

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11778	Date: January 6, 2023
	Change Request 13071

SUBJECT: Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens and New Updates for 2023

I. SUMMARY OF CHANGES: In the Calendar Year (CY) 2023 Physician Fee Schedule Final Rule, we finalized codification and clarifications of various laboratory specimen collection fee and travel allowance policies in subsection (§) 414.523(a)(1) and (2). This is because the policies implementing the statutory requirements under section 1833(h)(3) of the Act for the laboratory specimen collection fee and travel, which are currently described in the Medicare Claims Processing Manual Pub. 100-04, chapter 16, § 60, did not have corresponding regulations text and some of the manual guidance was no longer applicable.

This Change Request (CR) revises the payment of travel allowances when billed on a per mileage basis using Health Care Common Procedure Coding System (HCPCS) code P9603 and when billed on a flat rate basis using HCPCS code P9604 for CY 2023. In addition, it revises chapter 16, section 60.1 and 60.2 of the Claims Processing Manual to include the changes and clarifications related to the Final Rule.

Prior to January 1, 2023, this recurring update notification applied to chapter 16, section 60.2 of the Internet Only Manual. Going forward, this recurring update notification will apply to both sections 60.1 and 60.2.

EFFECTIVE DATE: January 1, 2023

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 23, 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
R	Table of Contents
R	16/60/1/Specimen Collection Fee
D	16/60/1.1/Physician Specimen Drawing
N	16/60/1.1/Independent Laboratory Specimen Drawing
D	16/60/1.2/Independent Laboratory Specimen Drawing
N	16/60/1.2/Coding Requirements for Specimen Collection
D	16/60/1.3/Specimen Drawing for Dialysis Patients
D	16/60/1.4/Coding Requirements for Specimen Collection
R	16/60/2/Travel Allowance

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:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 11778	Date: January 6, 2023	Change Request: 13071
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I. GENERAL INFORMATION

A. Background: Medicare Part B allows payment for a specimen collection fee and travel allowance, when medically necessary, for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under Section 1833(h)(3) of the Act. Payment for these services is made based on the clinical laboratory fee schedule.

In the Calendar Year (CY) 2023 Physician Fee Schedule Final Rule, we finalized codification and clarifications of various laboratory specimen collection fee and travel allowance policies in subsection (§) 414.523(a)(1) and (2). This is because the policies implementing the statutory requirements under section 1833(h)(3) of the Act for the laboratory specimen collection fee and travel, which are currently described in the Medicare Claims Processing Manual Pub. 100-04, chapter 16, § 60, did not have corresponding regulations text and some of the manual guidance was no longer applicable.

This Change Request (CR) revises the payment of travel allowances when billed on a per mileage basis using Health Care Common Procedure Coding System (HCPCS) code P9603 and when billed on a flat rate basis using HCPCS code P9604 for CY 2023. In addition, it revises chapter 16, section 60.1 and 60.2 of the Claims Processing Manual to include the changes and clarifications related to the Final Rule.

Prior to January 1, 2023, this recurring update notification applied to chapter 16, section 60.2 of the Internet Only Manual. Going forward, this recurring update notification will apply to both sections 60.1 and 60.2.

B. Policy:

Specimen Collection Policy

We finalized an increase to the nominal fee for specimen collection based on the Consumer Price Index for all Urban Consumers (CPI-U). Therefore, for CY 2023, the general specimen collection fee will increase from \$3 to \$8.57 and as required by Protecting Access to Medicare Act of 2014 (PAMA), we will increase this amount by \$2 for those specimens collected from a Medicare beneficiary in a Skilled Nursing Facility (SNF) or by a laboratory on behalf of a Home Health Agency (HHA), which will result in a \$10.57 specimen collection fee for those beneficiaries. In addition, we finalized a policy to update this fee amount annually by the percent change in the CPI-U. We also finalized our proposals to codify and clarify various laboratory specimen collection fee policies in § 414.523(a)(1).

In addition, we are clarifying:

To be eligible for a specimen collection fee, the specimen must be:

- used to perform a Clinical Diagnostic Laboratory Test (CDLT) paid under the Clinical Laboratory Fee Schedule (CLFS) regulations at 42 Code of Federal Regulation (CFR) part 414, subpart G, § 414.523;
- collected by a trained technician from a Medicare beneficiary who is homebound, as described in § 424.22(a)(1)(ii), or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; and,
- of the following type—a blood specimen collected through venipuncture or a urine sample collected by catheterization.

A specimen collection fee is allowed in two circumstances:

1. drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or
2. collecting a urine sample by catheterization.

A specimen collection fee is not payable for any other specimen types, including blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. This means that, if different types or multiple specimens are drawn from one patient, only one specimen collection fee would be allowed. Additionally, when a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

Medicare allows payment for a specimen collection fee when it is medically necessary for a trained technician to draw a specimen from either a nursing home patient, a non-hospital inpatient or homebound patient.

The trained technician must personally draw the specimen, *i.e.*, venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a trained technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound.

Where the specimen is a type that would require only the services of a messenger and would not require the skills of a trained technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary.

The phrase “trained technician” refers to those staff providing specimen collection services. However, “trained technician” does not mandate certain educational requirements and, for the purposes of the specimen collection provisions, the term includes a phlebotomist.

As a reminder, the HCPCS codes that describe specimen collection are as follows:

- 36415 - Collection of venous blood by venipuncture
- G0471 - Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)
- P9612 - Catheterization for collection of specimen(s), (single patient), all places of services
- P9615 - Catheterization for collection of specimen(s), (multiple patients)

Finally, beginning January 1, 2024, the specimen collection fee amount will update for each CY by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S city average) for the 12-month period ending June 30th of the year preceding the update year. We will issue this update through this Recurring update on an annual basis.

Travel Allowance Policy

We finalized as proposed to codify in our regulations, and make certain modifications and clarifications to, the Medicare CLFS travel allowance policies. We finalized the addition of § 414.523(a)(2) “Payment for travel allowance” to reflect the requirements for the travel allowance for specimen collection. Specifically, in accordance with section 1833(h)(3)(B) of the Act, we finalized to include in our regulations the following requirements for the travel allowance methodology: (1) a general requirement, (2) travel allowance basis requirements, and (3) travel allowance amount requirements.

In addition, we are clarifying:

CMS pays a travel allowance when the specimen collection fee is paid. Requirements regarding payment for specimen collection are described in Section 60.1 above and CFR § 414.523(a)(1). These requirements must be met for the travel allowance to be payable.

Travel for simple pickup of specimens or for specimen collection that does not require the services of trained technicians should not be considered in the calculation of the travel allowance. This means that the travel allowance amount may be paid only if a specimen collection fee is also payable; for example, no travel allowance would be paid if a trained technician merely performs a messenger service to pick up a specimen drawn by other technicians.

The travel allowance may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital), such that travel allowance may only be paid when a trained technician draws a specimen from a patient who either is in an inpatient facility that is not a hospital or is a homebound patient.

Only one travel allowance payment may be made for specimen collection for a Medicare beneficiary (including Medicare Advantage) based on the beneficiary’s location, and only when a Medicare beneficiary requires the collection of a specimen necessary for performance of CDLTs.

Only Medicare patients should be considered in the calculation and payment of the travel allowance, as the statutory language states “the location of an individual,” that is, the location of a Medicare beneficiary receiving specimen collection services. Non-Medicare patients should not be included in any portion of the calculation of the travel allowance.

Travel Allowance Eligible Miles

For the purposes of travel allowance for specimen collection, eligible miles are those miles traveled that may be included in the calculation to determine the travel allowance amount.

Eligible miles begin at the laboratory or the starting point of the trained technician's travel for specimen collection and end at the laboratory or the ending point of the trained technician's travel for specimen collection. A trained technician's travel for specimen collection from Medicare beneficiaries may begin at a laboratory or at a location other than the laboratory. Therefore, eligible miles begin at the laboratory or the starting point of the trained technician's travel for specimen collection. Additionally, a trained technician's travel for specimen collection from Medicare beneficiaries may end at a laboratory or at a location other than the laboratory. Therefore, eligible miles end at the laboratory or the ending point of the trained technician's travel for specimen collection.

Eligible miles do not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons. Therefore, any miles traveled to a location where no specimens are collected, such as to the location of a non-Medicare beneficiary for specimen collection, to a Medicare beneficiary where no specimen collection occurs, or for personal purposes, are excluded from the calculation of eligible miles.

As a reminder, effective January 1, 2022, CMS has made permanent the option for laboratories to maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained technicians to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic documentation applies to specimen collection for any CDLT. Laboratories may utilize electronic and/or other documentation in order to demonstrate miles traveled for the purposes of specimen collection. Laboratories need to be able to produce electronic documentation in a form and manner that can be shared with MACs and should continue to consult with their local MACs regarding the format and process for submission of this information if necessary.

Travel Allowance Mileage Rate

The Act requires the travel allowance to cover both the "transportation" and "personnel expenses" for trained personnel to travel to the location of an individual to collect a sample. The travel allowance mileage rate reflects both of these components.

The "transportation" component of the travel allowance mileage rate equals the Internal Revenue Service (IRS) standard mileage rate. The IRS updates and issues standard mileage rates on a periodic basis, generally annually and are used to calculate the deductible costs of operating an automobile for business, charitable, medical, or moving for the purpose of calculating Federal taxes.

The "personnel expenses" component of the travel allowance mileage rate where the trained technician's personnel expenses is based on a wages-per-mile amount.

Effective January 1, 2023, CMS uses wage data in the Bureau of Labor Statistics (BLS)-defined category of phlebotomist to establish the personnel expense component of the travel allowance mileage rate. Specifically, CMS uses the latest available published figure for the median hourly wage amount for phlebotomists, which is published by the BLS, for the purposes of annually updating the travel allowance amount for specimen collection.

CMS calculates a per-mile amount to derive the approximate number of miles traveled by the trained technician each hour by using an average driving speed. The average miles-per-hour driving speed is multiplied by the trained technician's estimated wages, as described above, and the result would be an amount that represents wages per mile, which is the personnel expenses associated with travel for specimen collection. CMS uses an average driving speed of 40 miles per hour, as most of the travel related to specimen collection would be performed in local and residential areas.

To establish the personnel expenses component of the travel allowance mileage rate, which is a per-mile amount, CMS divides the most recent median hourly wage for phlebotomists, as published by the BLS, by 40, to represent an average miles-per-hour.

The total travel allowance mileage rate, which includes both the "transportation" and "personnel expenses" for trained personnel to travel to the location of an individual to collect a sample, is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician which is equal to the most recent median hourly wage for phlebotomists, as published by the BLS, divided by 40 to represent an average miles-per-hour driving speed.

Updates to the Travel Allowance Mileage Rate

Updates to the travel allowance mileage rate are issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. Updates will be made to the travel allowance mileage rate based upon the most recently published IRS standard mileage rate, as well as the most recently published wage rate for phlebotomist as published by the BLS. The revised travel allowance mileage rate will be effective for the January update of the clinical laboratory fee schedule file.

The travel allowance mileage rate for CY 2023 is \$1.11:

- The IRS standard mileage rate, which is \$0.655; plus,
- The most recent median hourly wage for phlebotomists, as published by the BLS, which is \$17.97, divided by 40 to represent an average miles-per-hour driving speed, which is \$0.45.
- Yielding a total travel allowance mileage rate for CY 2023 of \$1.105, rounded to \$1.11.

Travel Allowance Bases: Flat-Rate and Per-Mile

CMS pays a travel allowance on the following bases:

(1) flat-rate travel allowance; and

(2) per-mile travel allowance.

Flat-Rate Travel Allowance

The flat-rate travel allowance basis applies when the trained technician travels 20 eligible miles or less to and from one location for specimen collection from one or more Medicare beneficiaries.

Laboratories bill Medicare using HCPCS code P9604 to receive payment for the flat-rate travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid.

Per-Mile Travel Allowance

The per-mile travel allowance basis applies in two circumstances:

1. When the round-trip travel to one location is greater than 20 eligible miles for specimen collection from one or more beneficiaries; or,
2. When travel is to more than one location, regardless of the number of miles traveled.

Laboratories bill Medicare using HCPCS code P9603 to receive payment for the per-mile travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid.

Calculation: Flat-rate Travel Allowance Basis

For flat-rate travel allowance basis, the travel allowance amount calculation is the travel allowance mileage rate multiplied by ten (10) and divided by the number of beneficiaries for whom a specimen collection fee is paid.

Dividing by the number of beneficiaries for whom a specimen collection fee is paid ensures that the flat-rate travel allowance amount is apportioned to each beneficiary receiving specimen collection services and that payment is calculated in an operationally feasible manner, as a laboratory must submit a claim for each beneficiary to receive payment for travel allowance. This method allows for a fixed payment amount to be straightforwardly apportioned to the number of beneficiaries for whom a specimen collection fee is paid in a single location.

Example: Flat-rate Travel Allowance Calculation

For an example of the flat-rate travel allowance calculation, consider a situation in which a trained technician travels seven (7) miles from the laboratory to a nursing home to collect blood specimens collected through venipuncture from five patients, four of whom are Medicare beneficiaries.

The trained technician collects three specimens from Medicare beneficiaries, collects one specimen from the non-Medicare patient, and simply picks up a previously collected specimen from one Medicare beneficiary. The trained technician then drives seven (7) miles back to the laboratory to deliver the specimens without making any other stops.

The trained technician has provided specimen collection services to three Medicare beneficiaries. One Medicare beneficiary did not require specimen collection services, and therefore, a specimen collection fee would not be payable.

In this example, the laboratory would use the flat-rate travel allowance basis because the trained technician traveled a total of 14 miles. To calculate the travel allowance mileage rate, the laboratory would divide flat-rate travel allowance amount of \$11.10 by the number of beneficiaries for whom a specimen collection fee is paid (three beneficiaries), which equals \$3.70. To bill for the travel allowance, the laboratory would submit one claim for each beneficiary for whom a specimen collection fee is paid by billing HCPCS code P9604.

Calculation: Per-mile Travel Allowance Basis

The calculation for the per-mile travel allowance amount is equal the number of eligible miles multiplied by the travel allowance mileage rate, divided by the number of beneficiaries for whom a specimen collection fee is paid.

To calculate the per-mile travel allowance amount, the laboratory would first calculate the total number of eligible miles that the trained technician traveled – this would be the total number of miles traveled by the trained technician to locations where one or more Medicare beneficiaries received specimen collection services and back to the laboratory where the technician returns the specimen(s) for testing.

The eligible miles would be multiplied by the travel allowance mileage rate as described above, then divided by the number of beneficiaries for whom a specimen collection fee is paid. This quotient yields a prorated travel allowance amount for each beneficiary. The laboratory receives payment for the total number of eligible miles traveled for specimen collection, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid. The laboratory then submits a claim billing HCPCS code P9603 for payment of the per-mile travel allowance amount for each beneficiary for whom a specimen collection fee is paid.

Examples: Per-mile Travel Allowance Amount Calculation

Example 1:

For an example of the per-mile travel allowance amount calculation, consider a trained technician traveling 45 miles from a laboratory in a city to a rural SNF, collecting blood specimens through venipuncture from six (6) Medicare beneficiaries, and then driving 45 miles to return to the laboratory.

In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled more than 20 eligible miles to one location for specimen collection.

To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles traveled to the location of Medicare beneficiaries receiving specimen collection services, which, in this case is 45 miles from the laboratory to the SNF and 45 miles from the SNF returning to the laboratory, for a total of 90 eligible miles.

The eligible miles would then be multiplied by the travel allowance mileage rate of \$1.11, yielding a total of \$99.90. This total amount would then be prorated by dividing by the number of Medicare beneficiaries for whom a specimen collection fee is paid (6), yielding a per-beneficiary amount of \$15.60 ($\$99.90/6 = \16.65). To bill for the travel allowance, the laboratory would submit one claim for each beneficiary in the amount of \$16.65 HCPCS code P9603.

Example 2:

In another example, a trained technician travels 40 miles from a laboratory to the location of a Medicare beneficiary to collect a blood specimen through venipuncture, then travels 10 miles to the location of a non-

Medicare patient to collect a blood specimen through venipuncture, then travels 20 miles to the location of two Medicare beneficiaries to collect urine specimens by catheterization, and then travels 20 miles to return to the laboratory.

In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled to more than one location for specimen collection.

To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles, which would include the miles traveled from the laboratory to the locations of Medicare beneficiaries to collect specimens plus the miles back to the laboratory for specimen drop-off. Eligible miles would not include the 10 miles traveled to the location of the non-Medicare patient to collect a specimen, but would include the 40 miles traveled from the laboratory to the location of the first Medicare beneficiary, the 20 miles to the location of the two Medicare beneficiaries, and the return trip to the laboratory of 20 miles, for a total of 80 eligible miles.

The eligible miles would then be multiplied by the travel allowance mileage rate of \$1.11, yielding a total of \$88.80. This total would then be prorated by dividing by three (3) Medicare beneficiaries for whom a specimen collection fee is paid, yielding an amount of \$29.60. The laboratory would then submit a claim using HCPCS code P9603 for travel allowance for each of the Medicare beneficiaries in the amount of \$29.60. The laboratory would receive payment for the eligible miles traveled by the trained technician, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid.

Neither the annual deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection or travel allowance amount for CDLTs.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13071.1	Contractors shall use the CY 2023 Travel Allowance for determining payment on a per mileage basis (P9603) or on a flat rate per trip basis (P9604) where applicable under Section 1833(h)(3) of the Act.	X	X							
13071.2	Contractors shall pay for code P9603, where the average trip to the beneficiaries' locations exceeds 20 miles round trip, at \$0.655 per mile, plus an additional \$0.45 per mile to cover the personnel expenses, for a total of \$1.11 per mile (the actual total of \$1.105 rounded up to reflect system capabilities).	X	X							
13071.3	Contractors shall pay for code P9604 on a flat-rate trip basis	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	travel allowance of \$11.10.									
13071.4	Contractors shall adjust previously paid travel allowance claims with dates of service on or after January 1, 2023, in order to apply the updated payment rate and initiate those adjustments within 60 days, if claims are paid at the prior year's rates before the new rate is entered into the MACs' systems.	X	X							
13071.5	Contractors shall be aware of and make note of the changes in the Chapter 16, Section 60 (also the Table of Contents) and update MAC guidance as necessary.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13071.6	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.	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:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Laura Ashbaugh, 410-786-1113 or Laura.Ashbaugh2@cms.hhs.gov , Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@cms.hhs.gov

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

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare Claims Processing Manual

Chapter 16 - Laboratory Services

Table of Contents
(Rev. 11778, 01-06-23)

Transmittals for Chapter 16

60.1 - Specimen Collection Fee

60.1.1 - Independent Laboratory Specimen Drawing

60.1.2 - Coding Requirements for Specimen Collection

60.2 - Travel Allowance

60.1 - Specimen Collection Fee

(Rev.11778, Issued:01-06-23; Effective:01-01-23; Implementation:01-23-23)

Section 1833(h)(3) of the Act specifies that the Secretary shall provide for and establish a nominal fee in addition to the payment amounts for CDLTs on the CLFS to cover the appropriate costs of collecting the sample on which a clinical diagnostic laboratory test (CDLT) was performed and for which payment is made with respect to samples collected in the same encounter. The nominal fee is intended to cover the appropriate costs in collecting the sample, which could include the costs related to drawing, collecting, or handling a specimen.

Specimen Collection Fee Eligibility

To be eligible for a specimen collection fee, the specimen must be:

- used to perform a CDLT paid under the CLFS regulations at 42 CFR part 414, subpart G, § 414.523;*
- collected by a trained technician from a Medicare beneficiary who is homebound, as described in § 424.22(a)(1)(ii), or is a non-hospital inpatient, but only when no qualified personnel are available at the facility to collect the specimen; **and,***
- of the following type—a blood specimen collected through venipuncture or a urine sample collected by catheterization.*

Trained Technician

The phrase “trained technician” refers to those staff providing specimen collection services. However, “trained technician” does not mandate certain educational requirements and, for the purposes of the specimen collection provisions, the term includes a phlebotomist.

Specimen Collection Type

A specimen collection fee is allowed in two circumstances:

- (1) drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or*
- (2) collecting a urine sample by catheterization.*

A specimen collection fee is not payable for any other specimen types, including blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. This means that, if different types or multiple specimens are drawn from one patient, only one specimen collection fee would be allowed. Additionally, when a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

Specimen Collection Fee Rate

Effective January 1, 2023, CMS pays a general specimen collection fee of \$8.57 for all specimens collected in one patient encounter. This fee is increased by \$2 (\$10.57) for specimen collection from a Medicare beneficiary in a skilled nursing facility (SNF) or on behalf of an home health agency (HHA) for all specimens collected in one patient encounter.

Specimen Collection Fee Annual Update

Beginning January 1, 2024, the specimen collection fee amount will update for each calendar year (CY) by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S city average) for the 12-month period ending June 30th of the year preceding the update year. CMS issues these updates to the specimen collection fee amounts through subregulatory guidance, specifically the existing CMS change request process, on an annual basis.

60.1.1 - Independent Laboratory Specimen Drawing ***(Rev.11778, Issued:01-06-23; Effective:01-01-23; Implementation:01-23-23)***

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another.

Payment for the specimen collection fee is made based on the clinical laboratory fee schedule.

Medicare allows payment for a specimen collection fee when it is medically necessary for a trained technician to draw a specimen from either a nursing home patient, *a non-hospital inpatient* or homebound patient.

The *trained* technician must personally draw the specimen, *i.e.*, venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a *trained* technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound.

However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a *trained* technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary. (See Chapters 7 and 15 of Pub. 100-02, the Medicare Benefit Policy Manual for a discussion of “homebound” and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

Claims Annotation

In addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing prescribed by a physician should be appropriately annotated, e.g., “patient confined to home,” “patient homebound,” or “patient in nursing home, no qualified person on duty to draw specimen.” A/B MACs (B) must assure the validity of the annotation through scientific claims samples as well as through regular bill review techniques. (This could be done by use of the information in A/B MAC (B) files, and where necessary, contact with the prescribing physician.)

Medical Necessity Requirement

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met.

The specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.

60.1.2 - Coding Requirements for Specimen Collection

(Rev.11778, Issued:01-06-23; Effective:01-01-23, Implementation:01-23-23)

The following HCPCS codes and terminology must be used:

- 36415 - Collection of venous blood by venipuncture.
- G0471 - Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)
- *P9612 - Catheterization for collection of specimen(s), (single patient), all places of services*
- P9615 - Catheterization for collection of specimen(s), *(multiple patients)*

The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS *via a Recurring Update Notification (RUN) change request.*

Neither the annual deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection fees.

60.2 - Travel Allowance

(Rev.11778, Issued:01-06-23; Effective:01-01-23, Implementation:01-23-23)

Section 1833(h)(3)(B) of the Act states that the Secretary shall provide for and establish a fee in addition to the payment amounts for CDLTs on the CLFS to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample.

Travel Allowance Eligibility

CMS pays a travel allowance when the specimen collection fee is paid. Requirements regarding payment for specimen collection are described in Section 60.1 above and CFR § 414.523(a)(1). These requirements must be met for the travel allowance to be payable.

Travel for simple pickup of specimens or for specimen collection that does not require the services of trained technicians should not be considered in the calculation of the travel allowance. This means that the travel allowance amount may be paid only if a specimen collection fee is also payable; for example, no travel allowance would be paid if a trained technician merely performs a messenger service to pick up a specimen drawn by other technicians.

The travel allowance may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital), such that travel allowance may only be paid when a trained technician draws a specimen from a patient who either is in an inpatient facility that is not a hospital or is a homebound patient.

Only one travel allowance payment may be made for specimen collection for a Medicare beneficiary based on the beneficiary's location, and only when a Medicare beneficiary requires the collection of a specimen necessary for performance of CDLTs.

Only Medicare patients should be considered in the calculation and payment of the travel allowance, as the statutory language states "the location of an individual," that is, the location of a Medicare beneficiary receiving specimen collection services. Non-Medicare patients should not be included in any portion of the calculation of the travel allowance.

Travel Allowance Eligible Miles

For the purposes of travel allowance for specimen collection, eligible miles are those miles traveled that may be included in the calculation to determine the travel allowance amount.

Eligible miles begin at the laboratory or the starting point of the trained technician's travel for specimen collection and end at the laboratory or the ending point of the trained technician's travel for specimen collection. A trained technician's travel for specimen collection from Medicare beneficiaries may begin at a laboratory or at a location other than the laboratory. Therefore, eligible miles begin at the laboratory or the starting point of the trained technician's travel for specimen collection. Additionally, a trained technician's travel for specimen collection from Medicare beneficiaries may end at a laboratory or at a location other than the laboratory. Therefore, eligible miles end at the laboratory or the ending point of the trained technician's travel for specimen collection.

Eligible miles do not include miles traveled for any purpose unrelated to specimen collection, such as collecting specimens from non-Medicare beneficiaries or for personal reasons. Therefore, any miles traveled to a location where no specimens are collected, such as to the location of a non-Medicare beneficiary for specimen collection, to a Medicare beneficiary where no specimen collection occurs, or for personal purposes, are excluded from the calculation of eligible miles.

Effective January 1, 2022, CMS has made permanent the option for laboratories to maintain electronic documentation of miles traveled for the purposes of covering the transportation and personnel expenses for trained technicians to travel to the location of an individual to collect a specimen sample. This option for laboratories to maintain electronic documentation applies to specimen collection for any CDLT. Laboratories may utilize electronic and/or other documentation in order to demonstrate miles traveled for the purposes of specimen collection. Laboratories need to be able to produce electronic documentation in a form and manner that can be shared with MACs and should continue to consult with their local MACs regarding the format and process for submission of this information if necessary.

Travel Allowance Mileage Rate

The Act requires the travel allowance to cover both the "transportation" and "personnel expenses" for trained personnel to travel to the location of an individual to collect a sample. The travel allowance mileage rate reflects both of these components.

The "transportation" component of the travel allowance mileage rate equals the IRS standard mileage rate. The IRS updates and issues standard mileage rates on a periodic basis, generally annually and are used to calculate the deductible costs of operating an automobile for business, charitable, medical, or moving for the purpose of calculating Federal taxes.

The "personnel expenses" component of the travel allowance mileage rate where the trained technician's personnel expenses is based on a wages-per-mile amount.

Effective January 1, 2023, CMS uses wage data in the Bureau of Labor Statistics BLS-defined category of phlebotomist to establish the personnel expense component of the travel allowance mileage rate.

Specifically, CMS uses the latest available published figure for the median hourly wage amount for phlebotomists, which is published by the BLS, for the purposes of annually updating the travel allowance amount for specimen collection.

CMS calculates a per-mile amount to derive the approximate number of miles traveled by the trained technician each hour by using an average driving speed. The average miles-per-hour driving speed is multiplied by the trained technician's estimated wages, as described above, and the result would be an amount that represents wages per mile, which is the personnel expenses associated with travel for specimen collection. CMS uses an average driving speed of 40 miles per hour, as most of the travel related to specimen collection would be performed in local and residential areas.

To establish the personnel expenses component of the travel allowance mileage rate, which is a per-mile amount, CMS divides the most recent median hourly wage for phlebotomists, as published by the BLS, by 40, to represent an average miles-per-hour.

The total travel allowance mileage rate, which includes both the “transportation” and “personnel expenses” for trained personnel to travel to the location of an individual to collect a sample, is equal to the IRS standard mileage rate plus an amount to cover expenses for a trained technician which is equal to the most recent median hourly wage for phlebotomists, as published by the BLS, divided by 40 to represent an average miles-per-hour driving speed.

Updates to the Travel Allowance Mileage Rate

Updates to the travel allowance mileage rate are issued through subregulatory guidance, specifically the existing CMS change request process, on an annual basis. Updates will be made to the travel allowance mileage rate based upon the most recently published IRS standard mileage rate, as well as the most recently published wage rate for phlebotomist as published by the BLS. The revised travel allowance mileage rate will be effective for the January update of the clinical laboratory fee schedule file.

The travel allowance mileage rate for CY2023 is \$1.11:

- The IRS standard mileage rate, which is \$0.655; plus,*
- The most recent median hourly wage for phlebotomists, as published by the BLS, which is \$17.97, divided by 40 to represent an average miles-per-hour driving speed, which is \$0.45.*
- Yielding a total travel allowance mileage rate for CY 2023 of \$1.105, rounded up to \$1.11.*

Travel Allowance Bases: Flat-Rate and Per-Mile

CMS pays a travel allowance on the following bases:

- (1) flat-rate travel allowance; and*
- (2) per-mile travel allowance.*

Flat-Rate Travel Allowance

The flat-rate travel allowance basis applies when the trained technician travels 20 eligible miles or less to and from one location for specimen collection from one or more Medicare beneficiaries.

Laboratories bill Medicare using HCPCS code P9604 to receive payment for the flat-rate travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid.

Per-Mile Travel Allowance

The per-mile travel allowance basis applies in two circumstances:

- 1) When the round-trip travel to one location is greater than 20 eligible miles for specimen collection from one or more beneficiaries; or,*
- 2) When travel is to more than one location, regardless of the number of miles traveled.*

Laboratories bill Medicare using HCPCS code P9603 to receive payment for the per-mile travel allowance amount, prorated by the number of beneficiaries for whom a specimen collection fee is paid.

Travel Allowance Amount Calculation

Calculation: Flat-rate Travel Allowance Basis

For flat-rate travel allowance basis, the travel allowance amount calculation is the travel allowance mileage rate multiplied by ten (10) and divided by the number of beneficiaries for whom a specimen collection fee is paid.

Dividing by the number of beneficiaries for whom a specimen collection fee is paid ensures that the flat-rate travel allowance amount is apportioned to each beneficiary receiving specimen collection services and that payment is calculated in an operationally feasible manner, as a laboratory must submit a claim for each beneficiary to receive payment for travel allowance. This method allows for a fixed payment amount to be straightforwardly apportioned to the number of beneficiaries for whom a specimen collection fee is paid in a single location.

Example: Flat-rate Travel Allowance Calculation

For an example of the flat-rate travel allowance calculation, consider a situation in which a trained technician travels 7 miles from the laboratory to a nursing home to collect blood specimens collected through venipuncture from five patients, four of whom are Medicare beneficiaries.

The trained technician collects three specimens from Medicare beneficiaries, collects one specimen from the non-Medicare patient, and simply picks up a previously collected specimen from one Medicare beneficiary. The trained technician then drives 7 miles back to the laboratory to deliver the specimens without making any other stops.

The trained technician has provided specimen collection services to three Medicare beneficiaries. One Medicare beneficiary did not require specimen collection services, and therefore, a specimen collection fee would not be payable.

In this example, the laboratory would use the flat-rate travel allowance basis because the trained technician traveled a total of 14 miles. To calculate the travel allowance mileage rate, the laboratory would divide flat-rate travel allowance amount of \$11.10 by the number of beneficiaries for whom a specimen collection fee is paid (three beneficiaries), which equals \$3.70. To bill for the travel allowance, the laboratory would submit one claim for each beneficiary for whom a specimen collection fee is paid by billing HCPCS code P9604.

Calculation: Per-mile Travel Allowance Basis

The calculation for the per-mile travel allowance amount is equal the number of eligible miles multiplied by the travel allowance mileage rate, divided by the number of beneficiaries for whom a specimen collection fee is paid.

To calculate the per-mile travel allowance amount, the laboratory would first calculate the total number of eligible miles that the trained technician traveled – this would be the total number of miles traveled by the trained technician to locations where one or more Medicare beneficiaries received specimen collection services and back to the laboratory where the technician returns the specimen(s) for testing.

The eligible miles would be multiplied by the travel allowance mileage rate as described above, then divided by the number of beneficiaries for whom a specimen collection fee is paid. This quotient yields a prorated travel allowance amount for each beneficiary. The laboratory receives payment for the total number of eligible miles traveled for specimen collection, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid. The laboratory then submits a claim billing HCPCS code P9603 for payment of the per-mile travel allowance amount for each beneficiary for whom a specimen collection fee is paid.

Examples: Per-mile Travel Allowance Amount Calculation

Example 1:

For an example of the per-mile travel allowance amount calculation, consider a trained technician traveling 45 miles from a laboratory in a city to a rural SNF, collecting blood specimens through venipuncture from 6 Medicare beneficiaries, and then driving 45 miles to return to the laboratory.

In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled more than 20 eligible miles to one location for specimen collection.

To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles traveled to the location of Medicare beneficiaries receiving specimen collection services, which, in this case is 45 miles from the laboratory to the SNF and 45 miles from the SNF returning to the laboratory, for a total of 90 eligible miles.

The eligible miles would then be multiplied by the travel allowance mileage rate of \$1.11, yielding a total of \$99.90. This total amount would then be prorated by dividing by the number of Medicare beneficiaries for whom a specimen collection fee is paid (6), yielding a per-beneficiary amount of \$16.65 ($\$99.90/6 = \16.65). To bill for the travel allowance, the laboratory would submit one claim for each beneficiary in the amount of \$16.65 HCPCS code P9603.

Example 2:

In another example, a trained technician travels 40 miles from a laboratory to the location of a Medicare beneficiary to collect a blood specimen through venipuncture, then travels 10 miles to the location of a non-Medicare patient to collect a blood specimen through venipuncture, then travels 20 miles to the location of two Medicare beneficiaries to collect urine specimens by catheterization, and then travels 20 miles to return to the laboratory.

In this example, the laboratory would use the per-mile travel allowance basis because the trained technician traveled to more than one location for specimen collection.

To calculate the per-mile travel allowance amount, the laboratory would sum the eligible miles, which would include the miles traveled from the laboratory to the locations of Medicare beneficiaries to collect specimens plus the miles back to the laboratory for specimen drop-off. Eligible miles would not include the 10 miles traveled to the location of the non-Medicare patient to collect a specimen, but would include the 40 miles traveled from the laboratory to the location of the first Medicare beneficiary, the 20 miles to the location of the two Medicare beneficiaries, and the return trip to the laboratory of 20 miles, for a total of 80 eligible miles.

The eligible miles would then be multiplied by the travel allowance mileage rate of \$1.11, yielding a total of \$88.80. This total would then be prorated by dividing by three (3) Medicare beneficiaries for whom a specimen collection fee is paid, yielding an amount of \$29.60. The laboratory would then submit a claim using HCPCS code P9603 for travel allowance for each of the Medicare beneficiaries in the amount of \$29.60. The laboratory would receive payment for the eligible miles traveled by the trained technician, apportioned equally to each Medicare beneficiary for whom a specimen collection fee is paid.

Neither the annual deductible nor the 20 percent coinsurance for Medicare apply to the travel allowance amount for CDLTs.