FUTURE Local Coverage Determination (LCD): Pneumatic Compression Devices (L33829)

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Please note: Future Effective Date.

Contractor Information

Contractor Name CGS Administrators, LLC Back to Top Contract Number 18003 Contract Type Juri DME MAC J-C

Jurisdiction

LCD Information

Document Information



LCD ID

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L33829

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CMS National Coverage Policy CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 280.6

Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (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.

PRESCRIPTIONS

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

For some items in this policy to be covered by Medicare, a written order prior to delivery (WOPD) is required. Refer to the DOCUMENTATION REQUIREMENTS section of this LCD and to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for information about WOPD prescription requirements.

Prescriptions for Pneumatic Compression Devices (PCDs) (E0650-E0652, E0675, E0676) are limited to Physicians (MD, DO, DPM) and physician extenders (NP, PA, CNS) to the extent allowed by their applicable state scope-of-practice and other license requirements. Providers must use care because the treatment of lymphedema, chronic venous insufficiency with ulceration and complications related to the treatment of these conditions by use of PCDs, commonly require consideration of diagnoses and management of systemic conditions. In no event should a provider order PCDs or PCD appliances that are to be used for or are to be applied to areas of the body that fall outside of their state scope of practice and other license limitations.

DEFINITIONS

For Medicare DMEPOS reimbursement purposes the following definitions are used in this policy.

Edema:

Edema is a non-specific term for the accumulation of fluid in tissue, most often in the extremities. There are numerous causes for edema, ranging from systemic disorders (e.g. congestive heart failure, etc.) to local conditions (post-surgery, congenital abnormalities, etc.). (Examples are not all-inclusive).

Lymphedema, as discussed below, is just one group of conditions that can be a cause of accumulation of fluid in the tissue. Lymphedema arises from disorders of the lymphatic system. It is essential to rule out other causes of edema in order to diagnose lymphedema. Edema from other causes is not classified as lymphedema for purposes Printed on 11/17/2015. Page 2 of 18

of Medicare reimbursement for PCDs (E0650-E0652).

Primary lymphedema:

Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

- Congenital lymphedema due to lymphatic aplasia or hypoplasia
- Milroy's disease, an autosomal dominant familial form of congenital lymphedema
- Lymphedema praecox
- Lymphedema tarda

Secondary lymphedema:

Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more componential primary lymphedema. It is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developin pountries, lymphatic filariasis. Scondary lymphedema may also result from compression of the lymphatic and bound channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. (See below)

Chronic Venous Insufficiency (CVI)

Lymphedema may also be caused by CVI when fluid leaks into the tissues from the venous system. CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The incidence of lymphedema from CVI is not well established.

Peripheral Arterial Disease (PAD)

Peripheral artery disease is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to the distal tissue and failure to keep up with oxygen demands.

GENERAL

PCDs coded as E0650-E0652 are used only in the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers. Reimbursement for these items is based upon the criteria in the following sections. PCD coded as E0675 is used in the treatment of peripheral arterial disease. Claims for E0675 will be denied as not reasonable and necessary as outlined below.

I - LYMPHEDEMA

A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all of the following three requirements are met:

- 1. The beneficiary has a diagnosis of lymphedema as defined above, and
- 2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:



- Marked hyperkeratosis with hyperplasia and hyperpigmentation
- Papillomatosis cutis lymphostatica,
- Deformity of elephantiasis,
- Skin breakdown with persisting lymphorrhea,
- Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
- 3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial (see below for trial guidelines)

A PCD coded as E0650 or E0651 used to treat lymphedema that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat edema from causes other than lymphedema is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of lymphedema of the extremities alone even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

Four-Week Trial for Lymphedema

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Regular exercise
- Elevation of the limb

When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive failure.

At the end of the four-week trial, if there has been improvement, then reimbursement for a PCD is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. Only when no further improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a PCD considered.

CMS' NCD for PCD (280.6) instructs: "The determination by the physician of the medical necessity of a pneumatic compression device must include...symptoms and objective findings, including measurements which establish the severity of the condition."

At a minimum, re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials Printed on 11/17/2015. Page 4 of 18

and therapy, with bilateral comparisons where appropriate.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

II - CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS (CVI)

A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all of the following:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician. (See below for trial guidelines)

A PCD coded as E0650 or E0651 used to treat CVI that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat ulcers in locations other than the lower extremity or ulcers and wounds from other causes is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of CVI even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no further improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's CVI treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

The CMS National Coverage Decision for Pneumatic Compression Devices (280.6) instructs:

"The only time that a segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber."

A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all of the following are met:

- The beneficiary has lymphedema of an extremity as defined above
- The coverage criteria for an E0650 or E0651 are met
- The beneficiary has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial. (See below for trial guidelines)

A PCD coded as E0652 used to treat lymphedema extending onto the chest, trunk and/or abdomen that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 used to treat lymphedema not extending onto the chest, trunk and/or abdomen or CVI is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

Four-Week Trial for Lymphedema Extending Onto the Chest, Trunk and/or Abdomen

A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:

- At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, inperson fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally
- Regular exercise

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- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change
- Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
- Correction (where possible) of anemia and/or hypoprotenemia

At the end of the four-week trial, if there has been any improvement of the lymphedema extending onto the chest, trunk and/or abdomen, then reimbursement for an E0652 is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no further improvement has occurred in the most recent four weeks and the coverage criteria above are still met, an E0652 is eligible for reimbursement.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650-E0652). This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the prescribing physician must receive and review the report of the evaluation. In addition, the prescribing physician must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.

IV - PERIPHERAL ARTERY DISEASE (PAD)

A PCD coded as E0675 to treat PAD is not eligible for reimbursement. There is insufficient evidence to demonstrate that reimbursement is justified. Claims for E0675 will be denied as not reasonable and necessary.

V – DEEP VENOUS THROMBOSIS PREVENTION

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

ACCESSORIES

PCD related accessories (E0655-E0673) are eligible for reimbursement only when the appropriate, related base PCDs (E0650-E0651, E0675) meets the applicable coverage criteria for that type of PCD. If the base PCD is not covered, related accessories are not eligible for reimbursement. Claims for related items will be denied as not reasonable and necessary.

PCD CODE SELECTION (E0650-E0652, E0675, E0676)

A PCD coded as E0650 or E0651 is used for lymphedema or CVI. An E0650 compressor with a segmented appliance/sleeve (E0671- E0673) is considered functionally equivalent to an E0651 compressor with a segmented appliance/sleeve (E0667-E0669).

A PCD coded as E0652 has limited coverage. The NCD for Pneumatic Compression Devices (IOM 100-03, §280.6) provides:

"The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber."

The only "unique characteristics" identified in the clinical literature that requires the use of an E0652 device is lymphedema extending onto the chest, trunk and/or abdomen which has remained unresponsive to all other therapies.

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A PCD coded as E0675 is used only for peripheral artery disease. Other PCD codes are not used for this condition

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

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Coding Information

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Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIER:

EY - No physician or other health care provider order for this item or service.

HCPCS CODES:

Group 1 Codes:

E0650 PNEUMATIC COMPRESSOR, NON-SEGMENTAL HOME MODEL E0651 PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITHOUT CALIBRATED GRADIENT PRESSURE E0652 PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITH CALIBRATED GRADIENT PRESSURE E0655 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF ARM E0656 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, TRUNK E0657 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, CHEST E0660 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG E0665 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM E0666 NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG E0667 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG E0668 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM E0669 SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, INTEGRATED, 2 FULL E0670 LEGS AND TRUNK E0671 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL LEG E0672 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL ARM E0673 SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, HALF LEG PNEUMATIC COMPRESSION DEVICE, HIGH PRESSURE, RAPID INFLATION/DEFLATION CYCLE, FOR E0675 ARTERIAL INSUFFICIENCY (UNILATERAL OR BILATERAL SYSTEM) E0676

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ICD-10 Codes that Support Medical Necessity Group 1 Paragraph: Not specified

Group 1 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity Group 1 Paragraph: Not specified

Group 1 Codes: N/A

ICD-10 Additional Information

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General Information

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Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing physician's name
- Date of the order and the start date, if the start date is different from the date of the order

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• Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.3.1)

ACA 6407 requires a written order prior to delivery (WOPD) for the HCPCS codes specified in the table contained in the Policy Specific Documentation Requirements Section below. The supplier must have received a complete WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item. Refer the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about the statutory requirements associated with a WOPD.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

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The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. 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. (PIM 5.2.3)

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The **Coverage Indications, Limitations and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Non-Medical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare 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.

CONTINUED MEDICAL NEED

For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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 (DOS) 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 DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- 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 elsewhere in the policy.

CONTINUED USE

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

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier 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
- Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill
 Documentation Requirements (This is deemed to be sufficient to document continued use for the base
 item, as well)
- Supplier 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 elsewhere in this policy.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item 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 signature and date the beneficiary or designee accepted delivery must be legible.

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

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For items addressed in this policy there are two methods of delivery:

- 1. Delivery directly to the beneficiary or authorized representative
- 2. Delivery via shipping or delivery service

Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers 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
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)

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- 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 the supplier. When the supplier's delivery documents have both a supplier-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 the supplier, 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 the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

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

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 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, the supplier:

 Must obtain a new POD as described above under "Methods of Delivery" (whichever method is applicable); or, 2. Must obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), attesting that the supplier has examined the DMEPOS item, it is in good working order and that it 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.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

General

For PCDs coded E0650 or E0651 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria for I - LYMPHEDEMA or II - CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS (CVI) are met.

For PCDs coded as E0652 the medical record must contain sufficient detailed and specific information to show that the applicable coverage criteria in III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN are met.

The documentation for each of the above must include careful, detailed records of measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to, at periodic times during and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

Certificate of Medical Necessity (CMN) (PIM 5.3)

A Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating physician must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for pneumatic compression pumps is CMS Form 846 (DME Form 04.04B). The initial claim must include an electronic copy of the CMN. In addition to the order information that the physician enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the physician can enter the other details directly.

If question #1 on the CMN ("Does the beneficiary have chronic venous insufficiency with venous stasis ulcers?") is answered "Yes", documentation reflecting all of the following must be in the beneficiary's medical record and made available upon request:

- 1. The location of venous stasis ulcer(s),
- 2. How long each ulcer has been continuously present,
- 3. Previous treatment with a compression bandage system or compression garment, appropriate dressings for the ulcer(s), exercise and limb elevation for at least the past 6 months,
- 4. Evidence of regular physician visits for treatment of venous stasis ulcer(s) during the past 6 months.

Refer to the Supplier Manual for more information on documentation requirements.

AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS

ACA 6407 contains provisions that are applicable to certain specified items in this policy. In this policy the specified items are:

E0650	PNEUMATIC COMPRESSOR, NON-SEGMENTAL HOME MODEL
E0651	PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITHOUT CALIBRATED GRADIENT PRESSURE
E0652	PNEUMATIC COMPRESSOR, SEGMENTAL HOME MODEL WITH CALIBRATED GRADIENT PRESSURE
E0655	NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF ARM
E0656	SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, TRUNK
E0657	SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, CHEST
E0660	

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	NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG
E0665	NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM
E0666	NON-SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG
E0667	SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL LEG
E0668	SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, FULL ARM
E0669	SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, HALF LEG
E0671	SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL LEG
E0672	SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, FULL ARM
E0673	SEGMENTAL GRADIENT PRESSURE PNEUMATIC APPLIANCE, HALF LEG
E0675	INFLATION/DEFLATION CYCLE, FOR ARTERIAL INSUFFICIENCY (UNILATERAL OR BILATERAL SYSTEM)

These items require an in-person or face-to-face interaction between the beneficiary and their treating physician prior to prescribing the item, specifically to document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items. A WOPD is required. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about these statutory requirements.

The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

Suppliers are reminded that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient information included in the medical record to demonstrate that all of the applicable coverage criteria are met. This information must be available upon request.

REPAIR/REPLACEMENT (100-02, Ch 15, §110.2)

A new Certificate of Medical Necessity (CMN) and/or physician'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 physician must document that that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and,
- 2. Either the treating physician or the supplier must document that the repair itself is reasonable and necessary.

The supplier 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.

A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

Miscellaneous

Refer to the Supplier Manual for additional information on documentation requirements.

Appendices

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08 Printed on 11/17/2015. Page 15 of 18

Utilization Guidelines

Refer to Coverage Indications, Limitations and/or Medical Necessity

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Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

Revision History Date	History Number	Revision History Explanation	Reason(s) for Change	
12/01/2015	R2	Revision Effective Date: 12/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	• Other (Draft Released to Final)	

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Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Added: Explicit statement on E0675 non-coverage Added: E0676 benefit exclusion reference in related Policy Article	
		Revised: Requirements for Four-Week Trial for Lymphedema	
		Revised: Requirements for Six-Month Trial for Chronic Venous Insufficiency	
		Revised: E0652 requirements HCPCS CODES AND MODIFIERS: Added: E0675 and E0676	
		POLICY SPECIFIC DOCUMENTATION REQUIREMENTS	
		Revised: Requirements for E0652 Added: E0675 to ACA 6407 requirements table	
		Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	
		Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS:	
10/01/2015	R1	Replaced: WOPD with ACA 6407 WOPD instructions Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer	 Provider Education/Guidance
		Revised: Standard Language Documentation verbiage for CMN Added: Repair/Replacement section	
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Associated Documents

Attachments <u>Certificate of Medical Necessity</u> (PDF - 67 KB) Response to Comments (a comment and response document) (PDF - 344 KB)

Related Local Coverage Documents Article(s) <u>A52488 - Pneumatic Compression Devices - Policy Article - Effective</u> December 2015

Related National Coverage Documents N/A

Public Version(s) Updated on 10/09/2015 with effective dates 12/01/2015 - N/A Updated on 05/07/2015 with effective dates 10/01/2015 - 11/30/2015 Updated on 04/04/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

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