Chapter 3 Contents

1. General Information

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5; ***Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)***

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. The "reasonable and necessary" criteria are based on Social Security Act §1862(a)(1)(A) provisions.

Before submitting a claim to the DME MAC, you must have on file a standard written order (SWO), a written order prior to delivery (WOPD) (if applicable), information from the treating practitioner concerning the beneficiary's diagnosis[1], and any information required for the use of specific modifiers or attestation statements as defined in certain Local Coverage Determinations (LCDs) (see Chapter 9 of this manual for information about LCDs). You should also obtain as much documentation from the beneficiary's medical record as you determine you need to assure that coverage criteria for an item have been met. If the information in the beneficiary's medical record does not adequately support the medical necessity for the item, you are liable for the dollar amount involved unless a properly executed advance beneficiary notice of non-coverage (ABN) (see Section 9 below) of possible denial has been obtained.

All documentation must be maintained in the supplier's files for seven (7) years from the date of service (DOS) and be available upon request.

[1] Diagnosis codes are required on all claims.

If the Medicare qualifying supplier documentation is older than seven years, proof of continued medical necessity of the item or necessity of the repair can be used as the supporting Medicare qualifying documentation.

Note: As of January 1, 2023, CMS has eliminated CMNs and DIFs. Therefore, for dates of service on or after January 1, 2023, CMNs and DIFs must not be submitted with claims.

2. Definition of Physician

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §40.4; Pub. 100-01, *Medicare General Information, Eligibility and Entitlement Manual*, Chapter 5, §70; *Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Physician means any of the following entities legally authorized to practice by a state in which he/she performs this function. The services performed by a physician within these definitions are subject to any limitations posed by the State on the scope of practice.

- Doctor of medicine
- Doctor of osteopathy (including osteopathic practitioner) - must be licensed to practice medicine and surgery
- Doctor of dental surgery or dental medicine
- Chiropractor (see below)
- Doctor of podiatry (see below) or surgical chiropody
- Doctor of optometry

The following practitioners may document the medical necessity of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) items, including completing orders, in place of a physician provided that they meet the practitioner requirements defined in Chapter 15 of the Benefit Policy Manual (Publication 100-02), the services performed are within their scope of practice as defined by their state, and they are treating the beneficiary for the condition for which the item is needed.

- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist

The term physician does not include such practitioners as Christian Science practitioner or naturopath. There is no Medicare benefit for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items ordered by these entities.

Medicare coverage for all items and services furnished or ordered by chiropractors is statutorily excluded, with the exception of treatment by means of manual manipulation of the spine to correct a subluxation. Therefore, all DMEPOS items ordered by chiropractors are denied.

Medicare coverage for all items and services furnished or ordered by podiatrists is limited by state statutes governing the scope of practice for podiatry. You should be familiar with the limitations imposed by the statutes of the state(s) in which you operate and dispense DMEPOS items. Claims

submitted to the DME MAC, when furnished or ordered by podiatrists practicing outside the limits of their licensure, will be denied as statutorily non-covered. Podiatrists are excluded by statute from ordering a power operated vehicle (POV) or power wheelchair.

3. Prescription (Order) Requirements

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

All items billed to Medicare require a prescription from the treating practitioner as a condition of payment. For each item billed, you must have a signed order/prescription from the treating practitioner. You must keep the order on file and make it available upon request. If these order/prescription requirements and those below are not met, then an EY modifier must be added to each affected HCPCS code when submitting the claim. Note: The claim submitted for the affected HCPCS codes (with EY modifier added) must be separate from claims submitted for HCPCS codes in which you have a complete and compliant order/prescription on file.

STANDARD WRITTEN ORDER (SWO)

An SWO must be communicated to the supplier prior to claim submission. For certain items of DMEPOS, a written order is required prior to delivery (WOPD) of the item(s) to the beneficiary.

An SWO must contain all of the following elements:

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of the item
    - The description can be a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
    - For equipment – In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately)
    - For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (list each separately)

      Note: If such items are not concurrently ordered, they nonetheless require an order for payment purposes.
- Quantity to be dispensed, if applicable
- Treating practitioner’s name or National Provider Identifier (NPI)
- Treating practitioner's signature

The “order date” ideally should reflect the date the order was first communicated to you by the treating practitioner.

Note also that while the SWO has a limited number of required order elements, additional elements may be included to provide clarity for issues such as length of need (LON), frequency of use, dosage

form/strength, refills frequency, etc. This additional information shall be corroborated by information in the medical record.

Suppliers may also wish to consult state law or regulation since some states may have additional requirements for the elements of an order/prescription (e.g., refill frequency).

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the standard written order, the type of supplies needed in such a manner that the supplier may calculate the necessary disbursement and assess the continued need for refill with the beneficiary. DME MACs, UPICs, and other contractors evaluate supply utilization information as part of their medical necessity and coverage determinations for DMEPOS. Reimbursement shall be based on the specific utilization amount that is supported by contemporaneous medical records, including orders that indicate "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements. Refer to the "Signature Requirements" section in this chapter.

The SWO must be available upon request.

An exception to the requirement for a written order applies in those limited instances in which the treating practitioner is also the supplier and is permitted to furnish specific items of DMEPOS and fulfill the role of the supplier in accordance with any applicable laws and policies. In such cases, a separate order is not required, but the medical record must still contain all of the required order elements.

A prescription is not considered as part of the medical record, except in the case of documenting medical necessity for replacement prosthetic limbs. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

NEW ORDER REQUIREMENTS

A new order/prescription is required:

- For all claims for purchases or initial rentals;
- There is a change in the order/prescription for the DMEPOS item (e.g., quantity);
- On a regular basis (even if there is no change in the order) only if it so specified in the documentation section of a particular medical policy;
- When an item is replaced (see explanation below); or
- When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order/prescription for the DMEPOS item from the transferring supplier.

A new order is required when an item is being replaced because the item is worn, or the beneficiary's condition has changed. Your records should also include beneficiary-specific information regarding the need for the replacement item. This information should be maintained in your files and be available to the DME MACs or UPICs upon request. Failure to provide the appropriate documentation or providing documentation that contains broad, nonspecific explanations will result in claim(s) denial.

A new order is required before replacing lost, stolen, or irreparably damaged items to reaffirm the medical necessity of the item. Proof of loss or damage through documentation such as a police report, picture, or corroborating statement should be kept on file and available to the contractor upon request.

WRITTEN ORDERS PRIOR TO DELIVERY (WOPD)

GENERAL

A WOPD is a completed SWO that is communicated to the DMEPOS supplier before delivery of the item(s).

Pursuant to Final Rule 1713 (84 Fed. Reg Vol 217) and 42 CFR §410.38, CMS created the "Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements." The Master List serves as a library of DMEPOS items from which items may be selected for inclusion in either, or both, of the following lists:

- Required Face-to-Face Encounter and Written Order Prior to Delivery List;
- Required Prior Authorization List.

Items included in either Required List are subject to the face-to-face encounter and WOPD or prior authorization requirements, respectively, as a condition of payment.

CMS and the DME MACs post on their websites the Required Face-To-Face Encounter and Written Order Prior to Delivery List, which contains the selected HCPCS codes, once also published through the Federal Register for notice. The published effective date will also be included on the DME MACs' websites. The Required Face-To-Face Encounter and Written Order Prior to Delivery List will be periodically updated.

Note that the face-to-face encounter and WOPD requirements are statutorily required for PMDs, and in accordance with this statutory obligation, both will continue to be required, and will be included in any future publications of the Required List.

The date of the WOPD shall be on or before the date of delivery or on or before the date shipped if the shipping date is used as the date of service.

A WOPD must be completed within six (6) months after the required face-to-face encounter.

For PMDs, the treating practitioner who conducted the face-to-face encounter must also complete the SWO for the PMD base item. If the treating practitioner who conducted the face-to-face encounter is not the same practitioner who wrote the order for the PMD base item, the claim will be denied as statutorily non-covered pursuant to the Social Security Act, Title XVIII, §1834(a)(1)(E)(iv).

Upon request by a contractor, DMEPOS suppliers must provide documentation of the completed WOPD.

Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.7

A nurse practitioner or clinical nurse specialist may write and sign the standard written order in the following situations:

- They are treating the beneficiary for the condition for which the item is needed;

- They are practicing independently of a physician;
- They bill Medicare for other covered services using their own provider number; and
- They are permitted to do all of the above in the State in which the services are rendered.

Signatures must comply with CMS signature requirements. Refer to the “Signature Requirements” section in this chapter.

Physician Assistant Rules Concerning Orders

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.8

Physician assistants may write and sign the standard written order if they satisfy all the following requirements:

- They meet the definition of physician assistant found in §1861(aa)(5)(A) of the Act;
- They are treating the beneficiary for the condition for which the item is needed;
- They are practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy;
- They have their own NPI; and
- They are permitted to perform services in accordance with State law.

Signatures must comply with CMS signature requirements. Refer to the “Signature Requirements” section in this chapter.

Supply Replacement/Utilization – Evidence of Medical Necessity

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.11

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the standard written order the type of supplies needed in such a manner that the supplier may calculate the necessary disbursement and assess the continued need for refill with the beneficiary. DME MACs, UPICs, and other contractors evaluate supply utilization information as part of their medical necessity and coverage determinations for DMEPOS.

The DME MACs and/or UPICs have procedures in place to monitor utilization of replacement supplies. You must submit updated medical information of the beneficiary’s condition resulting in changes of the equipment device, or supply utilization. Claims submitted with unexpected increases in supply utilization without supportive documentation will be denied. You must provide this information with the claim where indicated in published policy or make it available to the DME MACs or UPICs on request.

Acceptability of Faxed and Electronic Orders

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5

When reviewing claims and orders, DME MACs and UPICs may encounter faxed, copied, and electronic orders in supplier files. These documents are accepted by the DME MACs and UPICs.

The DME MACs and UPICs retain the authority to request additional documentation to support the claim. If a DME MAC finds indications of potential fraud or misrepresentation of these documents or the claims submitted, they will refer the matter to the UPIC for development.

4. Documentation in the Beneficiary's Medical Record

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.9; Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15; Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 12*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Medicare does not automatically assume payment for a DMEPOS item that was covered prior to a beneficiary becoming eligible for the Medicare Fee-for-Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding, and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary may be required upon request of the DME MAC.

For any DMEPOS item to be covered by Medicare, the beneficiary's medical record must contain sufficient documentation of the beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered and for replacement (if applicable). The information should include the beneficiary's diagnosis and other pertinent information including, but not limited to, duration of the beneficiary's condition, clinical course (worsening or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Neither a practitioner's order, nor a supplier-prepared statement, nor a practitioner's attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating practitioner or you. There must be information in the beneficiary's medical record that supports the medical necessity for the item and substantiates the information on a supplier-prepared statement or practitioner's attestation (if applicable).

Forms are subject to corroboration with information in the medical record.

Templates utilized by practitioners and licensed/certified medical professionals (LCMPs) in the documenting and gathering of clinical information during patient visits are considered part of the medical record for medical review purposes. Templates that offer limited options and space for documentation (such as those that make use of "check boxes"), may fail to capture sufficient clinical information to demonstrate coverage and coding requirements for items/services were met.

The beneficiary's medical record is not limited to the treating practitioner's office records. It may include hospital, nursing home, or home health agency records, records from other professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

The documentation in the beneficiary's medical record does not need to be routinely sent to you or to the DME MACs or UPICs; however, the DME MAC or UPIC may request this information. If the DME MAC or UPIC does not receive the information when requested, or if the information in the beneficiary's medical record does not adequately support the medical necessity for the item, then for assigned claims you are liable for the dollar amount involved unless a properly executed advance beneficiary notice of non-coverage (ABN) of possible denial has been obtained. See the Advance Beneficiary Notice of Non-coverage section below for information about ABNs.

FACE-TO-FACE ENCOUNTER

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Note: This section pertains to the Final Rule CMS-1713-F face-to-face requirements associated with the "Required Face-to-Face Encounter and Written Order Prior to Delivery List."

As a condition for payment, 42 CFR §410.38 and Final Rule CMS-1713-F (84 Fed. Reg Vol 217) require that a treating practitioner have a face-to-face encounter with a beneficiary within the six months prior to prescribing items that appear on the **Required Face-to-Face Encounter and Written Order Prior to Delivery List**.

The face-to-face encounter must support payment for the item(s) ordered/prescribed, and be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans, or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

This face-to-face requirement also includes examinations conducted via the CMS-approved use of telehealth examinations, which must meet the requirements of 42 CFR §§410.78 and 414.65 for purposes of DMEPOS coverage.

A WOPD must be completed within six months after the required face-to-face encounter.

Refer to the applicable LCD-related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for more information regarding documentation requirements.

The six-month timing requirement does not supplant other coverage or documentation requirements.

There must be sufficient medical information included in the medical record to demonstrate that all other applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

For items other than PMDs that appear on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner that conducted the face-to-face encounter does not need to be the prescriber for the DMEPOS item; however, the prescriber must:

- Verify that a qualifying face-to-face encounter occurred within the six months prior to the date of their prescription; and,
- Have documentation of the qualifying face-to-face encounter that was conducted.

A qualifying face-to-face encounter is required each time a new order/prescription for one of the specified items on the Required Face-to-Face Encounter and Written Order Prior to Delivery List is ordered. A single face-to-face encounter may document the clinical conditions necessitating multiple DMEPOS items. In this situation, regardless of whether the DMEPOS items are prescribed on different dates, the single face-to-face encounter may be utilized in support of the multiple items, so long as the encounter date is within six months prior to the date of the orders.

The CMS and DME MACs post on their websites the Required Face-to-Face Encounter and Written Order Prior to Delivery List of selected HCPCS codes, once published through the Federal Register Notice. The List will be periodically updated.

Upon request by a contractor, all DMEPOS suppliers must provide documentation of the face-to-face encounter.

Claim Denial

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes in the “Required Face-to-Face Encounter and Written Order Prior to Delivery List.”

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related *Standard Documentation Requirements Article* (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

DME MAC LCD-related Policy Articles also include information pertinent to the required Face-to-Face Encounter and Written Order Prior to Delivery List. This information is located within the section labeled "REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217)."

Suppliers are reminded that some DME MAC LCDs include requirements of an "in-person" visit or encounter between the practitioner and beneficiary. This "in-person" visit or encounter is not the requisite "face-to-face" encounter of the Required Face-to-Face Encounter and Written Order Prior to Delivery List requirements. While the "in-person" encounter requirement in LCDs and the "face-to-face" encounter in the Face-to-Face Encounter and Written Order Prior to Delivery List are separate requirements of documentation, both can be satisfied by a single qualifying interaction between the practitioner and the beneficiary when the requirements of each are supported in the medical record of the single interaction.

PMD Denials:

As a condition of payment pursuant to 42 CFR §410.38, Power Mobility Devices (PMDs) require a standard Written Order Prior to Delivery (WOPD) for the base item. If the supplier does not receive the order/prescription for the base item prior to delivery, the claim will be denied as not reasonable and necessary.

Pursuant to the Social Security Act, Title XVIII, §1834(a)(1)(E)(iv), payment may not be made for a motorized or power wheelchair unless the treating practitioner conducts the face-to-face encounter and writes the Standard Written Order (SWO). If the treating practitioner does not conduct the face-to-face encounter or write the SWO for the PMD base item, the claim will be denied as statutorily noncovered.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial date of service to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the date of service under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order/prescription by the treating practitioner for refills of supplies
- A recent order/prescription by the treating practitioner for repairs
- A recent change in order/prescription
- Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified in policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

You are responsible for monitoring utilization of DMEPOS rental items and supplies. Monitoring of purchased items or capped rental items that have converted to a purchase is not required. You must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or your records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories, and supplies.
- Your records documenting the request for refill/replacement of supplies in compliance with the refill documentation requirements section. This is deemed to be sufficient to document continued use for the base item as well.
- Your records documenting beneficiary confirmation of continued use of a rental item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified in policy.

5. Signature Requirements

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, §3.3.2.4

For medical review purposes, Medicare requires that services provided/ordered/certified be authenticated by the persons responsible for the care of the beneficiary in accordance with Medicare's policies. For example, if the practitioner's authenticated documentation corroborates the nurse's unsigned note, and the practitioner was the responsible party per Medicare's payment policy, medical reviewers would consider signature requirements to have been met. The method used shall be a handwritten or electronic signature. Stamped signatures are not acceptable.

The *Medicare Program Integrity Manual* notes several exceptions to normal signature requirements, as listed below:

EXCEPTION 1: Facsimiles of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice.

EXCEPTION 2: There are some circumstances for which an order does not need to be signed. For example, orders for some clinical diagnostic tests are not required to be signed. The rules in 42 CFR §410 and Pub.100-02 Chapter 15, §80.6.1 state that if the order for the clinical diagnostic test is unsigned, there must be medical documentation (e.g., a progress note) by the treating practitioner that they intended the clinical diagnostic test be performed. This documentation showing the intent that the test be performed must be authenticated by the author via a handwritten or electronic signature.

EXCEPTION 3: Other regulations and the CMS' instructions regarding conditions of payment related to signatures (such as timeliness standards for particular benefits) take precedence. For medical review purposes, if the relevant regulation, NCD, LCD, and CMS manuals are silent on whether the signature needs to be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed in the *Medicare Program Integrity Manual*, Chapter 3, to discern the identity and credentials (e.g., MD, RN, etc.) of the signator. In cases where the relevant regulation, NCD, LCD, and CMS manuals have specific signature requirements, those signature requirements take precedence.

EXCEPTION 4: CMS would permit use of a rubber stamp for signature in accordance with the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof to a CMS contractor of their inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.

6. Refills of DMEPOS Items Provided on a Recurring Basis

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.2.6*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

For DMEPOS items and supplies that are provided on a recurring basis, billing must be based on prospective, not retrospective use. The following scenarios are illustrative of this concept:

Scenario 1: The treating practitioner writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order, delivers 100 units, and bills the claim with a date of service as the date of delivery indicating 100 units. This is an example of prospective billing and is acceptable.

Scenario 2: The treating practitioner writes an order for enteral nutrition which translates into the dispensing of 100 units of nutrient for one month. The supplier receives the order and delivers 100 units. A claim is not billed. At the end of the month, the supplier determines that the beneficiary used 90 units for the month and delivers 90 units to replace the nutrient used. A claim is then submitted with a date of service as the date of delivery indicating 90 units of enteral nutrition. This is an example of retrospective billing and is not acceptable.

For DMEPOS products that are supplied as refills to the original order, you must contact the beneficiary or caregiver/designee and document an affirmative response, prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, you must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

You must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. You must stay attuned to changed or atypical utilization patterns on the part of your clients. You must verify with the prescribing practitioner that any changed or atypical utilization is warranted.

DME MACs allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting their supply.

REFILL DOCUMENTATION

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order/prescription for the DMEPOS item from the transferring supplier.
- There is a change in the order/prescription for the DMEPOS item.
- When an item is replaced.
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy.

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be individualized to the beneficiary (i.e., the beneficiary or their caregiver/designee affirms the need for refill) and documented in the record. Medicare does not prescribe the mode of communication used to gather the information. For example, the refill request communication may be performed via automated text messaging or email as long as each required aspect of the refill request is captured. The refill request and affirmative response must occur and be documented before shipment. A retrospective attestation statement by you or the beneficiary is not sufficient.

The refill record must include:

- The beneficiary's name or authorized representative, if different than the beneficiary.
- A description of each item that is being requested.
- Documentation of affirmative response indicating a need for refill.
- Date of refill request.

This information must be kept on file and be available upon request.

7. Beneficiary Authorization

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 1

You may only receive Medicare payment if the beneficiary assigns his or her Medicare benefits to you. Regulations authorize Medicare to pay for claims submitted by a supplier only if the beneficiary or the person authorized to request payment on the beneficiary's behalf assigns the claims to the supplier and the supplier accepts assignment. For all claims submitted on or after January 1, 2005, payment shall be made to physicians and suppliers even without a beneficiary-signed assignment of benefits (AOB) form when the service can only be paid on an assignment related basis. This includes any mandatory assignment situations and participating physician or supplier situations. When you accept assignment, you must accept Medicare's determination of the approved amount as the full fee for the service(s) rendered. For more information about beneficiary authorization, see the Chapter 6 of this manual.

8. Proof of Delivery (POD)

SUPPLIER PROOF OF DELIVERY DOCUMENTATION REQUIREMENTS

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual,* Chapter 17, §80.3.3; Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 4, §4.7.3.1 – 4.7.3.1.3 & Chapter 5, §5.10*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

You are required to maintain proof of delivery documentation in your files. Documentation must be maintained in your files for seven years.

Proof of delivery is one of the supplier standards as noted in 42 CFR §424.57(c)(12) and in Chapter 2 of this manual. In certain instances, compliance with proof of delivery may be required as a condition of payment and must be available to the DME MAC, RAC, SMRC, CERT, and UPIC on request. For such items, if the supplier does not have appropriate POD documentation within the prescribed timeframes, associated claims will be denied and overpayments will be recouped. Note that non-compliance with supplier standards may also result in revocation from the Medicare program. If you consistently do not provide documentation to support your services, you may be referred to the Office of Inspector General or the National Provider Enrollment (NPE) for investigation and/or imposition of sanctions. If the beneficiary is newly eligible to Medicare FFS, the proof of delivery standards require the supplier to obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item, and the supplier must attest that the item meets Medicare requirements.

PROOF OF DELIVERY AND DELIVERY METHODS

For the purpose of the delivery methods noted below, **designee** is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

You, your employees, or anyone else having a financial interest in the delivery of the item(s) are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The relationship of the designee to the beneficiary should be noted on the delivery document that you obtain (i.e., spouse, neighbor, etc.). The signature of the designee should be legible. If the signature of the designee is not legible, you (or the shipping service) should note the name of the designee on the delivery document.

There are three methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service
3. Delivery of items to a nursing facility on behalf of the beneficiary

Regardless of the method of delivery, the contractor must be able to determine that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are received by a specific Medicare beneficiary.

Method 1—Direct Delivery to the Beneficiary

You may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- A description of the item(s) being delivered. The description can be a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee, or you. When your delivery documents have both your entered date and a beneficiary or beneficiary's designee signature date on the POD document, the beneficiary or beneficiary's designee-entered date is the date of service.

In instances where the supplies are delivered directly by you, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If you utilize a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from you to the beneficiary. An example of acceptable proof of delivery would include both your detailed shipping invoice and the delivery service's tracking information. Your record must be linked to the delivery service record by some clear method like the delivery service's package identification number or your invoice number for the package sent to the beneficiary.

The POD document must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, your invoice number, or alternative method that links your delivery documents with the delivery service's records

- A description of the item(s) being delivered. The description can be a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.
- Quantity delivered
- Date delivered
- Evidence of delivery

If you utilize a shipping service or mail order, you have two options for the DOS to use on the claim:

1. You may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. You may use the date of delivery as the DOS on the claim.

You may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD document must contain the information specified above.

Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary

For items directly delivered by you to a nursing facility or when a delivery service or mail order is used to deliver the item(s) to a nursing facility, then you must have:

1. Documentation demonstrating delivery of the item(s) to the facility by you or delivery entity; and
2. Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the beneficiary. The quantities delivered and used by the beneficiary must justify the quantity billed.

This information must be available upon request.

EXCEPTIONS

Early Delivery to an Inpatient Facility in Anticipation of Discharge

Per the *Medicare Program Integrity Manual*, Chapter 4, you may deliver DME, prosthetic, or orthotic items, but not supplies, to a beneficiary in an inpatient facility that does not qualify as the beneficiary's home, for the purpose of fitting or training the beneficiary in the proper use of the item. Delivery may be done up to two days prior to the beneficiary's anticipated discharge to their home. You must bill the date of service on the claim as the date of discharge and shall use the Place of Service (POS) as 12 (home). The item must be medically necessary on the date of discharge and the item must be for subsequent use in the beneficiary's home. On the date of discharge, you must ensure that the beneficiary takes the item home, or that you pick up the item at the facility and deliver it to the beneficiary's home. No billing may be made for the item on those days the beneficiary was receiving training or fitting in the hospital or nursing facility.

Example:

1. A beneficiary is admitted to a hospital stay on June 1.

2. The beneficiary will require the use of a walker upon discharge and must be trained on its use while in the hospital. The walker is provided to the beneficiary in the hospital on June 5.

3. The beneficiary is discharged from the hospital on June 6.

You would then bill the claim to the DME MAC using June 6 as the date of service.

Early Delivery to Home in Anticipation of Discharge

In some cases, it would be appropriate for you to deliver a medically necessary item of DME, a prosthetic, or an orthotic (but not supplies) to a beneficiary's home in anticipation of discharge to a Place of Service (POS) that qualifies as home. You may deliver an item of DME, a prosthetic or an orthotic to a beneficiary's home in anticipation of discharge from a hospital or nursing facility. You may arrange for actual delivery of the item(s) no sooner than two days prior to the beneficiary's anticipated discharge to their home. You shall bill the date of service on the claim as the date of discharge and shall use the POS as 12 (home).

Early Delivery of Immunosuppressive Drugs

Per the *Medicare Program Integrity Manual*, Chapter 4, delivery of immunosuppressive drugs may be made to the beneficiary's home (i.e., their own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution— such as an assisted living facility or an intermediate care facility for individuals with intellectual disabilities [ICF/IID], but not a hospital or skilled nursing facility). In certain cases, a beneficiary who has received a transplant does not return home immediately after discharge. In order to ensure beneficiary access to prescribed immunosuppressive medications at the time of discharge, you may deliver the initial prescriptions of a beneficiary's immunosuppressive drugs to an alternate address, such as the inpatient hospital that performed the transplant or alternative location where the beneficiary is temporarily staying (e.g., temporary housing), instead of delivering the drugs to the beneficiary's home address.

This is an optional, not mandatory, process. If you ship immunosuppressive drugs to an alternate address, all parties involved, including the beneficiary and the transplant facility, must agree to the use of this approach. You will not receive additional payment for delivery to an alternate location.

Note that the following conditions also apply:

1. The facility remains responsible for all immunosuppressive drugs required by the beneficiary for the duration of the beneficiary's inpatient stay. You must not receive separate payment for immunosuppressive drugs prior to the date the beneficiary is discharged.

2. You must not mail or otherwise dispense the drugs any earlier than two days before the beneficiary is discharged. It is your responsibility to confirm the beneficiary's discharge date if they choose to utilize this option. You must enter the date of discharge as the date of service on the claim.

3. You must not submit a claim for payment prior to the beneficiary's date of discharge.

General Information

No billing may be made for any day prior to the date of discharge. You may not bill for drugs or other DMEPOS items used by the beneficiary prior to the beneficiary's discharge from the hospital or a Medicare Part A nursing facility stay. Billing the DME MAC for surgical dressings, urological supplies, or ostomy supplies that are provided during a stay in an inpatient facility that does not qualify as the beneficiary's home is not allowed. These items are payable to the facility under Medicare Part A. This applies even if the beneficiary wears the item home from the hospital or

nursing facility. Any attempt by you and/or the facility to substitute an item that is payable to you for an item that, under statute, should be provided by the facility, may be considered to be fraudulent. These statements apply to durable medical equipment delivered to a beneficiary in hospitals, skilled nursing facilities (Place of Service = 31), or nursing facilities (Place of Service = 32).

There is no separate payment from either Medicare or the beneficiary if, for any reason, redelivery is necessary. All other applicable Medicare and DME MAC billing requirements continue to apply.

Equipment Retained from a Prior Payer

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage Plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary's medical condition, the beneficiary must meet all Medicare coverage, coding, and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim.

A POD is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility. To meet the POD requirements for a beneficiary transitioning to Medicare you, the supplier, must have on record:

- A statement, signed and dated by the beneficiary (or beneficiary's designee), that you have examined the item; and
- Your attestation, that the item meets Medicare requirements.

For the purposes of reasonable useful lifetime and calculation of continuous use, the first day of the first rental month in which Medicare payments are made for the item (i.e., date of service) serves as the start date of the reasonable useful lifetime and period of continuous use. In these cases, the proof of delivery documentation serves as evidence that the beneficiary is already in possession of the item.

Please refer to the Internet Only Manual (IOM), 100-08, Chapter 4, for additional information regarding all proof of delivery requirements.

9. Advance Beneficiary Notice of Non-coverage (ABN)

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 20, §120 & Chapter 30, §§40.2.1-40.2.2 & §50

An Advance Beneficiary Notice of Non-coverage (ABN) is a written notice that allows the beneficiary to make an informed consumer decision as to whether or not to receive the items or services for which he or she may be required to pay out of pocket or through other insurance.

You must issue an ABN to a Medicare beneficiary before providing items and/or services when such items and/or services are those generally paid for by Medicare, but for which, in a particular situation, are expected to deny. In this scenario, the issuance of an ABN is considered mandatory. An ABN must be issued prior to dispensing an item or service expected to be disallowed for the following reasons:

- Lack of medical necessity
- Prohibited, unsolicited telephone contacts

- Supplier number requirements not met
- Medical equipment and/or supplies denied in advance
- Noncontracted suppliers in a competitive bidding area (CBA)

If you fail to issue a properly executed ABN, you will be held liable for the item and/or service and may not bill or collect, or must refund amounts collected, from the beneficiary.

Other situations may prompt provision of an ABN in which the use of the ABN is considered optional (not mandatory) yet strongly encouraged. Situations applicable to voluntary issuance of an ABN include notification to the beneficiary that an item or service is not covered by the Medicare Program due to either statutory exclusion or having not met a technical benefit requirement. When a voluntary ABN is issued, the beneficiary should not be asked to sign the notice or select an option box in the form. Voluntary ABNs are courtesy notifications informing beneficiaries of impending financial obligations.

You must retain a copy of the signed ABN on file. The ABN should not be submitted with the claim, but is required when responding to an additional documentation request for a complex review, in which case CGS will conduct a face validity assessment of the ABN to ensure liability is assigned appropriately in accordance with the Limitation of Liability Provisions.

The current version of the Advance Beneficiary Notice of Non-coverage (ABN) is form CMS-R-131 (Exp. 01/31/2026). Other forms will be considered invalid. The ABN form CMS-R-131 (Exp. 01/31/2026) and step-by-step completion instructions are available on CMS' Beneficiary Notices Initiative web page at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html.

For an ABN to be acceptable, it must:

- Be on the approved CMS-R-131 (Exp. 01/31/2026) form;
- Clearly identify your name, address, and telephone number;
- Clearly identify the beneficiary;
- Clearly identify the particular item and/or service;
- State that you believe Medicare is likely (or certain) to deny payment for the particular item and/or service; and
- Give your reason(s) for your belief that Medicare is likely (or certain) to deny payment for the item and/or service.
- Give a reasonable estimate cost of the noncovered item and/or service
- Be signed and dated by the beneficiary or representative.

As of October 14, 2021, once you have secured a valid ABN, the ABN remains effective and a new ABN is not required unless there is a change in any of the following:

- Care from what is described on the original ABN (such as the addition of items or services to the beneficiary's treatment that were not included on the original ABN).
- The beneficiary's health status which would require a change in the subsequent treatment for the non-covered condition.

- The Medicare coverage guidelines for the items or services in question (i.e., updates or changes to the policy of an item or service).

For items or services that are repetitive or continuous in nature, notifiers may issue another ABN to a beneficiary after one year for subsequent treatment for the non-covered condition. However, this is not required unless any of the conditions described above apply to the given situation.

ABNs apply to assigned and nonassigned claims, as there are financial liability provisions under Medicare law for both claim types:

Limitation of liability (LOL) applies to **assigned** claims for DMEPOS services disallowed because of medical necessity, due to prohibition on unsolicited telephone calls, no supplier number, or medical equipment and supplies denied in advance. Under LOL, a beneficiary can be held liable for a service denied due to reasons cited on the ABN.

Refund requirements (RR) apply to **assigned and non-assigned** claims for DMEPOS services disallowed because of medical necessity, due to prohibition on unsolicited telephone calls, no supplier number, or no ADMC. RR state that suppliers must make refunds of any amounts collected if the beneficiary was not properly notified of possible disallowed Medicare claims. The RR provisions require that the beneficiary is notified and agrees to be financially liable.

If you render a service which Medicare considers not medically necessary to a beneficiary, you should notify the beneficiary in writing, **before rendering the service**, that Medicare is likely to deny the claim and that the beneficiary will be responsible for payment. Modifier “GA” should be indicated on the Medicare claim with the appropriate HCPCS code when it is filed. See Chapter 16 of this manual for more information about modifiers.

The following statements are examples of reasons for your belief that Medicare is likely to deny payment:

- Medicare does not usually pay for this many treatments or services
- Medicare usually does not pay for this service
- Medicare does not pay for this because it is a treatment that has yet to be proved effective (experimental)
- Medicare does not pay for this many services within this period of time
- Medicare does not pay for such an extensive treatment

General statements such as “I never know if Medicare will deny payment” are not acceptable.

The beneficiary or their representative has the right to appeal a claim decision if there is dissatisfaction with the amount of payment, denial of coverage for services or supplies, or if the original claim was not acted upon within a reasonable time. You have the right to appeal a claim decision when you accept assignment.

As a supplier providing items and services to Medicare beneficiaries, you may appeal an initial determination if:

- You accepted assignment on the claim; or
- You are acting as the duly authorized representative of the beneficiary.

- You are a non-participating supplier of DME potentially responsible for making a refund to the beneficiary under §1834(a)(18) of the Act.
- You are a supplier of medical equipment and supplies not taking assignment and who is responsible for making a refund to the beneficiary under §1834(j)(4) of the Act.

See chapter 13 of this manual for more information about appeals.

When you furnish an upgraded item of DMEPOS and expect Medicare to reduce the level of payment based on a medical necessity partial denial of coverage for additional expenses attributable to the upgrade, you must give an ABN to the beneficiary for signature for holding the beneficiary liable for the additional expense.

In general, the "routine" use of ABNs is not effective. By "routine" use, CMS means giving ABNs to beneficiaries where there is no specific, identifiable reason to believe Medicare will not pay. Notifiers should not give ABNs to beneficiaries unless the notifier has some genuine doubt that Medicare will make payment as evidenced by their stated reasons. Giving routine notices for all claims or services is not an acceptable practice. If the contractor identifies a pattern of routine notices in situations where such notices clearly are not effective, it will write to the notifier and remind it of these standards. In general, routinely given ABNs are defective notices and will not protect the notifier from liability. However, ABNs may be routinely given to beneficiaries when all or virtually all beneficiaries may be at risk of having their claims denied. Please refer to the IOM, 100-04, Chapter 30, §40.2.2 for circumstances in which ABNs may be routinely given.

For complete instructions on using an ABN, refer to the CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 30, §50, which is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf. Instructions are also available on the Beneficiary Notices Initiative Web page at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html.

10. Amendments, Corrections, and Delayed Entries in Medical Documentation

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, §3.3.2.5

Per CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, all services provided to beneficiaries are expected to be documented in the medical record at the time they are rendered. Occasionally, certain entries related to services provided are not properly documented. In these cases, the documentation will need to be amended, corrected, or entered after rendering the service. When making review determinations, only entries that comply with the widely accepted Recordkeeping Principles described below will be considered. Entries that do not comply with the principles listed below will not be considered, even if such exclusion will lead to claim denial. For example, undated or unsigned entries handwritten in the margin of a document will not be considered.

Recordkeeping Principles

Both paper record and electronic health record documents containing amendments, corrections or addenda must:

1. Clearly and permanently identify any amendment, correction or delayed entry as such, and

2. Clearly indicate the date and author of any amendment, correction or delayed entry, and

3. Clearly identify all original content, without deletion.

Paper Medical Records—Corrections are generally accomplished by:

1. Using a single line strike through so the original content is still readable, and

2. The author of the alteration must sign and date the revision.

Amendments or delayed entries to paper records must be clearly signed and dated upon entry into the record. Amendments or delayed entries to paper records may be initialed and dated if the medical record contains evidence associating the provider's initials with their name. For example, the initials match the first and last name of the practitioner documented elsewhere in the medical records including typed or written identifying information.

Electronic Health Records (EHR): Records sourced from electronic systems containing amendments, corrections, or delayed entries must:

a) Distinctly identify any amendment, correction or delayed entry, and

b) Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record.

11. Repair/Maintenance/Replacement

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §§110.2 & 120; Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Under the circumstances specified in the *Medicare Benefit Policy Manual*, payment may be made for repair, maintenance, replacement, and delivery of medically-required DME which the beneficiary owns or is purchasing, including equipment which had been in use before the user enrolled in Part B of the Medicare program. In addition, payments for repair and maintenance may not include payment for parts and labor covered under a manufacturer's or supplier's warranty.

Repairs/Replacement to DMEPOS (Except Artificial Limbs)

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §110.2; Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.10.1; *Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Repair

A treating practitioner's order is not needed for repairs.

In the case of repairs to a beneficiary-owned DMEPOS item, if Medicare paid for the base equipment initially, medical necessity for the base equipment has been established. With respect to Medicare reimbursement for the repair, there are two documentation requirements:

1. The treating practitioner must document that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and

2. Either the treating practitioner or you must document that the repair itself is reasonable and necessary.

You must maintain detailed records describing the need for and nature of all repairs, including a detailed explanation of the justification for any component or part replaced, as well as the labor time to restore the item to its functionality.

Replacement

The CMS *Medicare Benefit Policy Manual* (IOM, Pub. 100-02), Chapter 15, §110.2.C, generally defines replacement as the provision of an entirely identical or nearly identical item when it is lost, stolen, or irreparably damaged.

Beneficiary-owned items or capped rental items may be replaced in cases of loss or irreparable damage. Irreparable damage may be due to a specific accident or to a natural disaster (e.g., fire, flood). Contractors may request documentation confirming details of the incident (e.g., police report, insurance claim report).

Replacement of items due to irreparable wear takes into consideration the reasonable useful lifetime (RUL) of the item. The RUL of DME is determined through program instructions. In the absence of program instructions, carriers may determine the RUL, but in no case can it be less than five years. If the item has been in continuous use by the beneficiary on either rental or purchase basis for its RUL, the beneficiary may elect to obtain a replacement.

Medicare does not cover replacement for items in the frequent and substantial servicing payment category, oxygen equipment, or inexpensive or routinely purchased rental items.

A treating practitioner's order, when required, is needed to reaffirm the medical necessity for replacement of an item.

Repair/Replacement Applying to Artificial Limbs

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §120*; Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*

Adjustments and repairs of prostheses and prosthetic components are covered under the original order for the prosthetic device.

Medicare payment may be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if a treating practitioner determines that the replacement device, or replacement part of such a device, is necessary.

Claims involving the replacement of a prosthesis or major component (foot, ankle, knee, socket) must be supported by a new treating practitioner's order and documentation supporting the reason for the replacement. The reason for replacement must be documented by the treating practitioner, either on the order or in the medical record, and must fall under one of the following:

1. A change in the physiological condition of the beneficiary resulting in the need for a replacement. Examples include but are not limited to: changes in beneficiary weight, changes in the residual limb, and beneficiary functional need changes; or

2. An irreparable change in the condition of the device or in a part of the device resulting in the need for a replacement; or

3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

The prosthetist must retain documentation of the prosthesis or prosthetic component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. This information must be available upon request. It is recognized that there are situations where the reason for replacement includes but is not limited to: changes in the residual limb, functional need changes, or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

Refer to the individual medical policies for specific coverage and payment provisions.

12. Delivery and Service Charges

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 20, §60

Delivery and service are an integral part of the costs of doing business if you are an oxygen and durable medical equipment (DME) supplier. Such costs are ordinarily assumed to have been taken into account (along with all other overhead expenses) in setting the prices that you charge for covered items and services. As such, these costs, whether rented or purchased, have already been accounted for in the calculation of the fee schedules. Therefore, separate delivery and service charges for DMEPOS items will not be allowed except in rare and unusual circumstances when the delivery is outside the normal range of your sphere of operation. For example, a reasonable delivery charge might be allowed if you had to deliver a DMEPOS item to a beneficiary who lived outside your usual customer area and who had no access to another supplier located nearer. You must fully document these “unusual circumstances” on claims filed for delivery charges. These claims will be considered on an individual basis.

13. Same/Similar Equipment and Advance Beneficiary Notices of Non-coverage (ABN)

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 30

This concerns ANSI Reason Code M3 - “Equipment is the same or similar to equipment already being used.” See Chapter 17 of this manual for information about ANSI Reason Codes.

Numerous claims for durable medical equipment are denied because the equipment involved is the same as or similar to equipment already in the possession of the beneficiary. The statutory basis for denial of such claims is medical necessity; therefore, the limitation of liability provision under §1879 of the law applies. Backup equipment (standby and precautionary) has no coverage benefit and is considered not medically necessary. See the section *Backup Equipment* below.

Liability is assessed on claims denied based on “same or similar equipment.” You are expected to be familiar with DME MAC coverage policies and any additional pertinent information that may have an impact on medical necessity determinations. In order to be protected under the limitation of liability provision, you must provide a proper advance beneficiary notice of non-coverage (ABN) for each item that you believe is likely to be denied as not medically necessary.

There must be a specific, identifiable reason to believe that Medicare may not pay for certain DME items (e.g., "same or similar equipment"). This means that you must obtain all the possible information from beneficiaries in order to determine whether "same or similar equipment" has previously been provided to that beneficiary. You should ask very specific questions when providing items to Medicare beneficiaries. When providing equipment to beneficiaries, the following information should always be obtained:

- The beneficiary's correct Medicare ID
- If the beneficiary has employer insurance or is enrolled in a Medicare Advantage Plan
- If the beneficiary currently has or had rental or ownership of an identical or similar item(s) in the past, you should obtain specific information about:
    a. When the beneficiary received the item(s), and if the item(s) was returned, when and why
    b. Who supplied the item(s)
- Where the item will be used
- A signed and dated written order from the prescribing practitioner
- Clinical documentation that demonstrates any change in medical need

You may also access information about previously submitted same or similar equipment through the myCGS Web Portal or the CGS Interactive Voice Response (IVR) System. For more information about myCGS and the IVR, see Chapter 13 of this manual. Also refer to the myCGS page on our website at https://cgsmedicare.com/jb/mycgs/index.html.

You should make certain that the beneficiary understands that items such as wheelchairs and power-operated vehicles are considered "similar equipment" and that Medicare will not cover both items when they are used simultaneously. You should strongly encourage the beneficiary to inform you if the medical need for the item changes and the beneficiary requires a different piece of equipment that serves a similar purpose. The Medicare program will only allow items that meet the beneficiary's current needs.

For example, if a beneficiary is renting a manual wheelchair and their condition worsens to the point that only a different wheelchair, such as a power wheelchair, will meet their medical need, coverage will be allowed for the power wheelchair and any subsequent claims for the manual wheelchair will be denied.

If there is no indication that same or similar equipment has been previously obtained, you would not have reason to provide an ABN. If the beneficiary or the beneficiary's authorized representative is unable to respond fully on the issue of "same or similar equipment," you may issue an ABN. In situations where the beneficiary is planning to use a piece of equipment as a backup (e.g., an extra wheelchair to keep in the car), you should ALWAYS obtain a signed ABN. In the event that you appeal a Medicare claim decision, you must submit a copy of the ABN with the appeal request (see Chapter 13 of this manual for information about appeals).

Same or similar rules may not necessarily apply to situations where a new device with additional technological features becomes available. The DME MAC or UPIC must evaluate whether the new feature(s) meets the beneficiary's medical need and that the need is not met by their current equipment. If the new feature or device meets a current medical need that is not met by the current equipment because the appropriate technology was not available at the time the beneficiary obtained the item, even if there has been no change in the beneficiary's condition, the five-year useful lifetime rules do not apply and the new item may be provided. However, if the new item is meeting the same medical need as the old item but in a more efficient manner or is more convenient, AND there is no change in the beneficiary's condition, Medicare will NOT reimburse for the new item.

The following examples illustrate these instructions:

1. The beneficiary receives a power wheelchair *without* power tilt/recline. Subsequently it is determined that the beneficiary needs a tilt/recline AND he/she has needed it since the provision of the initial power wheelchair. Often, the old wheelchair base will not accommodate the new tilt/recline system; therefore, in addition to the tilt/recline, you ask for a wheelchair base to be reimbursed. In this case one of the following options would apply:

   A. If the old wheelchair is rented, an additional amount for the tilt/recline would be allowed but not a new rental period for the new wheelchair base.

   B. If the old wheelchair was purchased, only reimbursement of the tilt/recline would be allowed and not the purchase of a new wheelchair base.

2. Code E2101 represents a code for a home glucose monitor that integrates the lancing and application of blood to the glucose testing strip in one machine. The Glucose Monitors LCD allows payment for these devices for beneficiaries with manual dexterity problems. If a beneficiary had manual dexterity problems at the time that an E0607 monitor was purchased and the technology of monitors coded E2101 was not available at the time the beneficiary obtained the E0607, they would be allowed to purchase the E2101 to address their medical need for a monitor that accommodates their dexterity problem. No "same or similar" denial would apply. The E0607 did not accommodate their medical need and while their medical need did not change, technology changed such that their medical need could now be met by the new technology.

These rules apply when the new device with advanced features is classified by the same HCPCS code as the older device or when described by a different HCPCS code. If, however, the new device is described by a different code, the beneficiary must also meet the coverage criteria of the new item.

Medicare regulation specifically forbids payments for multiple claims for rental of the same or similar equipment from either the same or a different supplier during the same rental month.

14. Pick-up Slips

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.14

A pick-up slip is written confirmation, provided by you, that you have removed an item of DME from the beneficiary's home. When making determinations, DME MACs or UPICs must ascertain not only whether equipment is present in the home, but must determine which equipment is actually being used by the beneficiary. Therefore, it is inappropriate to determine, solely based on lack of a pick-up slip that a piece of equipment may still be in use.

15. Backup Equipment

Backup medical equipment is defined as an identical or similar device that is used to meet the same medical need for the beneficiary but is provided for precautionary reasons to deal with an emergency in which the primary piece of equipment malfunctions. **Medicare does not pay separately or make an additional payment for backup equipment.**

When a determination is made that if a particular piece of equipment breaks down or malfunctions it will result in immediate life-threatening consequences for the beneficiary, Medicare will place that item in the frequent and substantial servicing payment category (see Chapter 5 of this manual for information about payment categories). For items in this payment category, Medicare will reimburse for monthly rental payments for as long as the equipment is medically necessary. Consequently, you are responsible for ensuring that there is an appropriate and acceptable contingency plan to address any emergency situations or mechanical failures of the equipment.

The expectation is that an acceptable plan would involve input from the beneficiary and the treating practitioner and would take into account the severity of the beneficiary's condition and time restraints in providing emergency support. This means that you are responsible for ensuring that the beneficiary's medical needs for the use of this equipment will be met on a continuous and ongoing basis and that there is a plan to deal with any interruptions in the use of the equipment that would be life-threatening to the beneficiary. The plan may be as simple as furnishing backup equipment; however, Medicare will not pay separately and/or make any additional payment for the backup equipment. The payment for the primary piece of equipment would include the cost of that piece of equipment and the frequent and substantial servicing plan that you must provide to ensure that the beneficiary always has a piece of equipment that is in working order. If the backup equipment is billed, it will be denied as not being reasonable and necessary.

Backup equipment must be distinguished from multiple medically necessary items that are defined as identical or similar devices, each of which meets a different medical need for the beneficiary. Although Medicare does not pay separately for backup equipment, Medicare will make separate payment for a second piece of equipment if it is required to serve a different purpose that is determined by the beneficiary's medical needs.

Examples (not all-inclusive) of situations in which multiple items may be covered are:

1. A beneficiary requires one type of ventilator (e.g., a negative pressure ventilator with a chest shell) for part of the day and needs a different type of device (e.g., positive pressure respiratory assist device with a nasal mask) during the rest of the day.

2. A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without both pieces of equipment, the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively.

3. A beneficiary requires one type of infusion pump for a particular drug (e.g., a pump with beneficiary control features for parenteral morphine) and needs a different type of pump for another drug (e.g., continuous infusion chemotherapy).

Examples (not all-inclusive) of situations in which a second or other multiple pieces of equipment would be considered a backup and therefore would not be covered are:

1. A ventilator-dependent beneficiary is confined to bed and a second ventilator of the same or similar type is provided at the bedside as a precaution in case of malfunction of the primary ventilator.

2. The drug epoprostenol (Flolan) is administered using an ambulatory infusion pump, and a second infusion pump is provided and billed as a precaution in case of malfunction of the primary pump. Because interruption of a continuous infusion of this drug results in immediate life-threatening consequences, a unique code, K0455, has been established for an infusion

pump used to administer this drug, and the code is in the frequent and substantial servicing payment category.

16. Correct Coding

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, §3.3

Correct coding is a determination that the item(s) provided to the beneficiary has been billed using the appropriate HCPCS code for the item. You are required to correctly code for the items billed. An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, or DME MAC articles. Information that is sufficiently detailed to unambiguously identify the specific product delivered to the beneficiary and the HCPCS code used to bill for that item must be maintained by the supplier and be available upon request.

For LCDs and LCD-related Policy Articles that use International Classification of Diseases 10th Edition Clinical Modification (ICD-10-CM) diagnosis codes, correct coding of the ICD-10-CM code is required. A diagnosis is correctly coded when it meets all the coding guidelines listed in International Classification of Diseases Guidelines (ICD), CMS ICD policy or guideline requirements, LCDs, or DME MAC articles. Information that is sufficiently detailed to unambiguously justify the ICD-10-CM code used to bill for DMEPOS items must be contained in the beneficiary's medical record and be available upon request.

17. Miscellaneous HCPCS Codes

Unusual services and items are generally reported to the contractor with miscellaneous HCPCS codes. These miscellaneous HCPCS codes do not have established fee schedule reimbursement rates. Each item/service is processed based on individual consideration. In these situations you must include a narrative on your claim that describes the service or item, manufacturer name, product name and number, supplier price list (PL) amount, and HCPCS code of a related item (if applicable). If it is a customized option/accessory, the statement must clearly describe what was customized. When necessary, consultants' advice will be obtained.

If the description, manufacturer name, product name, and product number, supplier PL amount, and HCPCS code of a related item (if applicable) are not provided with the claim, then the claim will be rejected for missing information and you will be responsible for resubmitting the claim with the appropriate information.

A claim for an option/accessory code as a replacement must be submitted with the make and model/brand name of the base equipment to which the replacement item is being added, along with the date of the purchase for the base equipment. Documentation of the medical necessity for the item must be kept on file and available upon request.

The definitions of HCPCS codes are meant to be broadly inclusive. All related components are included in the codes and should generally not be billed separately unless specifically allowed in the definition or description of a HCPCS code. If you choose to bill separately for an included component, consult DME MAC articles and applicable LCDs and LCD-related Policy Articles for specific coding and coverage information (where available) for such components. Unless specified otherwise in a DME MAC article or medical policy, when billing separately for an included component, you must use HCPCS code A9900 (MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE) for DME-related components, and L9900 (ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE

COMPONENT OF ANOTHER HCPCS "L" CODE) for orthotic and prosthetic-related components. Claim lines submitted for either HCPCS code (A9900 or L9900) will be denied as not separately payable.

18. Evidence of Medical Necessity: Power Mobility Devices (PMD)

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5

As the result of the way that the Social Security Act defines durable medical equipment, a power mobility device (PMD) is covered by Medicare only if the beneficiary has a mobility limitation that significantly impairs their ability to perform activities of daily living **within the home**. The beneficiary's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker. If the PMD is needed in the home, the beneficiary may also use it outside the home.

In order for Medicare to provide reimbursement for a PMD, there are specific requirements that must be met:

Standard Written Order

As a condition of payment pursuant to 42 CFR §410.38, PMDs require a standard written order prior to delivery (WOPD) for the base item. The order must only be written after the in-person visit has occurred and the medical evaluation is completed.

Pursuant to the Social Security Act, Title XVIII, §1834(a)(1)(E)(iv), the standard written order for the PMD base item must be written and signed by the treating practitioner who performed the face-to-face encounter.

You may provide a template, listing the elements of a WOPD, but you must not fill in or complete any of these elements.

An SWO is required prior to claim submission for all options, accessories, and/or supplies that are separately billed in addition to the base. This SWO obtained prior to claim submission may be prepared by someone other than a treating practitioner. If someone other than a treating practitioner prepares the SWO for separately billed options, accessories, and/or supplies, a treating practitioner must review and sign the order.

The treating practitioner who reviews and signs the SWO for separately billable options, accessories, and/or supplies does not need to be the same treating practitioner who completed the WOPD for the PMD base and conducted the face-to-face encounter. In this situation, the treating practitioner who orders the options, accessories, and/or supplies must:

- Verify that a qualifying face-to-face encounter occurred within six months prior to the date of the WOPD for the base item;
- Have documentation of the qualifying face-to-face encounter that was conducted for the base item; and,
- Review and sign their order.

Face-to-Face Encounter

There must be a face-to-face practitioner-beneficiary encounter (the face-to-face encounter may be an in-person or Medicare-approved telehealth visit). The face-to-face encounter must be conducted within six months prior to the order date on the WOPD for the PMD (base item).

Note: The face-to-face examination requirement does not apply when only accessories for power mobility devices are being ordered, nor does it apply for the ordering of replacement PMDs. A replacement PMD would be the same device as previously ordered. However, if a beneficiary has a POV but would like to replace the POV with a power wheelchair, then a face-to-face examination would need to be conducted.

Practitioners shall document the encounter in a detailed narrative note in their charts in the format that they use for other entries. The note must clearly indicate that a major reason for the visit was a mobility encounter. The evaluation should be tailored to the individual beneficiary's conditions. The history should paint a picture of your beneficiary's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the beneficiary's ambulatory difficulty or impact on the beneficiary's ambulatory ability. The evaluation must clearly distinguish the beneficiary's mobility needs within the home from their needs outside the home.

Documentation can also include copies of previous notes, consultations with other practitioners, and reports of pertinent laboratory, x-ray, or other diagnostic tests if they will help to support the severity of the beneficiary's ambulatory problems.

The practitioner may refer the beneficiary to a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), to perform part of the face-to-face encounter. This person may have no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, the PT or OT working in the inpatient or outpatient hospital setting may perform part of the face-to-face encounter.)

To accommodate the requirements at 42 CFR §410.38, when the treating practitioner sees the beneficiary, regardless of whether a referral to an LCMP is made, that visit date starts the six-month timeline for completion of the SWO for the wheelchair base. If the treating practitioner chooses to refer the beneficiary to an LCMP for a mobility evaluation, the treating physician's co-signature, dating and indicating agreement or disagreement with the LCMP evaluation must occur within this six-month timeframe. In cases where the LCMP evaluation is being adopted into the physician's documentation to substantiate the need for the base item, the SWO may not be written until the LCMP report is signed, dated and agreement/disagreement indicated.

Home Assessment

An on-site home assessment must be conducted to consider the home's physical layout, doorway widths, doorway thresholds, and floor surfaces. The beneficiary's home must provide adequate access between rooms, maneuvering space, and surfaces for the operation of the PMD. The assessment must be done prior to or at the time of delivery of the PMD. The written report of this evaluation must be available on request.

You should refer to the individual medical policies for specific coverage and payment provisions.

As defined in the CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 3, if data analysis indicates potentially aberrant billing, contractors shall continue to follow the general guidance for performing medical review on claims.

For more information regarding power mobility devices, please consult the appropriate LCD and Policy Article.

19. Comprehensive Error Rate Testing (CERT)

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 12

The Centers for Medicare & Medicaid Services (CMS) developed the Comprehensive Error Rate Testing (CERT) program to produce the Medicare Fee-For-Service improper payment rate, a national, contractor-specific, and service-specific claims error rate. The program has independent reviewers who periodically review representative random samples of Medicare claims. The independent reviewers medically review claims that are paid and claims that are denied to ensure the claim decision was appropriate. CERT was first developed by CMS in 1996 to measure Medicare FFS Improper Payment Rate for the purpose of reducing costs associated with improperly completed and improperly paid Medicare claims. It was later amended to comply with Improper Payment information Act of 2002 and again amended by Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012.

The CERT contractor selects a random sample of claims processed by each Medicare contractor, including the DME MACs. They then request medical records, Certificates of Medical Necessity, and supporting documentation from the provider of the service to verify services billed were paid or denied properly under Medicare coverage, coding, and billing rules. If you are contacted for a CERT review, you will be provided with the details regarding the needed information and how to submit it.

When no medical records or supporting documentation are received, a denial decision is made which ultimately results in a request for refund from the provider if the claim had been paid originally. These claims may be appealed through normal channels at the DME MAC (see Chapter 13 of this manual for information about appeals).

When records and/or documentation are received, the CERT contractor's medical review professionals (including nurses, physicians, and other qualified healthcare practitioners) then perform a complete review of the claims. If documentation fails to support the item(s) billed, an error is called and a refund will be requested. Documentation that supports the medical need will result in no further action needed by the provider.

Additional information about CERT may be found on the CERT C3HUB website at https://c3hub.certrc.cms.gov/ and through our website at https://www.cgsmedicare.com/jb/claims/cert/index.html.