompete the mail-order CBP.

The National Mail-Order Recompete CBP for mail-order DTS was effective from July 1, 2016, to December 31, 2018. As of January 1, 2024, payment for non-mail order DTS will continue in accordance with Section 1834(a)(1)(H) of the Act. These rates remain in effect until the new SPA rates are set under the national mail-order program.

Starting January 1, 2024, we're adjusting the mail-order DTS (with KL modifier) fee schedule amounts using the methods for areas that were formerly CBAs during periods when there's a temporary lapse in the CBP.

- For CY 2023, the adjusted CY 2022 mail-order DTS fees show the increase in the CPI-U of 6.4% for the 12-month period ending January 1, 2023
- For CY 2024, we increase the 2023 adjusted fee schedule amounts by the projected percentage change in the CPI-U of 2.9% for the 12-month period ending January 1, 2024

We'll use the national mail-order adjusted fee schedule amounts in paying mail-order DTS claims in all parts of the U.S., including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

12. 2024 Maintenance and Servicing Payment Amount for Certain Oxygen Equipment

We're updating the payment amount for maintenance and servicing for certain oxygen equipment. Payment for maintenance and servicing of certain oxygen equipment can occur every 6 months, starting 6 months after the end of the 36th month of continuous use or the end of the supplier's or manufacturer's warranty, whichever is later. This applies to HCPCS codes E1390, E1391, E0433, or K0738, billed with the MS modifier. Payment can't occur more than once per patient, regardless of the combination of oxygen concentrator equipment and transfilling equipment the patient uses for any 6-month period.

We're adjusting the 2024 maintenance and servicing fee by the 2.6% TFP-adjusted covered item update factor to give a CY 2024 maintenance and servicing fee of $85.76 for oxygen and transfilling equipment.

Continued >>

13. 2024 Labor Payment Amounts for Repairs & Service Codes

Attachment A of CR 13463 https://www.cms.gov/files/document/r12398CP.pdf has the CY 2024 allowed payment amounts for HCPCS labor payment codes K0739, L4205, and L7520. Since the percentage increase in the CPI-U for the 12-month period ending with June 30, 2024, is 3%, we apply this change to the 2023 labor payment amounts for the CY 2023 rates. The 2024 labor payment amounts in Attachment A are effective for claims sent using HCPCS codes K0739, L4205, and L7520 with dates of service from January 1-December 31, 2024.

More Information

We issued CR 13463 to your MAC as the official instruction for this change.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
December 12, 2023	Initial article released.

Medicare Physician Fee Schedule Final Rule Summary: CY 2024

Related CR Release Date: November 22, 2023
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13452
Related Change Request (CR) Number: CR 13452 https://www.cms.gov/files/document/r12372cp.pdf
Related CR Transmittal Number: R12372CP
Related CR Title: Summary of Policies in the Calendar Year (CY) 2024 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List

Affected Providers

- Physicians
- Hospitals
- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for Medicare services paid under the PFS

Action Needed

Make sure that your billing staff knows about changes to:

- Telehealth services
- Evaluation and management (E/M) visits
- Behavioral health services
- Dental and oral health services
- Therapy services
- Diabetes self-management training (DSMT) services
- Community Health Integration (CHI) services
- Principal Illness Navigation (PIN) services
- Social Determinants of Health (SDOH)
- Caregiver training

Background

CMS issued a final rule https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notices/cms-1784-f that updates payment policies and Medicare payment rates for services provided by physicians and NPPs that are paid under the MPFS in CY 2024. These changes apply to services you provide in CY 2024.

Medicare Telehealth Services

For CY 2024, we're adding new codes to the list of Medicare telehealth services, including:

- CPT codes 0591T - 0593T for health and well-being coaching services, which we're adding on a temporary basis

Continued >>

- HCPCS code G0136 for Social Determinants of Health Risk Assessment, which we're adding on a permanent basis.

We're implementing several telehealth-related provisions of the Consolidated Appropriations Act (CAA) https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf, 2023, including:

- The temporary expansion of the scope of telehealth originating sites for services provided via telehealth to include any site in the U.S. where the patient is at the time of the telehealth service, including a person's home
- The expansion of the definition of telehealth practitioners to include qualified occupational therapists (OTs), physical therapists (PTs), speech-language pathologists (SLPs), and audiologists
- The continued payment for telehealth services rural health clinics (RHCs) and federally qualified health centers (FQHCs) provide using the methodology established for those telehealth services during the public health emergency (PHE)
- Delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and, again, at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs
- The continued coverage and payment of telehealth services included on the Medicare Telehealth Services List (as of March 15, 2020) until December 31, 2024 https://www.cms.gov/medicare/coverage/telehealth/list-services
- Adding mental health counselors (MHCs) and marriage and family therapists (MFTs) as distant site practitioners for purposes of providing telehealth services

We're implementing that, starting in CY 2024, telehealth services provided to people in their homes will be paid at the non-facility PFS rate. We clarified that modifier '95' should be used when the clinician is in the hospital and the patient is in the home, as well as for outpatient therapy services provided via telehealth by PT, OT, or SLPs.

We removed frequency limitations in 2024 for:

- Subsequent inpatient visits
- Subsequent nursing facility visits
- Critical care consultation

We're allowing teaching physicians to use audio or video real-time communications technology when the resident provides Medicare telehealth services in all residency training locations through the end of CY 2024.

Telehealth Origination Site Facility Fee Payment Update

The MEI increase for 2024 is 4.6%. Therefore, for CY 2024, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80% of the lesser of the actual charge, or $29.96. The patient is responsible for any unmet deductible amount and Medicare coinsurance.

Payment for Outpatient Therapy (including PT, OT, SLP), DSMT, and Medical Nutrition Therapy (MNT) Services when Institutional Staff Provide the Services to Patients in Their Homes through Communication Technology

Institutional providers are able to continue to bill for PT, OT, SLP, DSMT and MNT services provided remotely in the same way they could during the PHE and through the end of CY 2023.

Continued >>

We're finalizing the proposed policy for CY 2024, with modifications, as follows:

- Hospitals and other providers of PT, OT, SLP, DSMT and MNT services that remain on the Medicare Telehealth Services List can continue to bill for these services when provided remotely in the same way they've been during the PHE and the remainder of CY 2023, except that:
    - For outpatient hospitals, patients' homes no longer need to be registered as provider-based entities to allow for hospitals to bill for these services
    - Except for Critical Access Hospitals (CAHs) electing Method II, the 95 modifier is required on claims from all providers, as soon as hospitals needing to do so can update their systems.

Telehealth Finalized Policies for DSMT Services

Distant Site Practitioners: To increase access to DSMT telehealth services, we're finalizing billing rules for telehealth DSMT services at 42 CFR 410.78(b)(2)(x) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.78 to allow distant site practitioners who can appropriately bill for DSMT services, such as registered dietitians (RDs) and nutrition professionals, physicians, NPPs, physician assistants (PAs), and clinical nurse specialists (CNSs), to do so on behalf of others who personally provide the services as part of the DSMT entity.

Injection Training for Insulin-Dependent Patients: During the PHE for COVID-19, we permitted insulin injection training to be done via telehealth for patients getting DSMT services. We're finalizing a policy to allow DSMT insulin injection training (for initial or follow-up training) to be provided via telehealth when it aligns with clinical standards, guidelines, or best practices, instead of the previous sub-regulatory policy that required certain hours of training be provided in-person. See Chapter 12, Section 190.3.6 of the Medicare Claims Processing Manual.
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf

Evaluation and Management (E/M) Visits

Complexity Add-on HCPCS Code G2211

With the end of the Congressionally mandated suspension of payment for Office Outpatient Evaluation Management (O/O E/M) visit complexity add-on HCPCS code G2211, for CY 2024, we're finalizing changing the status of code G2211 to make it separately payable by assigning it an "active" status indicator, effective January 1, 2024. We recognize that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with providing stand-alone office or outpatient E/M visits to warrant different payment. We're also finalizing that the O/O E/M visit complexity add-on code G2211 wouldn't be payable when you report the O/O E/M visit with payment modifier 25.

CR 13452 has more details along with several examples on the use of G2211.
https://www.cms.gov/files/document/r12372cp.pdf

Split (or Shared) Visits

Split (or shared) E/M visits refer to visits provided in part by physicians and in part by other NPPs in hospitals and other institutional settings. For CY 2024, we're finalizing a revision to our definition of "substantive portion" of a split (or shared) visit to include the revisions to the CPT guidelines. For Medicare billing purposes, the "substantive portion" means more than half of the total time spent by the physician and or non-physician practitioner performing the split (or shared) visit, or a substantive part of the medical decision making.

Continued >>

Behavioral Health Services

For CY 2024, we're are implementing Section 4121 of the CAA, 2023 https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf, which provides for Medicare Part B coverage and payment under the PFS for the services of MFTs and MHCs when billed by these professionals. We're also finalizing allowing addiction counselors that meet all of the applicable requirements to be an MHC and to enroll in Medicare as MHCs. MFTs and MHCs to enroll in Medicare and these providers would be able to bill Medicare for services, starting January 1, 2024, consistent with statute. We're also making corresponding changes to Behavioral Health Integration codes to allow MFTs and MHCs to provide integrated behavioral health care as part of primary care settings.

CMS is also implementing Section 4123 of the CAA, 2023, which requires the Secretary to establish new HCPCS codes under the PFS for psychotherapy for crisis services provided in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting, including the home or a mobile unit) provided on or after January 1, 2024. Section 4123 of the CAA, 2023, specifies that the payment amount for these psychotherapy for crisis services must be equal to 150% of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes:

- 90839 (Psychotherapy for crisis; first 60 minutes)
- 90840 (Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)), and any succeeding codes.

We're also finalizing allowing the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by clinical social workers, MFTs, and MHCs, in addition to clinical psychologists. HBAI codes are used to identify the psychological, behavioral, emotional, cognitive, and social factors included in the treatment of physical health problems.

We're also finalizing an increase in the valuation for timed behavioral health services under the PFS. We're going to apply an adjustment to the work Relative Value Units (RVUs) for psychotherapy codes payable under the PFS, which we're implementing over a 4-year transition.

We're finalizing an increase to the payment rate for office-based treatment for substance use disorders (HCPCS codes G2086 and G2087) to show 2 individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (Psychotherapy, 45 minutes with patient), rather than CPT code 90832 (Psychotherapy, 30 minutes with patient).

Dental and Oral Health Services

Medicare Parts A and B makes payment for certain dental services in circumstances where the services aren't considered to be in connection with dental services within the meaning of Section 1862(a)(12) of the Social Security Act https://www.ssa.gov/OP_Home/ssact/title18/1862.htm or our regulation at 42 CFR 411.15(i) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-411/subpart-A/section-411.15. Dental services that are so integral to other medically necessary services that they're inextricably linked to the clinical success of that medical services aren't in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of Section 1862(a)(12) of the Act. Rather,

Continued >>

these dental services are inextricably linked to the clinical success of an otherwise covered medical service, and are payable under Medicare Parts A and B.

For CY 2024, we're finalizing:

- Permitting payment for certain dental services inextricably linked to other covered services used to treat cancer, prior to, or contemporaneously with
    - Chemotherapy services,
    - Chimeric Antigen Receptor - T (CAR-T) Cell therapy, and,
    - The use of high-dose bone modifying agents (antiresorptive therapy)
- Codification of and amendments to the previously finalized payment policy for dental services prior to, contemporaneously with, or after treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these, whether primary or metastatic.

Therapy Services

Supervision Policy for Physical and Occupational Therapists in Private Practice

Since 2005, we've required PTs Private Practices and OTs Private Practices (PTPPs and OTPPs, respectively) to provide direct supervision of their therapy assistants. We're finalizing a regulatory change to allow for general supervision of therapy assistants by PTPPs and OTPPs for remote therapeutic monitoring (RTM) services, starting January 1, 2024.

The KX-modifier threshold amounts for CY 2024 are $2,330 for OT services and $2,330 for PT and SLP services combined.

DSMT Services Provided by Registered Dietitians (RDs) and Nutrition Professionals

We're finalizing an amendment to the regulatory provision at 42 CFR 410.72(d) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.72 established during CY 2022 PFS rulemaking that clarifies that an RD or nutrition professional must personally perform MNT services. The enrolled RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider, regardless of which professional personally delivers the service.

CHI Services

We're finalizing separate coding and payment for CHI services, which include person-centered planning, health system coordination, promoting patient self-advocacy, and facilitating access to community-based resources to address unmet social needs that interfere with the practitioner's diagnosis and treatment of the patient. These are the first PFS services designed to specifically include care involving community health workers, who link underserved communities with critical health care and social services in the community and expand equitable access to care, improving outcomes for the Medicare population.

PIN Services and SDOH

For CY 2024, we're finalizing new coding and payment for PIN services, HCPCS codes G0023, G0024, G0140, and G0146, which use auxiliary personnel such as patient navigators and peer support specialists to provide navigation in the treatment of a serious, high-risk condition or illness. These services include items such as person-centered planning, promoting patient self-advocacy, and facilitating access to community-based

Continued >>

resources to address unmet social needs and other factors that are relevant to the practitioner's diagnosis and treatment of the patient.

We're also finalizing new coding and payment for the administration of SDOH risk assessments (G0136), which must be provided in conjunction with a qualifying visit, including an E/M visit, some behavioral health visits, or the Annual Wellness Visit. The evidence-based, standardized SDOH risk assessment tool used must cover domains such as housing insecurity, food insecurity, transportation needs, and utility difficulty, but practitioners may choose to add other domains if prevalent or culturally salient to their patient population.

Caregiver Training

For CY 2024, we're finalizing new coding (CPT codes 96202, 96202, 97550, 97551, and 97552) to make payment when practitioners train and involve one or more caregivers to assist patients with certain diseases or illnesses (such as dementia) in carrying out a treatment plan.

We're finalizing our proposal to pay for these services when provided by a physician or a NPP (nurse practitioners, CNSs, certified nurse-midwives, PAs, and clinical psychologists), or therapist (PT, OT, or SLP) under an individualized treatment plan or therapy plan of care, without the patient present.

More Information

We issued CR 13452 to your MAC as the official instruction for this change.

Your MAC will use the prolonged preventive services G0513 and G0514 as an add-on to the covered preventive services list. https://www.cms.gov/medicare/payment/fee-schedules/physician/preventive-services

The list of codes subject to the CT modifier reduction is available.
https://www.cms.gov/medicare/payment/fee-schedules/physician/ct-modifier-reduction-list

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
November 22, 2023	Initial article released.

View the Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Product-Disclaimer

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).

Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

Related CR Release Date: November 16, 2023
Effective Date: October 13, 2023
Implementation Date: December 19, 2023, (MACs); April 1, 2024 (CWF, MCS, FISS)
MLN Matters Number: MM13429
Related Change Request (CR) Number: CR 13429
https://www.cms.gov/files/document/r12364CP.pdf
Related CR Transmittal Numbers: R12364CP
https://www.cms.gov/files/document/r12364CP.pdf and
R12364NCD https://www.cms.gov/files/document/r12364NCD.pdf
Related CR Title: NCD 220.6.20 – Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease

Affected Providers

- Physicians
- Hospitals
- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for services provided to Medicare patients

Action Needed

Make sure your billing staff knows:

- CMS removed NCD 220.6.20 from the Medicare National Coverage Determination (NCD) Manual, effective October 13, 2023
- Your MACs will make coverage determinations for Positron Emission Tomography (PET beta amyloid imaging for dementia and neurodegenerative disease

Background

Effective for claims with dates of service (DOS) after September 27, 2013, we covered the use of PET beta amyloid imaging to improve health outcomes for Medicare patients with dementia or neurodegenerative disease in certain scenarios under NCD 220.6.20. We allowed coverage for 1 PET beta amyloid imaging scan per lifetime through coverage with evidence development (CED).

On October 13, 2023, we removed NCD 220.6.20 entirely.

Effective for claims with DOS on and after October 13, 2023, we removed NCD 220.6.20 from the NCD Manual, ending CED and the once-per-lifetime requirement for PET beta amyloid imaging. Your MAC will make Medicare coverage determinations for PET beta amyloid imaging under Section 1862(a)(1)(A) of the Social Security Act https://www.ssa.gov/OP_Home/ssact/title18/1862.htm.

Note: Your MAC will adjust any PET beta amyloid claims processed incorrectly that you bring to their attention, effective for claims with DOS on or after October 13, 2023.

Continued >>

More Information

We issued CR 13429 as the official instruction for this change. CR 13429 consists of 2 transmittals:

- Transmittal R12364CP updates the Medicare Claims Processing Manual. The updated portion of the manual is part of the transmittal.
- Transmittal R13429NCD removes NCD 220.6.20 from the NCD Manual.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
November 20, 2023	Initial article released.

View the Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Product-Disclaimer

Edits to Prevent Payment of G2211 with Office/Outpatient Evaluation and Management Visit and Modifier 25

Related CR Release Date: November 21, 2023
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13272
Related Change Request (CR) Number: CR 13272
Related CR Transmittal Number: R12370CP
https://edit.cms.gov/files/document/r12370cp.pdf
Related CR Title: Implement Edits to Prevent Payment of Complexity Add-On Code G2211 When Associated Office/Outpatient Evaluation and Management (O/O E/M) Visit (Codes 99202-99205, 99211-99215) is Reported With Modifier 25

Affected Providers

- Physicians
- Nonphysician practitioners
- Hospitals
- Other providers who bill Medicare Administrative Contractors (MACs) for O/O E/M services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about complexity add-on code G2211:

- Medicare pays separately starting January 1, 2024
- We don't pay when you report an associated O/O E/M visit with modifier 25

Background

CR 13272 tells MACs to implement edits to deny payment of O/O E/M visit complexity add-on code G2211 when you report an associated O/O E/M visit, codes 99202-99205 and 99211-99215, with modifier 25 for the same patient by the same practitioner.

For CY 2024, with the end of the Congressional mandated suspension of payment for O/O E/M visit complexity add-on code G2211, CMS finalized a rule to make the code separately payable by assigning the active status indicator to it, effective January 1, 2024.

Separately identifiable visits occurring on the same day as minor procedures, such as zero-day global procedures, have resources sufficiently distinct from the costs associated with providing stand-alone O/O E/M visits to justify different payment.

Therefore, we finalized the rule that the O/O E/M visit complexity add-on code G2211 isn't payable when you report the O/O E/M visit with payment modifier 25.

For institutional claims, this applies to Method II Critical Access Hospitals on the same encounter for type of bill 85X only.

Continued >>

More Information
We issued CR 13272 to your MAC as the official instruction for this change.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
November 21, 2023	Initial article released.

Medicare Program Integrity Manual: CY 2024 Home Health Prospective Payment System Updates

Related CR Release Date: December 7, 2023
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13333
Related Change Request (CR) Number: CR 13333 https://www.cms.gov/files/document/r12393PI.pdf
Related CR Transmittal Number: R12393PI
Related CR Title: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub. 100-08) – Home Health Prospective Payment System (HH PPS) Final Rule

Affected Providers

- Physicians
- Hospices
- Home Health Agencies (HHAs)
- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about:

- Expanding the HHA 36-month rule
- Moving hospices into the high level of categorical risk-screening
- Other updates to Chapter 10 of the Medicare Program Integrity Manual

Background

The CY 2024 HH PPS final rule https://www.govinfo.gov/content/pkg/FR-2023-11-17/pdf/2023-25408.pdf contains provisions about Medicare provider enrollment. These include, but aren't limited to:

- Expanding the HHA 36-month rule to include hospice changes in majority ownership
- Moving hospices into the high level of categorical risk-screening

CR 13333 updates Chapter 10 of the manual with instructions regarding these regulatory provisions. The main manual revisions are:

- Section 10.1.1: CMS revised the definition of managing employee. For purposes of this definition of managing employee, this includes, but isn't limited to, a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director. https://www.cms.gov/files/document/r12393PI.pdf
- Section 10.6.1.1.5: We added this section to give details on reporting HHA and hospice majority ownership changes occurring within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice most recent change in majority ownership. https://www.cms.gov/files/document/r12393PI.pdf
- Section 10.6.15: We updated this section to show the revised screening requirements for hospices. https://www.cms.gov/files/document/r12393PI.pdf

Continued >>

More Information
We issued CR 13333 to your MAC as the official instruction for this change.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
December 7, 2023	Initial article released.

View the Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Product-Disclaimer

New Waived Tests

Related CR Release Date: December 19, 2023 Revised
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13455
Related Change Request (CR) Number: CR 13455 https://www.cms.gov/files/document/r12415cp.pdf
Related CR Transmittal Number: R12415CP
Related CR Title: New Waived Tests

What's Changed: We revised the QW code information among the 80 tests and added 24 new waived tests with their corresponding QW codes the FDA approved as of December 5, 2023 (pages 2-5).

Affected Providers

- Hospitals
- Physicians
- Suppliers

Action Needed

Make sure your billing staff knows about:

- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New CLIA-waived tests approved by the FDA
- Use of modifier QW for CLIA-waived tests

Background

CLIA regulations require a facility to be appropriately certified for each test they do. CMS edits laboratory claims at the CLIA certificate level to make sure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate.

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The HCPCS codes for the following new tests must have the modifier QW to be recognized as a waived test.

The HCPCS code, effective date, and description for the latest tests approved by the FDA as waived tests under CLIA are:

- 83036QW September 27, 2023, Abbott Diagnostics Technologies AS Afinion 2 analyzer {Afinion HbA1c} • 83036QW September 27, 2023, Abbott Diagnostics Technologies AS AS100 Analyzer {Afinion HbA1c}
- 87635QW August 10, 2023, Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)
- 80061QW, 82465QW, 83718QW, 84478QW September 20, 2023, Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)
- 80305QW May 15, 2023, American Screening Corporation Discover Plus Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation G-Card Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation G-Cup Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Onescreen Multi-Panel Drug Test Cup

Continued >>

- 80305QW May 15, 2023, American Screening Corporation Precision DX Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision DX Multi-Panel Drug Test Cup
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Drug Test Dip Card
- 80305QW May 15, 2023, American Screening Corporation Precision Plus Multi-Panel Drug Test Cup
- 85610QW July 27, 2023, ARKRAY USA Assure PT Care Prothrombin Time PT/INR Monitoring System Professional Use
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M2000
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M300
- 80305QW July 11, 2023, Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test
- 87631QW May 5, 2023, Biofire Diagnostics SPOTFIRE Respiratory Panel Mini
- 80305QW August 23, 2023, BTNX Inc. Rapid Response Multi-Drug One Step Cup
- 80305QW July 11, 2023, BTNX Inc. L-Cup Home Rapid Test (Urine)
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Marijuana test kit (THC urine test)
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Cup
- 80305QW May 19, 2023, Carethetic Group Corporation Carethetic Multi Drug Test Panel
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Cup (Urine)
- 80305QW August 28, 2023, Citest Diagnostics Inc. Citest Multiplex DOA Home Test Panel (Urine)
- 80305QW August 24, 2023, Clarity Diagnostics LLC. Clarity Multi-Drug Urine Test Cup (Urine)
- 87635QW June 20, 2023, Cue Health Inc. Cue Health Monitoring System (For use with Anterior Nasal Swabs)
- 80305QW October 2, 2023, Dochek USA Inc. Amazewell Multi-Drug Urine Test Cup
- 80305QW August 2, 2023, Easy Healthcare Corporation Easy@Home Single Drug Screen Test (Cocaine Urine Test)
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit For Cannabis
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Five (5) Drugs
- 80305QW August 28, 2023, Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Twelve (12) Drugs
- 83986QW September 22, 2023, Genabio Diagnostics Inc. GenaCheck Vaginal Health pH Screening Test
- 87420QW June 29, 2023, Healgen Scientific LLC Rapid Check RSV Antigen Test (Nasopharyngeal swabs)
- 80305QW August 24, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Compact Round Cup
- 80305QW August 24, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Round Cup
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN CLICK CUP
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREEN FLAT CUP
- 80305QW August 3, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card
- 80305QW July 11, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Buprenorphine (BUP))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Methamphetamine (MET))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card

Continued >>

(Methylenedioxymethamphetamine (MDMA))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Morphine (MOP))
- 80305QW July 17, 2023, Instant Technologies Inc. iSCREENâ„¢ Urine Test Dx Drug Screen Dip Card (Oxycodone (OXY))
- 80305QW May 25, 2023, Instant Technologies Inc. iSCREENâ„¢ URINE TEST DRUG SCREENING CLICK CUP
- 80305QW May 25, 2023, Medical Distribution Group Bicycle Health CLIA WAIVED DRUG TEST
- 80305QW May 25, 2023, Neopharma Technologies Sdn. NEOTEST Drug Test Dip Card
- 80305QW May 25, 2023, Neopharma Technologies Sdn. NEOTEST Drug Test Multi Panel Cup (Urine)
- 80305QW June 22, 2023, Pregmate LLC ez level DRUG TEST
- 80305QW June 22, 2023, Pregmate LLC ez level MARIJUANA THC DRUG TEST
- 86769QW, 87426QW, 87811QW September 20, 2023, Quidel Sofia 2
- 87631QW July 27, 2023, Roche Molecular cobas Liat System {Cobas SARS-CoV-2 & Influenza A/B}
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Cup
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Dip Card
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine Cassette
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine DipCard
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine Cassette
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine DipCard
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana Cassette
- 80305QW July 11, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana DipCard
- 80305QW July 10, 2023, Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW THC Urine Strip Test
- 85018QW October 2, 2023, Sanguina Inc. AnemoCheck Home
- 80305QW August 14, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi Panel Drug Urine Test Cup
- 80305QW May 31, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Cup
- 80305QW May 31, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Dip Card
- 80305QW August 14, 2023, Shanghai Douglas Medical Device Co. Ltd. ACCUBIO THC One Step Marijuana Test Dip Card
- 83036QW September 29, 2023, Siemens Healthcare Diagnostics Inc. DCA Vantage Analyzer {Siemens DCA Systems Hemoglobin A1c Reagent Kit}
- 80305QW August 15, 2023, Smartox SMARTEST Drug of Abuse Urine Test Cup
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Cup
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Cup LC

Continued >>

- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card
- 80305QW July 7, 2023, Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card LC
- 87420QW August 21, 2023, Versea Diagnostics LLC Versea Easy Lab PRO Rapid RSV Test
- 80305QW September 8, 2023, Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Panel 50
- 80305QW September 8, 2023, Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ„¢ Marijuana Test Strip 50
- 80305QW June 23, 2023, VivaChek Diagnostics Inc. BioSieve Multi-Drug Urine Test Cup
- 80305QW June 26, 2023, Walgreen Co. Walgreens Multi Panel Urine Test Cup
- 80305QW June 5, 2023, Wal-Mart Stores Inc. Equate Multi Panel Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife C-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife T-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Multi-Drug Urine Test Panel
- 80305QW October 18, 2023 McKesson Medical-Surgical Inc. McKesson Drugs of Abuse Test 14- Drug Panel with Adulterants
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 87420QW October 19, 2023 Clarity Diagnostics LLC Clarity RSV Antigen Test
- 85018QW October 20, 2023 Henry Schein OneStep+ Pro Hb System
- 80305QW October 24, 2023 FSA Store Inc. Caring Mill Amphetamine Tests Strip
- 80305QW October 26, 2023 Wondfo USA Co. Ltd. SAFElife T-Dip Amphetamine (AMP500) Urine Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Panel
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Drug Urine Test Cup
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Panel Urine Test
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Cup
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Panel
- 80305QW November 6, 2023 Hangzhou AllTest Biotech Co. Ltd. AllTest Fentanyl Urine Test Cassette
- 80305QW November 6, 2023 2San LLC. 2SAN Home Drug Test Cup
- 80305QW November 16, 2023 American Screening Corporation Discover Multi-Drug Rapid Test Cup (Urine)
- 80305QW November 16, 2023 Lendas UAB Exploro Highly Sensitive 5-Panel Urine Drug Test
- 80305QW November 16, 2023 VivaChek Biotech (Hangzhou) Co. Ltd. BioSieve Multi-Drug Urine Test Panel
- 86769QW, 87426QW, 87811QW November 17, 2023 ACON Laboratories Inc. Flowflex COVID-19 Antigen Home Test (For use with Anterior Nasal Swabs)
- 80305QW December 1, 2023 Medical Distribution Group Inc. DrugTect Fentanyl Urine Cassette
- 80305QW November 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Accurate Oral Fluid Drug Test COT

Continued >>

The tests on the first page of the list attached to CR 13455 (in other words, HCPCS codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) don't require a QW modifier to be recognized as a waived test.

MACs won't search their files to either take back payment or retroactively pay claims affected by CR 13455. They'll adjust claims you bring to their attention.

More Information
We issued CR 13455 to your MAC as the official instruction for this change.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
December 20, 2023	We revised the QW code information among the 80 tests and added 24 new waived tests with their corresponding QW codes the FDA approved as of December 5, 2023 (pages 2-5)
November 27, 2023	Initial article released.

Clinical Laboratory Fee Schedule: 2024 Annual Update

Related CR Release Date: November 30, 2023
Effective Date: January 1, 2024
Implementation Date: January 2, 2024
MLN Matters Number: MM13467
Related Change Request (CR) Number: CR 13467 https://edit.cms.gov/files/document/r12389cp.pdf
Related CR Transmittal Number: R12389CP
Related CR Title: Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

Affected Providers

- Laboratories
- Other providers billing Medicare Administrative Contractors (MACs) for laboratory services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about changes and instructions effective January 1, 2024:

- Delay in Clinical Laboratory Fee Schedule (CLFS) data reporting period
- Mapping for new test codes
- Updates for costs subject to the reasonable charge payment

Background

Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests (CDLTs)--DELAYED

Under the CLFS final rule https://www.govinfo.gov/content/pkg/FR-2016-06-23/pdf/2016-14531.pdf, reporting entities must give CMS certain private payor rate information for their component applicable laboratories. On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act https://www.congress.gov/117/plaws/publ71/PLAW-117publ71.pdf (S. 610) delayed the reporting requirement and also delayed the application of the 15% phase-in reduction.

On November 16, 2023, Section 502 of the Further Continuing Appropriations and Other Extensions Act of 2024 https://www.congress.gov/118/bills/hr6363/BILLS-118hr6363enr.pdf was passed and delayed data reporting requirements for CDLTs that aren't advanced diagnostic laboratory tests (ADLTs), and it also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation.

- The next data reporting period of January 1, 2025–March 31, 2025, is based on the original data collection period of January 1, 2019–June 30, 2019. After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs (example: 2028, 2031).
- A 0% payment reduction will be applied for CY 2024 so that a CDLT that isn't an ADLT may not be reduced compared to the payment amount for that test in CY 2023. For CYs 2025-2027, payment may not be reduced by more than 15% per year compared to the payment amount established for a test the preceding year.

ADLTs

See the CMS ADLT website for more information about these tests.
https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs

Continued >>

Clinical Laboratory Fee Schedule Update to Fees

- For a pap smear test, Section 1833(h)(7) of the Social Security Act (the Act) https://www.ssa.gov/OP_Home/ssact/title18/1833.htm requires payment to be the lesser of the local fee or the national limitation amount, but not less than a national minimum payment amount. Payment for pap smear tests may not exceed the actual charge. The CY 2024 national minimum payment amount is $17.76 This value is the CY 2023 national minimum payment with a 2.6% increase or $17.31 times 1.026.
- 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 is the Consumer Price Index-Update (CPI-U), which for CY 2024 is 3.0%, per 42 CFR 405.509(b)(1). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-405/subpart-E/section-405.509

The Part B deductible and coinsurance don't apply for services paid under the CLFS.

Access to Data File

The CY 2024 CLFS https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs data file will be available after December 1, 2023. It will be available in multiple formats including Excel®, text, and comma delimited.

Public Comments and Final Payment Determinations

On June 22, 2023, CMS hosted a public meeting to solicit comments on the reconsidered codes from CY 2023 codes and new CY 2024 CPT codes. A summary of the meeting and the tentative payment determinations is available. https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings

Pricing Information

The CY 2024 CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, P9615, and G0471). We establish the fees based on Section 1833(h)(4)(B) of the Act.

We update the fees for clinical laboratory travel codes P9603 and P9604 annually. The clinical laboratory travel codes are billable only for traveling to perform a specimen collection for either a nursing home or homebound patient. If there's a revision to the standard mileage rate for CY 2024, we'll issue a separate instruction on the clinical laboratory travel fees.

The CY 2024 clinical laboratory fee schedule 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.

Mapping Information

Tab A of the table attached to CR 13467 lists the mapping information for codes. https://www.cms.gov/files/document/r12389cp.pdf

Continued >>

Laboratory Costs Subject to Reasonable Charge Payment in CY 2024
We pay hospital outpatient claims on a reasonable charge basis per Section 1842(b)(3) of the Act https://www.ssa.gov/OP_Home/ssact/title18/1842.htm. The reasonable charge can't 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 CPI-U for CY 2024 is 3.0%.

Services described by HCPCS codes in the following lists are for independent dialysis facility patients. However, when you perform these services for hospital-based renal dialysis facility patients, we pay on a reasonable cost basis. Also, when these you perform these services for hospital outpatients, we make payment under the hospital Outpatient Prospective Payment System (OPPS).

Blood Products, Transfusion Medicine, and Reproductive Medicine Procedures
Tab B of the table attached to CR 13467 lists the codes in these categories subject reasonable charge payment in CY 2024. https://www.cms.gov/files/document/r12389cp.pdf

New Codes - Proprietary Laboratory Analysis (PLAs)
Tab C of the table attached to CR 13467 lists the new codes effective January 1, 2024.
https://www.cms.gov/files/document/r12389cp.pdf

We added these new codes to the national HCPCS file with an effective date of January 1, 2024. These new codes are MAC-priced (where applicable) until they're nationally priced. MACs will only price PLA codes for laboratories within their jurisdiction.

Deleted Codes
Tab D of the table attached to CR 13467 lists the codes deleted effective January 1, 2024.
https://www.cms.gov/files/document/r12389cp.pdf

More Information
We issued CR 13467 to your MAC as the official instruction for this change.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
November 30, 2023	Initial article released.

View the Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Product-Disclaimer

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).

Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting & Reporting Data for the Private Payor Rate-Based Payment System

MLN Matters Number: SE19006 Revised
Article Release Date: December 4, 2023
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation Date: N/A

What's Changed: We revised this Article to note that for CDLTs that aren't ADLTs, the data reporting period is delayed and resumes starting January 1, 2025 - March 31, 2025. Also, we extended the 0% limit on laboratory payment reductions to the end of CY 2024 and the 15% limit on payment reductions per year to CY 2025 - 2027 (see pages 2, 14, 15, and 20-24).

Provider Type Affected
This MLN Matters Article is for Medicare Part B clinical laboratories that must report private payor rate data to CMS.

Provider Action Needed
Make sure your staff knows about:
- Clarifications for deciding whether a hospital outreach laboratory meets the requirements to be an "applicable laboratory"
- Applicable information (private payor rate data) that you must collect and report to us
- The entity responsible for reporting applicable information to us
- The data collection and reporting periods
- Information about our online data collection system
- Our schedule for implementing the next private payor-rate based Clinical Laboratory Fee Schedule (CLFS) update
- Information about the condensed data reporting option for reporting entities

Background
Section 1834A of the Social Security Act (the Act) https://www.ssa.gov/OP_Home/ssact/title18/1834A.htm, as established by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) https://www.congress.gov/113/plaws/publ93/PLAW-113publ93.pdf, required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS. The CLFS final rule Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) https://www.govinfo.gov/content/pkg/FR-2016-06-23/pdf/2016-14531.pdf implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to us certain private payor rate information (applicable information) for their component applicable laboratories. In general, the payment amount for a test on the

Continued >>

CLFS you provide on or after January 1, 2018, is equal to the weighted median of private payor rates for the test. We base the calculations on the applicable information that laboratories collect during a data collection period and report to us during a data reporting period. We use cross walking or gap filling methods to establish payment amounts for new CDLTs and CDLTs for which we don't get applicable information.

We published the Physician Fee Schedule (PFS) final rule entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F) https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf on November 23, 2018. In this rule, we made 2 revisions to the regulatory definition of applicable laboratory:

- We excluded Medicare Advantage plan revenues from total Medicare revenues, the denominator of the majority of Medicare revenues threshold
- Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 Type of Bill (TOB) 14x to decide whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold

Since 2019, Congress has passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS. Most recently, section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 https://www.congress.gov/118/bills/hr6363/BILLS-118hr6363eh.pdf delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in payment reductions. In summary, the revisions are:

- We'll base the next data reporting period of January 1, 2025 - March 31, 2025, on the original data collection period of January 1, 2019 - June 30, 2019.
- After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that are not ADLTs, (in other words, 2028, 2031, and so on).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended an additional year. There was a 0.0% reduction for CYs 2021-2023, and a 0.0% payment reduction limit will be applied for CY 2024. We won't reduce payment by more than 15% per year compared to the payment amount established for a test the preceding year for CYs 2025 - 2027.

Also, for the January 1, 2025 - March 31, 2025 (previously scheduled to take place from January 1, 2024 - March 31, 2024) data reporting period, we'll allow reporting entities the option to condense certain applicable information at the Tax Identification Number (TIN) level, instead of reporting for each applicable laboratory individually at the NPI level.

Applicable Laboratory

Section 1834A of the Act defines an applicable laboratory as one that gets the majority of its Medicare revenues under the CLFS or PFS or both. It also provides the authority to set a low volume or low expenditure threshold.

Under the revised final policies for the Medicare CLFS, an applicable laboratory is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (42 CFR 493.2 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493) that bills Part B under its own NPI or, for hospital outreach laboratories, bills Part B on the Form CMS-1450 TOB 14x. Also, the laboratory must meet a "majority of Medicare revenues" threshold. This means that in a data collection period, it gets more than 50% of its Medicare revenues from 1 or a combination of the CLFS and PFS. It also must

Continued >>

meet a low expenditure threshold. it gets at least $12,500 of its Medicare revenues from the CLFS in a data collection period.

For purposes of deciding applicable laboratory status under the CLFS, a hospital outreach laboratory is a hospital-based laboratory that provides laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Part B services it provides to non-hospital patients using the Form CMS-1450 TOB 14x.[1]

[1] The Form CMS-1450 14x is a type of bill as defined by the National Uniform Billing Committee. Hospitals use it in hospital claims submission, and it's associated with hospital laboratory services provided to non-hospital patients.

I. Determination of Applicable Laboratory Status Based on the NPI

This section includes information on how independent laboratories and physician office laboratories that bill Part B under their own NPI and hospital outreach laboratories that bill Part B under their own NPI. separate from the hospital's NPI. decide whether they're an applicable laboratory. As we discuss later in this Article, hospital outreach laboratories that bill Part B using the hospital's NPI must decide applicable laboratory status based on its revenues attributed to the Form CMS-1450 TOB 14x.

There are 4 steps in deciding whether you meet the requirements to be an applicable laboratory based on your own billing NPI:

- Is the laboratory certified under CLIA
- Does the CLIA-certified laboratory bill Part B under its own NPI
- Does the laboratory meet the majority of Medicare revenues threshold
- Does the laboratory meet the low expenditure threshold

Step 1: CLIA Certification

CLIA applies to all laboratories performing testing on human specimens for a health purpose. A laboratory must be a CLIA-certified laboratory to get Medicare payment. So, the first step in identifying an applicable laboratory is to decide whether the laboratory is CLIA-certified. The CLIA regulatory definition of a laboratory is codified in regulation in 42 CFR 493.2. **We consider a facility that gets any CLIA certificate, including a CLIA certificate of waiver, a laboratory as defined in 42 CFR 493.2.**

Step 2: NPI

The second step is to decide whether the CLIA-certified laboratory bills Part B under its own NPI. We use the laboratory's own billing NPI as the mechanism for defining an applicable laboratory.

Step 3: Majority of Medicare Revenues Threshold

For a CLIA-certified laboratory that bills Part B under its own NPI to be an applicable laboratory, it must meet the majority of Medicare revenues threshold. A laboratory, by its own billing NPI, meets the majority of Medicare revenues threshold if it gets more than 50% of its total Medicare revenues from payments under the Medicare CLFS or PFS or both. The CLFS and PFS are under Part B, also known as Original Medicare or Fee-for-Service (FFS) Medicare.

Continued >>

To decide whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims they get from their Medicare Administrative Contractor (MAC) under their own billing NPI during the data collection period. See the Applicable Information Section below for more information on the concept of final paid claims.

The 3 steps to decide whether a laboratory meets the majority of Medicare revenues threshold are:

1. Sum the CLFS and PFS payment amounts the laboratory gets on its billing NPI during the data collection period.
   - The revenues from the CLFS include payments for all laboratory services under the CLFS
   - The revenues from the PFS include all payments from all services paid under the PFS . for instance, laboratory services and services that aren't laboratory services such as pathology services, evaluation and management services, and radiology services
   - The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation
2. Sum the total Medicare revenues the laboratory gets on its billing NPI during the data collection period.
   - Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare patient deductible or coinsurance for services you provided during the data collection period
   - The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation

3. Divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues you got during the data collection period. We give more information on the data collection period below.

Note: Effective January 1, 2019, don't include Medicare Advantage plan payments under Medicare Part C in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.

If the Medicare revenues you got from the CLFS and PFS are greater than 50% of the total Medicare revenues for the laboratory's billing NPI, you meet the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:
If:

$$\frac{\text{Medicare CLFS revenues (for billing NPI)} + \text{Medicare PFS revenues (for billing NPI)}}{\text{Total Medicare revenues (for billing NPI)}} \quad \text{is} \quad >50\%$$

Then: The laboratory meets the majority of Medicare revenues threshold.

Step 4: Low Expenditure Threshold
An applicable laboratory must also meet the low expenditure requirements. A laboratory, as defined under the CLIA regulations, meets the low expenditure threshold if, by its own billing NPI, it gets at least $12,500 in Medicare revenues from the CLFS under Part B during the data collection period. To meet the low expenditure threshold, the laboratory must look to its final Medicare paid claims it gets from the MAC under its billing NPI during the data collection period.

Continued >>

To decide whether the laboratory meets the low expenditure threshold, sum all final payments for the laboratory's own billing NPI it got from Medicare CLFS services during the data collection period (completed under Step 3: Majority of Medicare Revenues Threshold). It's important to note that the low expenditure threshold applies only to **CLFS services. It doesn't** include revenues you got under the PFS. In other words, to meet the low expenditure threshold, the laboratory's own billing NPI must get at least $12,500 under only the CLFS during the data collection period.

The low expenditure threshold equation is: Medicare CLFS revenues (for billing NPI) ≥ $12,500.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold apply to the CLIA-certified laboratory's own billing NPI for purposes of deciding whether the laboratory is an applicable laboratory:

Example 1: A laboratory organization includes 5 CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI and bills the Medicare Program and other payors for laboratory tests separately under each NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to each NPI in the laboratory organization. You must individually decide whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all 5 laboratories may be under the same TIN, we consider each to be a separate laboratory for purposes of deciding an applicable laboratory because each bills Part B for laboratory tests using its own unique NPI.

Example 2: A laboratory organization includes 5 CLIA-certified laboratories. Each CLIA-certified laboratory has the same NPI and bills for laboratory tests under the same NPI for each of its CLIA-certified laboratories. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI. In other words, for purposes of applying the applicable laboratory thresholds, we consider all 5 CLIA-certified laboratories in the laboratory organization to be a single laboratory because they all bill Part B using the same NPI.

Example 3: A laboratory organization includes 5 CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI. However, only 1 laboratory's NPI is used for billing all laboratory tests provided by all 5 laboratories in the laboratory organization. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing all tests the laboratory organization provides.

Example 4: An entity consists of 5 physician offices and 1 CLIA-certified laboratory. All 5 physician offices and the CLIA-certified laboratory have the same NPI and bill for services under the same NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Part B under the same NPI, we consider the entity to be a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

Continued >>

Example 5: An entity consists of 5 physician offices and 1 CLIA-certified laboratory. Each of the 5 physician offices and the CLIA-certified laboratory have unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold only to the CLIA-certified laboratory's own billing NPI.

Example 6: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI. The hospital outreach laboratory bills Part B for laboratory tests it provides to non-hospital patients using its own unique NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's own unique NPI and not to the hospital's NPI.

Example 7: A hospital includes 3 CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory has the same NPI, separate from the hospital's NPI, and bills Part B separately for laboratory tests under the same NPI for each of its CLIA-certified hospital outreach laboratories. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all CLIA-certified hospital outreach laboratories of the hospital that use the same billing NPI that's separate from the hospital's NPI. For purposes of applying the applicable laboratory thresholds, we consider all 3 CLIA-certified hospital outreach laboratories of the hospital to be a single laboratory because they all bill Part B using the same unique billing NPI.

Example 8: A hospital includes 3 CLIA-certified hospital outreach laboratories. Each CLIA-certified hospital outreach laboratory has its own unique NPI separate from the hospital's NPI. However, the 3 CLIA-certified outreach laboratories use only 1 outreach laboratory's NPI for billing all laboratory tests provided by all 3 hospital outreach laboratories of the hospital. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing all tests provided by the 3 hospital outreach laboratories of the hospital.

Example 9: A hospital includes 3 CLIA-certified hospital outreach laboratories. Only 1 out of the 3 has its own unique NPI separate from the hospital's NPI and bills Part B for laboratory services it performs for non-hospital patients using its own unique NPI. Two out of the 3 hospital outreach laboratories bill for laboratory services they perform for non-hospital patients using the hospital's NPI. In this example, the hospital outreach laboratory that bills Part B under its own unique NPI separate from the hospital's NPI uses the Medicare revenues attributed to its own billing NPI to decide whether it meets the majority of Medicare revenues threshold and low expenditure threshold.

The 2 hospital outreach laboratories that bill for laboratory services performed for non-hospital patients under the hospital's NPI must decide applicable laboratory status based on revenues attributed to the Form CMS-1450 TOB 14x. Below, we give instructions for deciding applicable laboratory status for hospital outreach laboratories that bill Part B using the hospital's NPI.

II. Hospital Outreach Laboratories That Bill Part B under the Hospital's NPI

Similar to the preceding section, in order for hospital outreach laboratories that bill Part B using the hospital's NPI to be an applicable laboratory, the hospital outreach laboratory must be a laboratory based on the CLIA

Continued >>

regulatory definition of a laboratory in 42 CFR 493.2 and meet the majority of Medicare revenues threshold and low expenditure threshold.

However, a hospital outreach laboratory that bills Part B using the hospital's NPI must decide if it meets the majority of Medicare revenues threshold and low expenditure threshold based on revenues attributed to the Form CMS-1450 TOB 14x. In other words, when using CMS Form-1450 TOB 14x for deciding applicable laboratory status, the majority of Medicare revenues threshold and low expenditure threshold only applies to the hospital outreach laboratory portion of the hospital's NPI, rather than to the NPI of the entire hospital.

So, if a CLIA-certified hospital outreach laboratory that bills Part B under the hospital's NPI meets the requirements of an applicable laboratory, we only consider the hospital outreach laboratory to be an applicable laboratory. The hospital laboratory components providing laboratory services to hospital patients aren't part of the applicable laboratory determination.

Majority of Medicare Revenues Threshold

To be an applicable laboratory, a hospital outreach laboratory that bills Part B under the hospital's NPI must meet the majority of Medicare revenues threshold. A hospital outreach laboratory, by its revenues attributed to the Form CMS-1450 TOB 14x, meets the majority of Medicare revenues threshold if it gets more than 50% of its total Medicare revenues from payments under the Medicare CLFS or PFS or both. The CLFS and PFS are under Part B.

To decide whether the hospital outreach laboratory that bills using the hospital's NPI meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from the MAC for the TOB 14x received during the data collection period. See the Applicable Information Section below for more information on the concept of final paid claims.

You use the same 3 steps discussed earlier to decide whether a hospital outreach laboratory that bills Part B under the hospital's NPI meets the majority of Medicare revenues threshold:

1. Sum the CLFS and PFS payment amounts the hospital outreach laboratory gets due to the TOB 14x during the data collection period. The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.

2. Sum the total Medicare revenues the hospital outreach laboratory gets under the TOB 14x during the data collection period.

- Total Medicare revenues include the sum of all FFS payments under Parts A and B, prescription drug payments under Part D, and any associated Medicare patient deductible or coinsurance for services you provided during the data collection period
- The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation
- Effective January 1, 2019, don't include Medicare Advantage plan payments under Part C in the total Medicare revenues component of the majority of Medicare revenues threshold calculation

3. Divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues you got during the data collection period. We provide more information on the data collection period below.

Continued >>

If the Medicare revenues you got from the CLFS and PFS are greater than 50% of the total Medicare revenues you got during the data collection period, you meet the majority of Medicare revenues threshold.

For hospital outreach laboratories that bill Part B under the hospital's NPI, the majority of Medicare revenues threshold equation is:

If:
Medicare CLFS revenues (based on 14x TOB) + Medicare PFS revenues (based on 14x TOB) is >50%
Total Medicare revenues (based on 14x TOB)
Then: The laboratory meets the majority of Medicare revenues threshold.

NOTE: Hospital outreach laboratories that bill Part B under the hospital's NPI, and decide applicable laboratory status based on its Medicare revenues from TOB 14x, will most likely meet the majority of Medicare revenues threshold. This is because their Medicare revenues are primarily, if not entirely, derived from the CLFS and PFS. In other words, the revenues from the CLFS and PFS services included in the numerator are essentially the same as the total Medicare revenues included in the denominator.

Low Expenditure Threshold
To be an applicable laboratory, a hospital outreach laboratory that bills Part B under the hospital's NPI must also meet the low expenditure threshold requirement. A CLIA-certified hospital outreach laboratory meets the low expenditure threshold if, by the Form CMS-1450 TOB 14x, it gets at least $12,500 in Medicare revenues from the CLFS under Part B during the data collection period. To meet the low expenditure threshold, the hospital outreach laboratory must look to its final Medicare paid claims it gets from its MAC under the TOB 14x during the data collection period.

To decide whether the hospital outreach laboratory that bills Part B under the hospital's NPI meets the low expenditure threshold, sum all final payments attributed to the TOB 14x it got from Medicare CLFS services during the data collection period.

It's important to note that the low expenditure threshold applies only to CLFS services. It doesn't include revenues you get under the PFS.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold apply to the CLIA-certified hospital outreach laboratory using the Form CMS-1450 TOB 14x for purposes of deciding whether the hospital outreach laboratory is an applicable laboratory:

Example 1: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients bills Part B using the same NPI as the hospital. In other words, laboratory services you performed for non-hospital patients are billed on the TOB 14x using the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's Medicare revenues it got from the TOB 14x.

Example 2: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI but doesn't use it to bill Part B. Instead, the hospital outreach laboratory continues to bill Part B for laboratory tests it provides to non-hospital

Continued >>

patients using the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to Medicare revenues you got from the TOB 14x. Since you bill laboratory services performed for non-hospital patients using the hospital's NPI. and not the hospital outreach laboratory's own unique billing NPI. apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's Medicare revenues it got from the TOB 14x.

Example 3: A hospital includes 3 CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory bills Part B under the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues attributed to the 14x TOB of all CLIA-certified hospital outreach laboratories of the hospital.

In summary, you must collect and report applicable information. as discussed in the next section. from all applicable laboratories during the data collection period and reported by reporting entities to us during the data reporting period. We use the applicable information you report to establish payment rates under the CLFS. All CLIA-certified laboratories. both applicable laboratories and laboratories that aren't applicable laboratories. are subject to the Part B private payor rate-based CLFS.

Applicable Information

The applicable laboratory along with its reporting entity are responsible for collecting applicable information and reporting that data to us. We provide more information about reporting entities below.

Applicable information includes 3 major components:

- The specific HCPCS code associated with the test
- The private payor rate for each test for which final payment has been made during the data collection period
- The associated volume for each test

Private Payor Defined

The definition of the term "private payor" is 1 of the following:

- A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act
- A group health plan as defined in Section 2791(a)(1) of the PHS Act
- A Medicare Advantage plan under Part C as defined in Section 1859(b)(1) of the Act https://www.ssa.gov/OP_Home/ssact/title18/1859.htm
- A Medicaid Managed Care Organization (MCO) as defined in Section 1903(m) of the Act https://www.ssa.gov/OP_Home/ssact/title19/1903.htm

Note: Applicable information doesn't include information on tests for which we make payment on a capitated basis, where payments don't reflect specific HCPCS code-level amounts. (See below for more information on payments made on a capitated basis.) So, we consider private payor rates from Medicaid MCO plans applicable information only to the extent that you can identify an individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test.

We include these specific private payor claims data as applicable information:

- **Laboratory tests subject to the data collection and reporting requirements.** Applicable information includes the specific HCPCS code for the test, each different private payor rate for the test, and the volume associated with each private payor rate for the test. There's a list of laboratory tests

Continued >>

https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs subject to the data collection and data reporting requirements. At that site, select: CLFS Applicable Information HCPCS Codes https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Applicable-Information-HCPCS-Codes.zip [ZIP, 57KB].

- **Final amount paid by a private payor for laboratory tests after applying all private payor price concessions.** A final paid claim is the final amount a private payor paid for a laboratory test during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection period change that initial payment amount, the final payment is the private payor rate for purposes of deciding applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then the initial claim is corrected, with final payment made by the private payor during the data collection period, consider the final corrected payment amount for the test as the private payor rate for purposes of deciding applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final payment made after the data collection period, the payment amount isn't a private payor rate for purposes of applicable information, and you don't report it to us.
- **Payments from secondary insurance payors.** We consider final payments from secondary insurance payors in calculating private payor rates if the final payment was made during the data collection period. The private payor rate is 100% of the primary private payor's fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities the primary private payor requires, such as patient deductible and coinsurance amounts, and any payments gotten from a secondary insurer, if applicable. The important concept here is the reporting entity reports 100% of the primary private payors' fee schedule amount for the laboratory test. Don't report payments you get from secondary insurers separately.
- **Any patient cost sharing amounts, if applicable.** For purposes of applicable information, the private payor rate for a test should include any patient cost sharing responsibilities the private payor requires, such as patient deductible or coinsurance amounts. As noted above, the private payor rate is 100% of the private payor's fee schedule amount for the test.
- **Multiple payment rates for the same test.** If an applicable laboratory gets more than 1 payment rate from the same private payor for the same test or more than 1 payment rate from different private payors for the same test, include each unique payment rate along with the associated volume for the test code at each such rate as applicable information.
- **Appeals resolved during the data collection period**. Include payment rates and the associated volume of tests for claims under appeal as applicable information if the private payor decides and pays the final payment amount during the data collection period. For example, if a laboratory filed an appeal for a test it provided before a data collection period and resolved the appeal so that it made final payment for the test during the data collection period, consider the final rate paid as applicable information.
- **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories if the private payor made final payment for the laboratory test during the data collection period. Non-contracted amounts paid to laboratories include any patient cost sharing amounts . for example, deductible and coinsurance responsibilities, if applicable.

Continued >>

Exclude these specific private payor claims data from applicable information:

- **Private payor rates for laboratory test codes paid only under the PFS.** If payment for a laboratory test code isn't paid under the CLFS and is paid under the PFS, the test code, private payor rate, and the test volume associated with the private payor rate isn't applicable information.
- **Price concessions applied by a laboratory.** Don't factor a laboratory's decision to waive a patient's deductible, copay, or coinsurance responsibility for given tests into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it doesn't reflect the rates paid by private payors. As noted above, the private payor rate is 100% of the private payor's fee schedule amount for the test.
- **Information about denied payments.** When a private payor denies payment for a laboratory test, don't consider payments of $0.00 a private payor rate for purposes of deciding applicable information under the new CLFS. Report only the final paid claim amount and the associated volume of tests paid at the final paid claim amount.
- **Unresolved appeals.** Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount already paid isn't considered a final payment rate and so isn't considered applicable information. If the appeal was settled during the data collection period but the private payor didn't make final payment until after the data collection period, the payment amount can't be used for a private payor rate and so is excluded from applicable information.
- **Payments made on a capitated basis.** Generally, a capitated payment is made for health care services based on a set amount for each enrolled patient in the plan for a given period, regardless of whether the patient gets services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there's no way to decide payment specifically for a given test, don't report it as applicable information.
- **Payments where you can't decide the associated test volume.** As discussed above, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate can't be discerned by a laboratory from the private payor's remittance, we don't consider those payment amounts as applicable information. Don't report them to us.
- **Remittances where the payor has grouped individual HCPCS code payments into an encounter or claim level payment.** When a private payor groups payments for individual HCPCS codes into a single encounter or claim-level payment that isn't represented by another HCPCS code, those payments aren't applicable information.

Note: In general, if a laboratory can't correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount isn't a private payor rate for purposes of applicable information. Estimated private payor rates and volumes aren't considered applicable information.

Schedule for Data Collection & Reporting

The most recent data collection period . the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory got final payment during the period . was from January 1, 2019 - June 30, 2019. Typically, there's a 6-month review and validation period.

During the review and validation period between the end of the data collection period and the start of the data reporting period, you should assess whether you met the applicable laboratory thresholds. In other words,

Continued >>

decide whether each laboratory component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims they got during the data collection period. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information (private payor data) before reporting it to us.

Section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 further delayed the reporting requirement under Section 1834A of the Act. In summary, the revisions are:

- We'll base the next data reporting period of January 1, 2025 - March 31, 2025, on the original data collection period of January 1, 2019 - June 30, 2019. After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs (2028,2031, and so on).

Table 1 shows the next data collection and reporting periods for CDLTs.

Table 1: Data Collection and Reporting Periods for CDLTs

Data Collection Period	Six-Month Review and Validation Period	Data Reporting Period	Used for CLFS Rate Years
01/01/2019 -06/30/2019	07/01/2019 -12/31/2019	01/01/2025 - 03/31/2025	2026-2028
01/01/2027 -06/30/2027	07/01/2027 -12/31/2027	01/01/2028 -03/31/2028	2029-2031
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

While we require reporting every 3 years for CDLTs that aren't ADLTs, reporting entities must report applicable information annually for ADLTs, except for ADLTs in an initial data collection period . in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period. We've issued more information about ADLTs through separate instructions.

Online Data Collection System

We developed an online data collection system to help laboratories submit data to us. Data is due by March 31, 2025. Review the detailed user guide on how to access and use this system. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Data-Collection-System-User-Guide.pdf

You must appoint both a CLFS submitter and CLFS certifier in the data collection system. These must be 2 different individuals.

A data collection template is available for your use. Laboratories looking to upload their data to the CLFS data collection system should use this template. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Data-Collection-Form.zip

Tips for Smooth Data Submissions:

- Follow the formatting guidelines in the user guide and on the data collection template. The CLFS data collection system will find formatting errors in your file before you're able to certify the data and submit

Continued >>

it. For large volumes of data, this process may take several hours to confirm. Files with fewer formatting errors will process more efficiently.
- Use the available CLFS Applicable Information HCPCS Codes file. The system will only accept HCPCS codes listed on this file. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Applicable-Information-HCPCS-Codes.zip
- The cleaner the file, the smoother the upload process.

Important information for large laboratories: If your laboratory expects to submit over 100,000 lines of data in the .csv template, first contact the CMS/CLFS helpdesk at clfshelpdesk@dcca.com.

Reporting Entity

The TIN-level entity reports applicable information individually for all its laboratory components that are applicable laboratories. As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI or the 14x TOB. in the case of a hospital outreach laboratory that bills Part B under the hospital's NPI. meets the majority of Medicare revenues threshold and low expenditure threshold. We discuss a condensed data reporting option later in this section.

I. Reporting for an Applicable Laboratory That Bills Part B Under its Own NPI

This section provides examples of reporting entities reporting applicable information for independent laboratories and physician office laboratories that bill Part B under their own NPI and hospital outreach laboratories that bill Part B under their own NPI separate from the hospital's NPI. The examples below show reporting entities that must report applicable information individually for all NPI-level components that are applicable laboratories:

Example 1: A TIN-level entity consists of 5 CLIA-certified laboratories. Each laboratory bills using its own unique NPI and all 5 CLIA-certified laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 5 unique applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that's an applicable laboratory, not collectively for all NPIs that are applicable laboratories under the TIN. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for 5 applicable laboratories.

Example 2: A TIN-level entity consists of 5 CLIA-certified laboratories, each billing for services under its own unique NPI. However, only 3 of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining 2 laboratories don't individually meet the low expenditure threshold. In other words, 2 of the 5 CLIA-certified laboratories get less than $12,500 of revenue under the CLFS during the data collection period. This TIN-level entity consists of 3 unique applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that's an applicable laboratory, but won't report information on the 2 individual NPIs of the laboratories that aren't applicable laboratories. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for 3 applicable laboratories.

Example 3: A TIN-level entity consists of 5 CLIA-certified laboratories, and each laboratory has the same NPI and bills Part B under the same NPI. Collectively, the 5 CLIA-certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 1 applicable

Continued >>

laboratory. In this case, the reporting entity reports applicable information for all laboratories associated with the same NPI as a single applicable laboratory. In this example, we consider the 5 CLIA-certified laboratories as 1 applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Part B under the same NPI.

Example 4: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories. Each hospital outreach laboratory bills using its own unique NPI, separate from the hospital's NPI, and all 3 CLIA-certified hospital outreach laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 3 applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that's an applicable laboratory, not collectively for all NPIs that are applicable laboratories under the TIN. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for 3 applicable laboratories.

Example 5: A TIN-level entity consists of 3 CLIA-certified hospital outreach laboratories, each billing for services under its own unique NPI, separate from the hospital's NPI. However, only 2 of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold, while the remaining laboratory doesn't individually meet the low expenditure threshold. In other words, 1 of the 3 CLIA-certified hospital outreach laboratories gets less than $12,500 in revenues from the CLFS during the data collection period. This TIN-level entity consists of 2 applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that's an applicable laboratory, but won't report information on the 1 individual NPI of the laboratory that isn't an applicable laboratory. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for 2 applicable laboratories.

Example 6: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories and all 3 laboratories have the same unique NPI and bill Part B under the same unique NPI, separate from the hospital's NPI. Collectively, the 3 CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 1 applicable laboratory. In this case, the reporting entity reports applicable information for all 3 hospital outreach laboratories associated with the same NPI as a single applicable laboratory. In this example, we consider the 3 CLIA-certified hospital outreach laboratories as 1 applicable laboratory for purposes of reporting applicable information because they all have the same NPI separate from the hospital's NPI and all bill Part B under the same NPI.

Note: For a hospital outreach laboratory that bills Part B under its own unique billing NPI separate from the hospital's NPI, the reporting entity reports applicable information by the hospital outreach laboratory's own unique billing NPI.

II. Reporting for Hospital Outreach Laboratories that Bill Part B Under the Hospital's NPI

This section provides examples of reporting entities reporting applicable information for hospital outreach laboratories that bill Part B under the hospital's NPI. The examples below show reporting entities that must report applicable information for hospital outreach laboratories that bill Part B under the hospital's NPI that are applicable laboratories:

Continued >>

Example 1: A TIN-level entity includes a CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients and bills Part B using the hospital's NPI. Based on its Medicare revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold and so is an applicable laboratory. In this example, the reporting entity reports applicable information for its hospital outreach laboratory that bills Part B under the hospital's NPI.

Example 2: A TIN-level entity consists of 3 CLIA-certified hospital outreach laboratories and each laboratory bills Part B under the hospital's NPI. Collectively, the 3 CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 1 applicable laboratory. In this example, the reporting entity collectively reports applicable information for its 3 hospital outreach laboratories that bill Part B under the hospital's NPI.

Example 3: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories. Two of the 3 hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital's NPI. Collectively, the 2 CLIA-certified hospital outreach laboratories that bill using the hospital's NPI meet the majority of Medicare revenues threshold and low expenditure threshold. However, 1 out of the 3 bills Part B for laboratory services performed for non-hospital patients using its own unique NPI separate from the hospital's NPI and meets the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 2 applicable laboratories. In this example, the reporting entity reports applicable information for the hospital outreach laboratories that bill Part B for non-hospital patients under the hospital's NPI separately from the hospital outreach laboratory that bills Part B under its own unique NPI.

Note: You must report applicable information for hospital outreach laboratories that are applicable laboratories based on the NPI used for billing Part B. For hospital outreach laboratories that bill Part B under the hospital's NPI, and so decides applicable laboratory status based on its Medicare revenues attributed to the 14x TOB, the reporting entity reports applicable information by the hospital's NPI.

Only Applicable Information Attributed to Non-Hospital Patients is Reported

As discussed previously in this Article, a CLIA-certified hospital outreach laboratory that bills Part B using the hospital's NPI must decide whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on its Medicare revenues attributed to the Form CMS-1450 14x TOB. If a CLIA-certified hospital outreach laboratory that bills Part B under the hospital's NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory . laboratory tests provided to non-hospital patients . is considered an applicable laboratory. So, report only applicable information attributed to the laboratory's non-hospital patients to us.

The reporting entity for the hospital outreach laboratory that bills Part B under the hospital's NPI, and finds applicable laboratory status based on Medicare revenues attributed to the 14x TOB, may not report applicable information for other parts of a hospital's laboratory business such as testing performed for hospital outpatients or inpatients.

Continued >>

III. Additional Reporting Instructions That Apply to All Applicable Laboratories

This section provides additional reporting instructions for reporting entities reporting applicable information for its component applicable laboratories.

Reporting Entity Must Ensure Accurate Collection and Reporting of Applicable Information

The TIN-level entity along with its applicable laboratories should establish their own approach for making sure the TIN-level entity can report applicable information. To that end, applicable laboratories and their reporting entity should decide the best approach to collect applicable information from final paid claims data and for submitting applicable information to us during the data reporting period.

Voluntary Reporting isn't Permitted

The reporting entity reports only applicable information for laboratory components that meet the definition of an applicable laboratory. Don't report applicable information for laboratories that don't meet the definition of an applicable laboratory.

Example 1: A TIN-level entity consists of 4 NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and 1 NPI-level entity doesn't. In this example, the reporting entity reports applicable information for only the 3 NPI-level entities that are applicable laboratories.

Example 2: A TIN-level entity includes 1 hospital outreach laboratory that bills Part B under the hospital's NPI. Based on revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold but doesn't meet the low expenditure threshold. The hospital outreach laboratory doesn't get at least $12,500 in revenues from the Medicare CLFS during the data collection period. So, the hospital outreach laboratory doesn't meet the definition of an applicable laboratory. Don't report applicable information to us for the hospital outreach laboratory.

Reporting Applicable Information isn't Discretionary

Reporting entities must report all applicable information for its laboratory components that are applicable laboratories. You don't have the discretion to selectively omit reporting certain applicable information.

Example: An applicable laboratory has various final paid claims for laboratory tests from the data collection period that are only in hard copy paper format. The reporting entity along with its applicable laboratory perceives that reporting applicable information derived from the paper claims has minimal impact on the final payment rate calculated for the tests. In this case, the reporting entity can't selectively omit reporting applicable information due to the perception that reporting such applicable information won't influence the final weighted median private payor rates for a given test. In this example, you must report the applicable information obtained from the paper-based claims to us during the data reporting period.

IV. Condensed Data Reporting Option

For the next data reporting period, January 1, 2025 - March 31, 2025 (previously scheduled for January 1, 2024 - March 31, 2024), reporting entities may condense certain applicable information at the TIN level, instead of reporting individually for each component that's an applicable laboratory. You may use the condensed data reporting option when more than 1 applicable laboratory under the TIN is paid at the same private payor rate for a specific HCPCS code.

Continued >>

For example, if 3 of the reporting entity's corresponding applicable laboratories get the same private payor rate for a specific HCPCS code, the reporting entity may report 1 record of data showing the HCPCS code, the payment rate, and the associated volume, across the 3 applicable laboratories, rather than reporting 3 separate records. In other words, the reporting entity may combine the volume paid at the same private payor rate for the same HCPCS code for its component applicable laboratories.

Under the condensed data reporting option, the reporting entity must select 1 NPI as the reporting NPI. That means the reporting entity will designate 1 applicable laboratory's NPI as the reporting NPI for each instance of condensed reporting. The reporting entity can select any NPI under the TIN that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI for reporting the condensed applicable information.

You must report each unique private payor rate for each laboratory test code to us during the data reporting period. You may only use the condensed data reporting option when a specific laboratory test code is paid at the same private payor rate to more than 1 applicable laboratory under the same TIN. Unique private payor rates paid to only 1 applicable laboratory under the TIN, and the volume paid at such rates, must be reported individually by the applicable laboratory.

Reporting entities have the option of condensing the volume paid at the same private payor rate for a specific HCPCS code during a data collection period across its components that are applicable laboratories. However, if the reporting entity prefers to report applicable information individually for each of its component applicable laboratories, they may continue to do so.

To show how reporting entities may report condensed applicable information when 3 different applicable laboratories under the same TIN get the same private payor rate for the same laboratory test code during a data collection period, see the comparative examples below in Tables 2a and 2b. These examples are meant to show the difference between the individual applicable laboratory data reporting method, by each component that's an applicable laboratory, and the condensed data reporting method and aren't intended to be representative of every possible scenario.

TABLE 2a: Example of Individual Applicable Laboratory Reporting for 2025 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
2	Lab Test Code (1)	$15.00	300
3	Lab Test Code (1)	$15.00	200

In this example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid the same private payor rate for "Lab Test Code 1." So, the reporting entity reports applicable information individually for each of its component applicable laboratories.

TABLE 2b: Example of Condensed Reporting for 2025 Data Submission (TIN Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume

Continued >>

Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900

This example shows how the scenario presented in Table 2a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN Level). The reporting entity designates 1 of its 3 component applicable laboratories as the reporting NPI.

TABLE 3a: Example of Individual Applicable Laboratory Reporting for 2025 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
1	Lab Test Code (1)	$17.00	100
2	Lab Test Code (1)	$15.00	300
2	Lab Test Code (1)	$17.00	150
3	Lab Test Code (1)	$15.00	200
3	Lab Test Code (1)	$17.00	75

In this Table 3a example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid a private payor rate of $15 for "Lab Test Code 1," and the same 3 applicable laboratories are also paid a private payor rate of $17 for "Lab Test Code 1." In this example, the reporting entity reports each HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 3b: Example of Condensed Reporting for 2025 Data Submission (TIN Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900
Designated NPI for Condensed Reporting	Lab Test Code (1)	$17.00	325

This Table 3b example shows how the scenario presented in Table 3a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN Level). The private payor rate of $15 and associated volume is combined, and the private payor rate of $17 and associated volume is combined.

Continued >>

TABLE 4a: Example of Individual Applicable Laboratory Reporting for 2025 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
1	Lab Test Code (1)	$17.00	100
1	Lab Test Code (1)	$18.50	50
2	Lab Test Code (1)	$15.00	300
2	Lab Test Code (1)	$17.00	150
2	Lab Test Code (1)	$19.50	40
3	Lab Test Code (1)	$15.00	200
3	Lab Test Code (1)	$17.00	75
3	Lab Test Code (1)	$20.00	30

In this Table 4a example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid a private payor rate of $15 for "Lab Test Code 1," and the same 3 applicable laboratories are also paid a private payor rate of $17 for "Lab Test Code 1." Also, 1 of the 3 applicable laboratories is paid a private payor rate of $18.50, another applicable laboratory is paid a private payor rate of $19.50, and another applicable laboratory is paid a private payor rate of $20 for "Lab Test Code 1." The reporting entity reports the HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 4b: Example of Condensed Reporting for 2025 Data Submission (TIN Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900
Designated NPI for Condensed Reporting	Lab Test Code (1)	$17.00	325
1	Lab Test Code (1)	$18.50	50
2	Lab Test Code (1)	$19.50	40
3	Lab Test Code (1)	$20.00	30

This Table 4b example shows how the scenario presented in Table 4a would be reported under the condensed data reporting method. As discussed previously, the reporting entity must report each unique private payor rate for each specific HCPCS code, and the associated volume paid at each such rate. Since some private payor rates are paid to only 1 applicable laboratory under the TIN, a combination of the condensed data reporting method and individual applicable laboratory reporting is used to report applicable information.

The condensed data reporting method may be used when more than 1 applicable laboratory under the TIN is paid the same private payor rate for a specific laboratory test code. In this example, the volume among the 3 applicable laboratories for the private payor rate of $15 may be combined, and the volume among the 3 applicable laboratories for the private payor rate of $17 may be combined.

However, condensed reporting wouldn't be permitted for the unique private payor rates for "Lab Test Code 1" that are paid to only 1 applicable laboratory under the same TIN. So, the private payor rate of $18.50 paid to

Continued >>

"NPI 1," the private payor rate of $19.50 paid to "NPI 2," the private payor rate of $20 paid to "NPI 3," and the associated volume paid at each of these unique private payor rates must be reported individually for each applicable laboratory.

More Information

See more information https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs about the private payor rate-based payment system including a summary of the private payor rate-based CLFS, the CLFS final rule, related press release and fact sheet, frequently asked questions on our final policies, and a PowerPoint slide presentation of the private payor rate-based CLFS and ADLTs.

See the CLFS Reporting webpage https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-reporting for future implementation updates regarding data collection, data reporting, and other related information.

See the CLFS final rule https://www.govinfo.gov/content/pkg/FR-2016-06-23/pdf/2016-14531.pdf entitled Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) and the PFS final rule https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F).

If you have questions about requirements for the private payor rate-based CLFS, send an email to the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov.

For more information, find your MAC's website. https://www.cms.gov/MAC-info

Document History

Date of Change	Description
December 4, 2023	We revised this Article to note that for CDLTs that aren't ADLTs, the data reporting is delayed and resumes starting January 1, 2025 - March 31, 2025. Also, we extended the 0% limit on laboratory payment reductions to the end of CY 2024 and the 15% limit on payment reductions per year to CY 2025 - 2027 (see pages 2, 14, 15, and 20-24).
March 24, 2022	We revised this Article to note that for CDLTs that aren't ADLTs, the data reporting is delayed by 1 year and must now be reported from January 1, 2023-March 31, 2023 (previously January 1, 2022-March 31, 2022). All references to the 2021 data reporting period have been changed to 2023. You'll find substantive content updates in dark red font (see pages 2,14,15 and 20-23). There are no other changes to the substance of the Article.

Continued >>

November 4, 2021	We revised this Article to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1, 2022 through March 31, 2022 (previously January 1, 2021 through March 31, 2021). All references to the 2021 data reporting period have been changed to 2022. In addition, we included information about the Online Data Collection System. You'll find substantive content updates in dark red font (see pages 2, 3,13-15 and 21-23). There are no other changes to the substance of the Article.
January 8, 2020	We revised this Article to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1, 2021 through March 31, 2021 (previously January 1, 2020 through March 31, 2020). All references to the 2020 data reporting period have been changed to 2021. We added the "CLFS Data Reporting Period Delayed" Section on page 24 to summarize the changes. All other information remains the same.
September 5, 2019	We revised this Article to delete incorrect information in the section titled Only Applicable Information Attributed to non-Hospital Patients is Reported, which is on page 18. All other information remains the same.
February 27, 2019	Initial Article released

View the Medicare Learning Network® Content Disclaimer and Department of Health & Human Services Disclosure.
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Product-Disclaimer

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 November 22, 2023
https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-11-22-mlnc

MLN Connects™ for Thursday, November 30, 2023
https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-11-30-mlnc

MLN Connects™ for Thursday, December 7, 2023
https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-12-07-mlnc

MLN Connects™ for Thursday, December 14, 2023
https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-12-14-mlnc

MLN Connects™ for Thursday, December 21, 2023
https://www.cms.gov/training-education/medicare-learning-network/newsletter/2023-12-21-mlnc

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 articles, educational tools, booklets, fact sheets, web-based training courses (many of which offer continuing education credits) – all available to you free of charge!

You can find links to the following resources on the CMS MLN web page at:
https://www.cms.gov/Medicare-Learning-Network/MLN

- Publications & Multimedia
- Web-Based Training
- MLN Matters® Articles
- MLN Connects® Newsletter
- Provider Compliance

MLN Connects Newsletter
Subscribe to the MLN Connects weekly email newsletter for all national Fee-for-Service (FFS) program news, including MLN Matters Article and MLN product updates.

To subscribe to the service:
1. Go to https://public.govdelivery.com/accounts/USCMS/subscriber/new?pop=t&topic_id=USCMS_7819. Enter you email address and select Submit.
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.

Get Your Railroad Medicare News Electronically

Register now to receive customized daily or weekly emails on the latest Medicare news and Palmetto GBA features.

How to register to receive Palmetto GBA Railroad Medicare email updates:
Subscribing to our email updates is quick, easy and free! Go to https://tinyurl.com/RailroadMedicareEmailUpdates. Enter your email address and select the topics you are interested in receiving updates about. Complete the CAPTCHA equation and submit.

Note: After you click "Submit", a confirmation email will be sent to your email address. Please use the link provided in the email to confirm your registration.

PTAN Lookup and Request Tool

Want to verify if you have a Railroad Medicare Provider Transaction Access Number (PTAN)? Need to request a Railroad Medicare PTAN for new provider? You can do both through our "PTAN Lookup and Request Tool" at https://www.PalmettoGBA.com/RR/PTAN. This tool first validates the provider identification information you enter — local Part B MAC PTAN, National Provider Identifier (NPI) and Tax Identification Number (TIN) — against enrollment information in our files. If a match is found, the tool retrieves and releases the Railroad Medicare PTAN. If a match is not found, the tool gives providers the option to request a new Railroad Medicare 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/rr.nsf/DID/AK7K447304
- Railroad Medicare PTAN Lookup and Request Tool FAQs https://www.palmettogba.com/palmetto/rr.nsf/DID/KB6799Q6E8

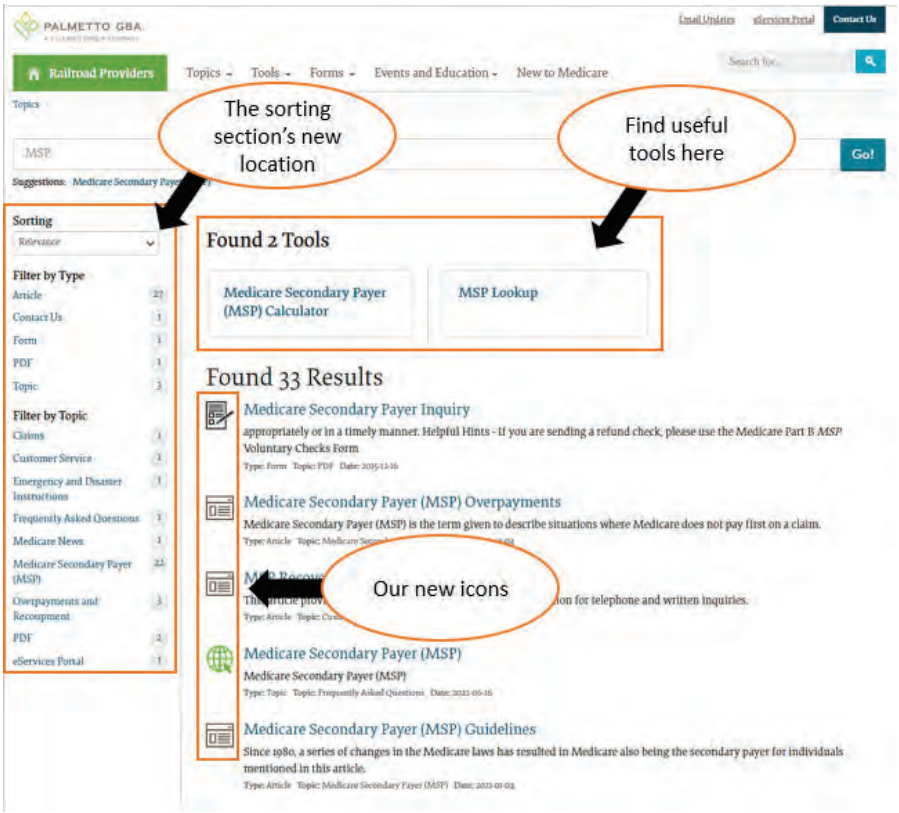
We Made Exciting Changes to Your Search Experience

Palmetto GBA is pleased to announce improvements to our website's search engine. While the function and location of our search tool will remain the same, we have added features to make the search experience more intuitive. These include:

- Our sorting section is migrating from the right-hand to the left-hand side of the screen. The section itself is also revamped to make it easier to locate the information you need.
- We have created new, user-friendly icons to help you quickly navigate search results
- Useful results and tools are now shown at the top of the page, making locating these features less of a hassle

These enhancements were made with you in mind. Palmetto GBA strives to improve the customer experience based on the feedback we receive from our providers.

Our new look is below:



Keep Your Railroad Medicare Enrollment Record Up to Date

As a Medicare provider, you are responsible for notifying Medicare of changes to the information in your Medicare enrollment record, including provider name and address changes. Incorrect information in your enrollment file could lead to claim rejections or correspondence being delivered to an incorrect address.

Railroad Medicare does not automatically receive updates you make to your enrollment record with your Part B Medicare Administrative Contractor (MAC). Please notify Railroad Medicare promptly of any enrollment changes once those changes have been made by your Part B MAC.

Types of Enrollment Changes to Report to Railroad Medicare include:

- Provider name changes
- Practice name changes
- Billing address changes
- Practice address changes
- Practice location added (only if the additional practice location is in a different contractor locality, or you have been assigned a new NPI for the location)
- Provider has retired
- Provider has left group

Railroad Medicare cannot accept enrollment changes by telephone. You can find instructions for faxing or mailing enrollment changes to Railroad Medicare on our Provider Enrollment Update an Enrollment Record webpage at https://www.palmettogba.com/palmetto/rr.nsf/DID/H4AZXTC6NU.

Using ePass 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.

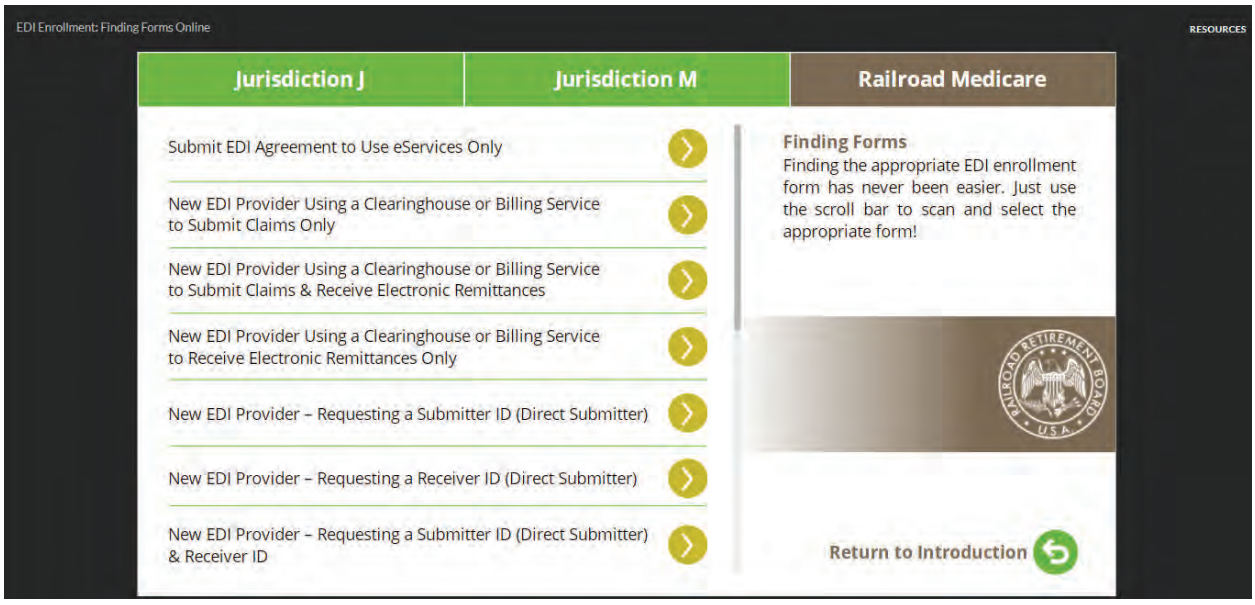
The goal of the ePass is to ease provider burden by eliminating the need to repeatedly authenticate the same provider each time you contact the IVR in a given day.

We hope this service will be effective and helpful to you.

Electronic Data Interchange (EDI) Enrollment: Help Completing Online Forms

Did you know Palmetto GBA offers online enrollment to our Electronic Data Interchange (EDI)? The EDI Online Enrollment Tool allows you to submit the EDI enrollment forms electronically online. Once the forms have been completed, you will receive a tracking number. This tracking number can be used to check the status of your request using our EDI Request for Enrollment Status Tool. Please allow 15 days for processing before checking status.

Our new EDI Enrollment: Finding Forms Online interactive tool provides a quick shortcut to all of the forms you need for enrollment. To get started on the tool, choose the Railroad Medicare tab. Then choose from the list of actions. Click on the yellow arrow icon to see a list of the answers you will need to select on the EDI Online Enrollment Tool for the action selected.



Continued >>

If you need additional assistance completing EDI enrollment, Palmetto GBA has dedicated representatives available to provide technical assistance and answer questions about EDI. 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 EDI representative, select option 2 from the main menu for EDI/eServices. Then select option 0 for technical assistance with electronic billing, electronic remittance advice (ERA) and other EDI issues.

EDI representatives are also available to chat when the green "Chat Now" icon is visible in the lower right corner of an EDI resource webpage.

EDI Online Enrollment Tool -
https://www.palmettogba.com/internet/PCIDN.nsf/R?OpenAgent&DID=BXEPDW14&url=yes

EDI Enrollment: Finding Forms Online Tool –
https://www.palmettogba.com/internet/PCIDN.nsf/R?OpenAgent&DID=C7QGRA26&url=yes

EDI Request for Enrollment Status Tool –
https://www.palmettogba.com/internet/PCIDN.nsf/R?OpenAgent&DID=BBJQE954&url=yes&v3=yes

Online Options for Researching, Refunding and Requesting Offsets of Overpayments

Need information about an overpayment? Looking for an alternative to sending an overpayment refund by check? Use our eServices Financial Tools!

Our Overpayment Data function allows you to check for overpayment balances, adjustment details, collections, and recoupments online. To show you how beneficial this tool is, we are providing you with a short video walkthrough of the benefits and features of our Overpayment Data function. We hope you enjoy this visual and see how a small part of eServices can be of great service to you. You can find the video demo here: https://palmettogba.com/palmetto/rr.nsf/DID/7GZUWJTJTI.

In addition to researching your overpayments online, you can use the following eServices Financial Forms:

- Use the eServices eCheck function to send payments electronically via ACH to Palmetto GBA
- Use the eOffset function to request an immediate offset when you receive a demanded overpayment or make a permanent request for all future demanded overpayments

You can find details about using these helpful Financial Tools in the eServices User Manual at http://www.palmettogba.com/eservicesuserguide.

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!

With the resumption of Targeted Probe and Educate (TPE) reviews on September 1, 2021, providers with an active eServices account will automatically receive their TPE notification letters, TPE ADR letters and TPE review results letters via eDelivery.

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.

eServices: Part B Claims Features Enhancements

Palmetto GBA is pleased to announce we have implemented several enhancements to our Part B claims features within our eServices portal. These updates are designed to make searching for claims information easier and to enhance your online experience.

Dates of Service No Longer Required for Part B Claim Search
You will be able to search for claims using the Medicare ID (MBI) without having to enter any dates of service. The dates of services fields will still appear but are no longer required and will display as an optional function.

- If you search with the Medicare ID and leave the dates of service blank, all claims under that ID over the past three years will be returned. This could be particularly helpful if you treat patients for a long period of time (e.g., psychiatrists)

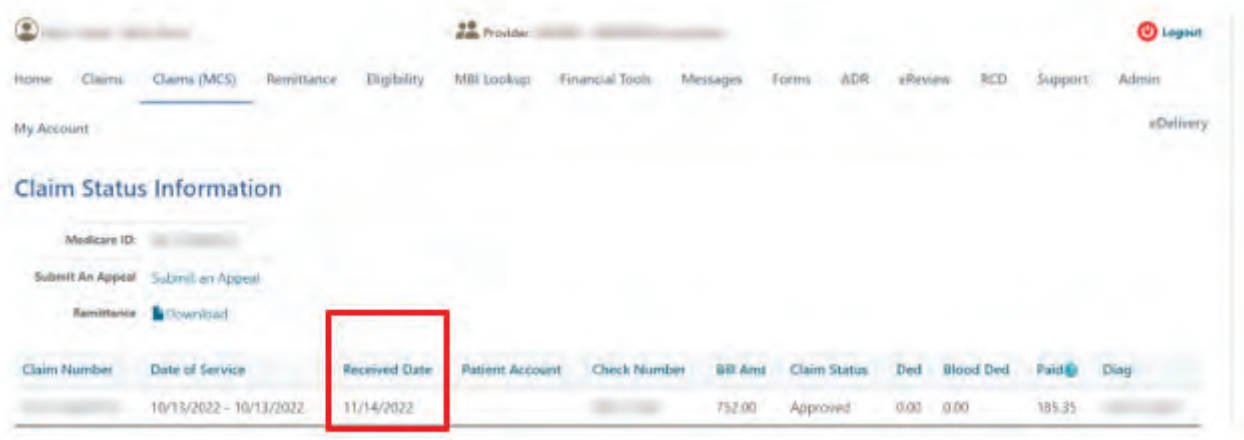
Note: When searching without a date span, you will need to search to find specific claims.

Part B Claim Inquiry Results
You will now have access to additional claims information on the claims summary results page. This enhancement will allow you to see more claims status information in one place, reducing the amount of clicks needed to view additional claim status items. Enhancements include:

- New fields added to the claim **summary results** page
  - Paid Amount
  - Check Number
  - Paid Date
- The ability to sort columns on the claim summary results page

Continued >>

- New field added to the **claim detail** page: Receipt Date



Part B Cash Flow Snapshot: Additional Payment Information Available
You will now be able to see additional payment information when viewing the Cash Flow Snapshot screen. Enhancements include the ability to view payments made during the last 30 days. The list of payments will now include:

- Check Number
- Amount
- Status
- Issue Date

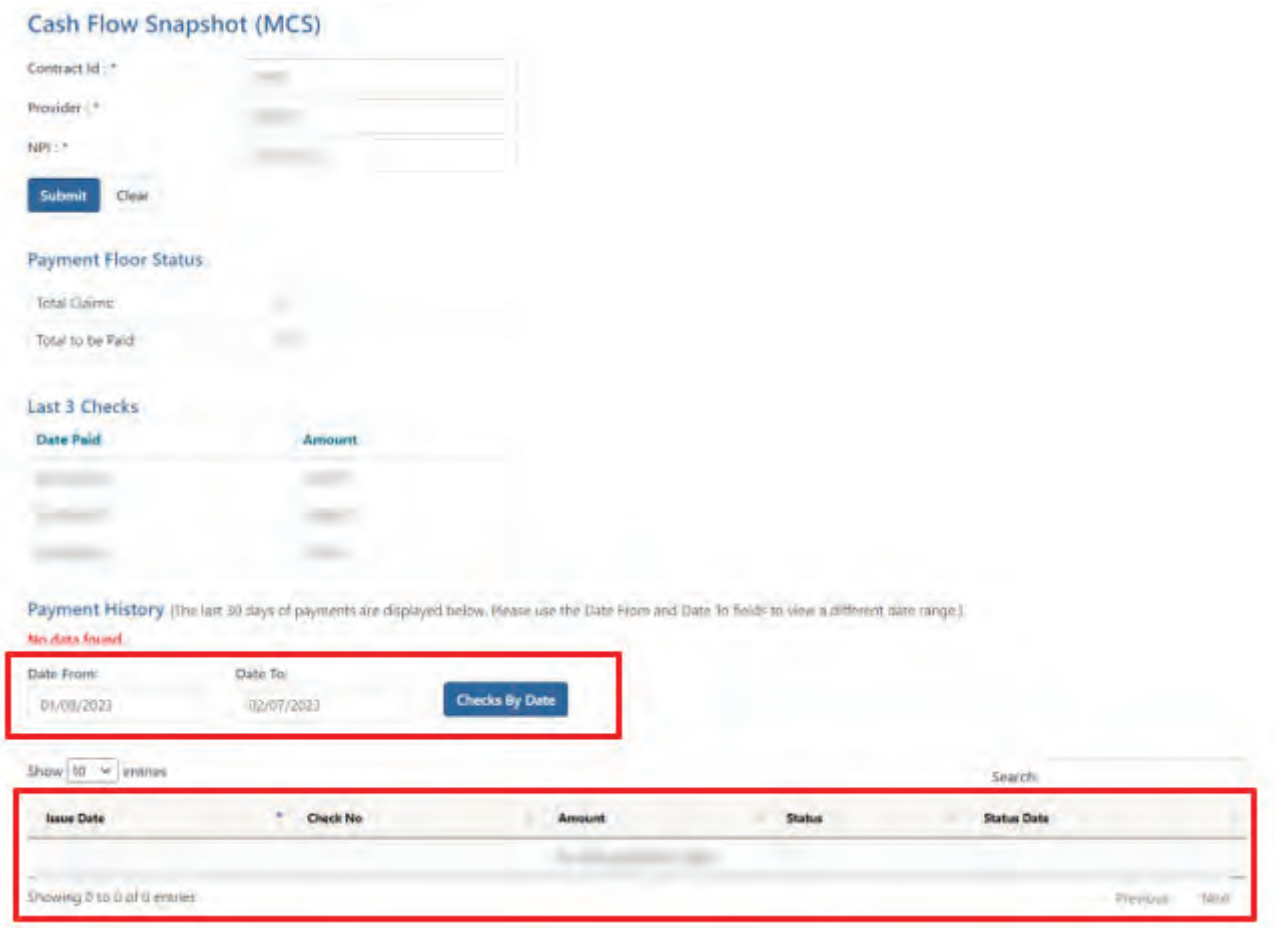
Note: You will have the option to search for other date ranges by entering the "From" and "To" dates.

Accessing Your Financial Information

- Select the **Financial Tools** tab. The "Cash Flow Snapshot MCS" link will display. Enter:
  - Contract ID
  - Provider Number/PTAN
  - NPI

Continued >>

- Click **Submit** to populate information



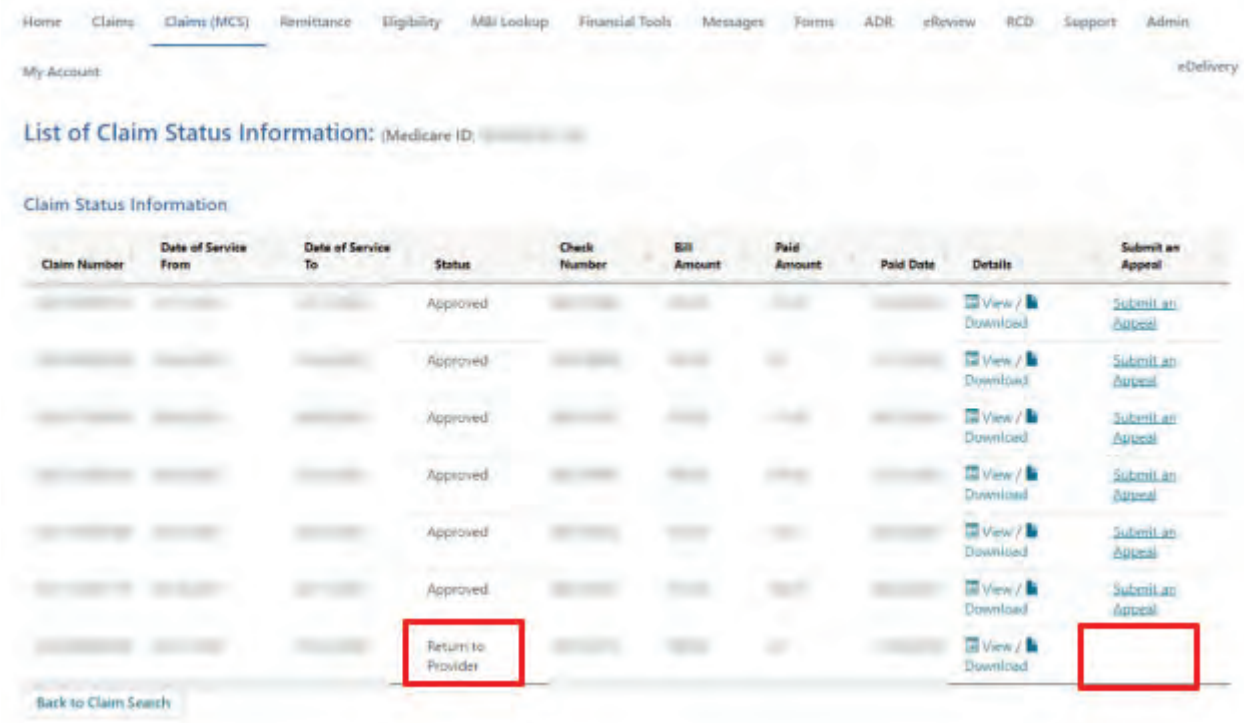
Claims Tab: Appeals Enhancement

We have made several changes to the appeals (redeterminations) option within the eServices claims feature.

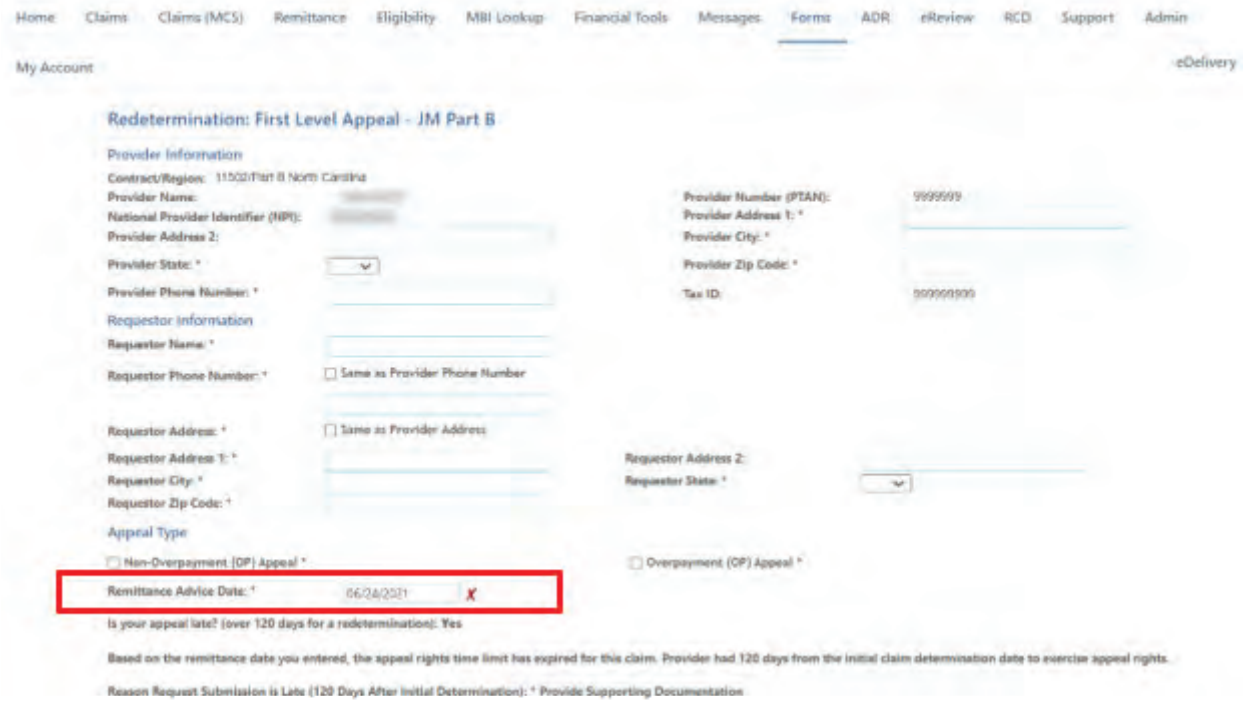
- The option to submit an appeal **will not** display on the claim inquiry function if a claim has a status of «**rejected" (Example 1)**
  - This enhancement prevents you from submitting an appeal on a claim that can't be appealed. The field will remain blank.
- If you navigate from the claim function to the redetermination form, the remittance date will be pre-populated to save you time from entering it **(Example 2)**

Continued >>

Example 1



Example 2



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

Tell Us What You Think of Our Service

If your experience with Railroad Medicare was awesome or not, we'd like to hear from you! Telling us what we do well lets us know what we should keep doing, and telling us how we can improve gives us room to grow.

All Railroad Medicare Providers and their staff can give immediate feedback about their customer experience by completing the MAC Customer Experience (MCE) surveys.

To provide feedback for the Palmetto GBA Railroad Medicare website and the Palmetto GBA eServices portal, complete the online experience MCE survey by using the blue FEEDBACK button that appears on the right side of each web page and portal screen, or accept the pop-up invitation when it presents itself.

You can also provide feedback for your experience with selected areas by selecting the green "Your Opinion Matters / Share Your Feedback" button on the right side of select topic website pages or select one of the survey links below:
- Appeals experience (Redetermination — 1st level appeals - https://tinyurl.com/MCEAppeals
- Electronic Data Interchange (EDI) experience - https://tinyurl.com/MCEEDI
- Medical Review Targeted Probe and Educate (TPE) experience - https://tinyurl.com/MCEMRTPE
- Prior Authorization experience - https://tinyurl.com/MCEPriorAuth
- Provider Outreach and Education (POE) experience - https://tinyurl.com/MCEProvOutreachEduc
- Written General Correspondence experience - https://tinyurl.com/MCEWrittenCorr
- Additional surveys will be added in the future

When completing an MCE survey, please be sure to add details about your experience so we know exactly what you liked or what we could do better. We value your comments and opinions, and we look forward to a culture of continuous improvement in the way we conduct business and serve our providers.

Railroad Medicare Customer Information and Outreach

Important Telephone Numbers

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

Provider Contact Center
888-355-9165
Select Option 5

Telephone Reopenings
888-355-9165
Select Option 4

Provider Enrollment
888-355-9165
Select Option 3

Electronic Data Interchange (EDI)
Technical Support
888-355-9165
Select Option 2

Palmetto GBA
Railroad Medicare
P.O. Box 10066
Augusta, GA 30999-0001

www.PalmettoGBA.com/RR

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