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Introduction

In this chapter, you will find information regarding DMEPOS benefit categories, the DME MAC Medical Review Department, medical policies, and the Advance Determination of Medicare Coverage (ADMC) process. In order for any item to be covered by the DME MAC, it must fall into one of the benefit categories defined below. The medical policies used by the DME MAC to make coverage determinations may be either national or local. The national policies can be found on the CMS website in the *Medicare National Coverage Determinations Manual* and in the *Medicare Benefit Policy Manual*. Both of these manuals can be viewed at www.cms.gov/Manuals/IOM/list.asp. The local policies can be found in Local Coverage Determinations (LCDs), which are available at <http://www.cignagovernmentservices.com/jc/coverage/LCDinfo.html>. See the “Medical Policies” section below for more specific information.

1. DMEPOS Benefit Categories

CMS Manual System, Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, §§50.5.1-50.6 & 110-140
CMS Manual System, Pub. 100-03, *Medicare National Determinations Manual*, Chapter 1, §180

All Medicare Part B covered services processed by the DME MAC fall into one of the following benefit categories specified in the Social Security Act (§1861(s)):

1. Durable medical equipment (DME)
2. Prosthetic devices (including nutrition)
3. Leg, arm, back and neck braces (orthoses) and artificial leg, arm and eyes, including replacement (prostheses)
4. Home dialysis supplies and equipment
5. Surgical dressings
6. Immunosuppressive drugs
7. Erythropoietin for home dialysis patients
8. Therapeutic shoes for diabetics
9. Oral anticancer drugs
10. Oral antiemetic drugs (replacement for intravenous antiemetics)
11. Intravenous immune globulin

General definitions and coverage issues relating to the preceding categories are listed below.

Durable Medical Equipment (DME)

Durable medical equipment is equipment which (a) can withstand repeated use, (b) is primarily and customarily used to serve a medical purpose, (c) generally is not useful to a person in the absence of an illness or injury, and (d) is appropriate for use in the home.

Supplies and accessories that are necessary for the effective use of medically necessary DME are covered. Supplies may include drugs and biologicals that must be put directly into the equipment in order to achieve the therapeutic benefit of the DME or to assure the proper functioning of the equipment.

Repairs, skilled maintenance, and replacement of medically necessary DME are covered.

Prosthetic Devices

Prosthetic devices are items which replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The test of permanence is considered met if the medical record, including the judgment of the attending physician, indicates that the condition is of long and indefinite duration.

In addition to artificial arms and legs, coverage under this benefit includes, but is not limited to, breast prostheses, eye prostheses, parenteral and enteral nutrition, ostomy supplies, urological supplies in patients with permanent urinary incontinence, and glasses or contact lenses in patients with aphakia or pseudophakia.

Enteral and Parenteral Nutrition therapy is covered under the prosthetic device benefit provision, which requires that the patient must have a permanently inoperative internal body organ or function thereof.

Supplies that are necessary for the effective use of a medically necessary prosthetic device are covered. Equipment, accessories, and supplies (including nutrients) which are used directly with an enteral or parenteral nutrition device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device are covered.

Repairs, adjustments, and replacement of medically necessary prosthetic devices are covered.

Dental prostheses (i.e., dentures) are excluded from coverage. Claims for internal prostheses (e.g., intraocular lens, joint implants, etc.) are not processed by the DME MAC.

Braces (Orthotics)

A brace is a rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Repairs, adjustments, and replacement of medically necessary braces are covered.

Home Dialysis Supplies and Equipment

Dialysis supplies and equipment used by patients with end stage renal disease who are being dialyzed at home under the supervision of a Medicare-approved dialysis facility are covered. DME MACs have jurisdiction for payment of dialysis supplies and equipment for Method II dialysis patients only.

Surgical Dressings

Surgical dressings are therapeutic and protective coverings applied to surgical wounds or debrided wounds. Surgical dressings include primary and secondary dressings.

Immunosuppressive Drugs

Immunosuppressive drugs used in patients who have received a Medicare-covered organ transplant are covered. Immunosuppressive drugs used for indications other than transplantation do not fall into the DME MAC's jurisdiction.

Supplies used in conjunction with parenterally administered immunosuppressive drugs are not covered under this benefit category.

Erythropoietin

Claims for erythropoietin administered in the home to home dialysis patients are processed by the DME MAC. Supplies necessary for the administration of medically necessary erythropoietin are covered.

Therapeutic Shoes for Diabetics

Custom molded or extra-depth shoes and inserts for use by patients with diabetes are covered under this benefit.

Oral Anticancer Drugs

Certain oral cancer drugs are covered if they have the same chemical composition and indications as the parenteral form of the drug.

Oral Antiemetics (used as full replacement for IV form)

Certain oral antiemetic drugs are covered when used as full replacement for the intravenous (IV) form of the same drug during chemotherapy treatment.

Intravenous Immune Globulin

Intravenous immune globulin is covered when it is administered in the home to treat primary immunodeficiency. Infusion pumps and other administration supplies are not covered under this benefit.

2. Medical Review Program

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 1, §1.2.1

The goal of the medical review program is to reduce payment errors by identifying and addressing billing errors concerning coverage and coding made by providers. The medical review staff at CIGNA Government Services (CGS) consists of a medical director (physician), clinical staff (registered nurses and other allied health professionals), and experienced support personnel.

Medical Review Responsibilities

- Develop Local Coverage Determinations (coverage policies)

- Analyze claim data
- Perform probe reviews and audits to validate if problems exist
- Perform corrective actions to reduce errors, including prepay review of claims with clinical staff
- Advance Determination of Medicare Coverage (ADMC)
- Develop an annual Medical Review Strategy, based on data analysis, that details the problems and interventions in the jurisdiction
- Partner with the Communications Department to offer provider outreach and education

3. Medical Policies

CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations Manual*
CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 13

General Information

Medical policies may be either national or local.

National medical policies are established by the Centers for Medicare and Medicaid Services (CMS). These policies are found on the CMS website in the *Medicare National Coverage Determinations Manual* and in the *Medicare Benefit Policy Manual*. Both manuals can be viewed at www.cms.gov/Manuals/IOM/list.asp. You can search for National Coverage Determinations (NCDs) using the Medicare Coverage Database at www.cms.gov/MCD/search.asp. The DME MACs, CERT, Zone Program Integrity Contractors (ZPICs), and Administrative Law Judges (ALJ) follow national policy when it exists.

Local medical policies are developed by the DME MACs. The DME MACs have the authority and responsibility to establish local policies when there is no national policy on a subject or when there is a need to further define a national policy. The DME MACs' medical directors jointly develop local medical policies. The medical policies are identical for all DME MACs.

Local medical policies consist of two separate, though closely related, documents: a Local Coverage Determination (LCD) and a Policy Article. A link to the CMS Medicare Coverage Database can be found on the home page of CGS's DME MAC Jurisdiction C website, listed under Coverage & Pricing. The LCDs can be viewed at <http://www.cignagovernmentservices.com/jc/coverage/LCDinfo.html>.

Major sections of an LCD

Indications and Limitations of Coverage and/or Medical Necessity

Defines coverage criteria based on a determination of whether an item is reasonable and necessary. It includes information from National Coverage Determinations (when applicable). When an item does not meet these criteria, **it will be denied as "not medically necessary."**

HCPCS Codes and Modifiers

A list of the HCPCS codes and modifiers that are applicable to the LCD. The presence of a code in this section does not necessarily indicate coverage.

ICD-9 Codes and Diagnoses that Support Medical Necessity

A list of the ICD-9 codes that relate to coverage criteria described in the *Indications and Limitations of Coverage and/or Medical Necessity* section.

Documentation Requirements

States the necessary documentation requirements that you must have on file and/or submit with your claim.

Revision History

Attachments

CMN or DIF (if applicable)

Other suggested forms (if applicable)

Major sections of a Policy Article

Non-Medical Necessity Coverage and Payment Rules

Identifies situations in which an item does not meet the statutory definition of a benefit category (e.g., durable medical equipment, prosthetic devices, etc.) or when it doesn't meet other requirements specified in regulations. It also identifies situations in which an item is statutorily excluded from coverage for reasons other than medical necessity. In these situations, the term used to describe the denial is "noncovered." This section may also include statements defining when an item will be denied as "not separately payable" or situations in which claim processing for the item is not within the DME MAC's jurisdiction.

Coding Guidelines

ICD-9 Codes that are covered

A list of the ICD-9 codes that relate to statutory or regulatory coverage issues, as described in the Non-Medical Necessity Coverage and Payment Rules section.

Revision History

At the end of each LCD, there is a link to the related Policy Article and at the end of each Policy Article there is a link to the related LCD. New or revised policies are generally released on a quarterly basis: March, June, September, and December. Posting of new and revised policies will be announced in a ListServ message from CIGNA Government Services (CGS) and on our website at <http://www.cignagovernmentservices.com/jc>.

Most new or revised policies have a future effective date at the time of posting. The LCD page on our website includes links to current/active LCDs and Policy Articles, Future LCDs and Policy Articles, Draft LCDs, and Retired LCDs and Policy Articles. This page can be viewed at <http://www.cignagovernmentservices.com/jc/coverage/LCDinfo.html>.

Development of Local Coverage Determinations

The development of Local Coverage Determinations (LCDs) is a collaborative effort led by the medical directors of the DME MACs. The intent of the policy development process is to provide the

opportunity for input from the supplier and medical community to assure that the final policy is consistent with sound medical practice.

The initial stage of the process is the development of a draft policy. This stage is based on a review of the medical literature and the contractor's knowledge of medical practice relating to the item. The medical directors seek input from various individuals and groups during the drafting phase of policy development.

Drafts of new medical policies or revised policies that propose more restrictive medical necessity coverage criteria are sent for comment to a wide spectrum of national and regional organizations representing manufacturers, suppliers, physicians, and other healthcare professionals. These draft medical policies are announced in a ListServ message from CGS and a posting on the CGS website at <http://www.cignagovernmentservices.com/jc>. The DME MAC website lists both a mail address and an e-mail address to which comments may be sent. There are 45 days allowed for comments to draft policies. The website lists the start date and end date of the comment period.

The DME MAC encourages written comments to its draft policies. If commentators disagree with any aspects of the policy, they should offer specific alternative wording and support their suggestions with references from the published medical literature.

The DME MAC also holds an open meeting to hear public comments on each draft policy that is sent for comment. The meeting is scheduled during the comment period for a draft policy. Notice of the meeting is placed on the DME MAC website. The notice includes the date, time, and location of the meeting and instructions for those who wish to make a presentation at the meeting. Interested parties may present scientific, evidence-based information, professional consensus opinions, or any other relevant information. The meeting is led by the DME MAC Medical Director.

After the close of the comment period, the DME MAC medical directors review all of the comments that have been received and revise the policy as appropriate. The medical directors summarize the comments and provide a response to each indicating whether or not they agree with the suggestion. If they do not agree, they give reasons for the decision. This "Response to Comments" document is found as an LCD attachment link at the end of the LCD. Following adoption, final medical policies are posted on the DME MAC website.

LCD Reconsideration Process

There is a formal process for requesting revision of a LCD. Information can be found on the Medical Policy page of the DME MAC Jurisdiction C home page: <http://www.cignagovernmentservices.com/jc/coverage/LCDinfo.html>.

Local Coverage Determinations (LCD) Exceptions

In rare and unusual circumstances during complex medical review, ACs, MACs, CERT, and RACs have the authority to make single claim exceptions to the coverage criteria in an LCD. For ACs and MACs, exceptions can be applied during all complex reviews including redeterminations. This exception authority applies only to clinical criteria and cannot be applied to override missing or insufficient documentation. Only the Contractor Medical Director (CMD) has the authority to apply an exception. ACs, MACs, and CERT can use the exceptions process to approve or deny a claim. Unless otherwise directed by CMS, RACs can only use the exceptions process to not deny a claim. ACs, MACs, CERT, and RACs shall not make exceptions to NCDs, CMS manuals, or MAC articles.

The ACs, MACs, CERT, and RACs shall exercise their exception authority only after a thorough review of the patient's medical record and a comprehensive analysis of the evidence in the medical literature.

Claim Determination in the Absence of Medical Policy

The **DME MACs and ZPICs** have the authority to review any claim even if there is no formal national or local policy. In those situations, the contractor first determines whether the item falls within a statutory benefit category that is within its jurisdiction. If it is, then the reviewer determines whether the item is reasonable and necessary for the individual patient. This may include a review of pertinent medical literature. It also includes review of detailed documentation from the ordering physician and supplier supporting the medical necessity of the item in the individual case, as described in the preceding section on “Special Circumstances/Individual Consideration.”

4. Advance Determination of Medicare Coverage (ADMC) for Wheelchairs

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.16

Advance Determination of Medicare Coverage (ADMC) is an optional process by which the DME MAC provides you and the beneficiary with a coverage decision prior to delivery of an item.

An ADMC is available only for the following wheelchair base HCPCS codes and related options and accessories:

E1161

E1231-E1234

K0005

K0009

K0835-K0843

K0848-K0855 (only if an alternative drive control interface will be provided at the time of initial issue)

K0856-K0864

K0868-K0871 (only if an alternative drive control interface will be provided at the time of initial issue)

K0877-K0891

When a particular wheelchair base is eligible for ADMC, all wheelchair options and accessories ordered by the physician for that beneficiary along with the base HCPCS code will be eligible for ADMC.

The ADMC request should include the wheelchair base and each option and accessory that is to be provided. Do not submit an ADMC request for options and/or accessories without a wheelchair base.

All requests for Advance Determination of Medicare Coverage should be submitted to CIGNA Government Services. **Clearly indicate “ADMC” on the first page of all requests.** For your convenience, an ADMC request form is provided on the DME MAC Jurisdiction C website. You can access and fill out the form online at

http://www.cignagovernmentservices.com/jc/forms/pdf/JC_ADMC_request_form.pdf.

ADMC requests may be faxed to (615) 782-4647 or mailed to the following address. ADMC request cannot be submitted electronically.

CIGNA Government Services
Attn: ADMC
P.O. Box 20010
Nashville, TN 37202

The first page of the ADMC request must contain all of the following demographic information:

- **Beneficiary information**
 - Name
 - HICN
 - Address
 - Date of birth
- **Place of service**
- **ICD-9 diagnosis code** (narrative description is not sufficient)
- **Supplier information**
 - Company Name with a contact name
 - NSC number
 - Address
 - Phone number
- **Physician's information**
 - Name
 - NPI
 - Address
 - Phone number
- **Physician's information**
 - Name
 - NPI
 - Address
 - Phone number
- **Item code list requirements for wheelchair base and each option and accessory, you must enter all of the following:**

- HCPCS code
- Narrative description of the HCPCS code
- Manufacturer name and model name/number
- Supplier's charge
- Medicare fee schedule allowance

If there is no fee schedule allowance, you must enter "not applicable."

If the information listed above is not present, the request will be rejected. You will receive written notification of the rejection.

Rejections

ADMC requests are reviewed to determine whether or not they meet the requirements for ADMC requests. **Reasons to reject an ADMC request include:**

1. The item being submitted is not one of the ADMC eligible wheelchair bases
2. The request exceeds the limit of two within six months.
3. The beneficiary does not live in Jurisdiction C.
4. When missing one or more of the requirements listed in the above "Item code list"
5. The request is missing demographic information (i.e., beneficiary's name, current address, date of birth, Medicare identification number [HICN], the supplier's National Supplier Clearinghouse [NSC] number and/or the provider's National Provider Identification [NPI] number).
6. It is the 2nd request, but no new information was submitted.
7. The place of service is a hospital or skilled nursing facility.
8. Two different wheelchair base item codes (HCPCS) are listed on the request.
9. A faxing error has occurred which resulted in missing, blackened, partial and/or incomplete documentation.
10. A duplicate request is submitted.
11. A request is submitted for an advance determination on previously denied accessories and/or additional accessories when the base was previously approved.
12. The item that is being submitted for advanced determination is NOT a wheelchair.

Power Wheelchair Documentation

Include **all** of the following items with the ADMC request:

1. The **written order** that you received within 45 days following the completion of the in-person examination. This order must be written by the treating physician and contain the following elements:

- a) Beneficiary name
 - b) Description of the item. This may be general – e.g., “power wheelchair” or “power mobility device” – or may be more specific.
 - c) Date of the in-person examination. If the evaluation involved multiple visits, enter the date of the last visit. Refer to the Power Wheelchairs policy for additional information.
 - d) Pertinent diagnoses/conditions that relate to the need for the power wheelchair.
 - e) Length of need
 - f) Physician’s signature (handwritten or electronic only – stamped signatures are not acceptable)
 - g) Date of physician signature (handwritten or electronic only – stamped signature dates are not acceptable)
 - h) Date you received the physician’s order – there must be a clear date stamp or equivalent; fax dates are not acceptable.
2. A **detailed product description** must be signed and dated by the physician (handwritten or electronic only – stamped signature and dates are not acceptable). It must list the specific wheelchair base and all options and accessories that will be separately billed. For each item, you must enter all of the following:
- HCPCS code
 - Narrative description of the HCPCS item
 - Manufacturer name and model name/number
 - Supplier’s charge
 - Medicare fee schedule allowance
- (If there is no fee schedule allowance, you must enter “not applicable.”)
- The second element, the narrative description, does not have to be the full narrative of the HCPCS code. However, it must be sufficiently detailed to describe the features of the item that distinguish it from items billed with similar codes.
- The physician must sign and date (handwritten or electronic only – stamped signature dates are not acceptable) this detailed product description, and the supplier must receive it prior to delivery of the PWC or POV.
- A date stamp or equivalent must be used to document receipt date of the detailed product description.
3. A report of the **in-person examination**. The treating physician must conduct an in-person examination of the beneficiary before writing the order. Refer to the Documentation Requirements section of the Power Mobility Devices (PMD) LCD for guidance about the type of information to be included in the in-person examination and specialty evaluation.

4. **Attestation of “no financial involvement.”** The PMD LCD requires a signed and dated affirmation from the supplier that the licensed/certified medical professional (LCMP) performing the specialty evaluation has no financial relationship with the supplier. CGS will also accept an attestation of no financial relationship from the LCMP conducting the specialty evaluation.
5. **Evidence of RESNA certification by the supplier’s Assistive Technology Professional (ATP).** This can be documented by providing a copy of the RESNA certificate or a printout from the RESNA website showing that the individual’s ATP credentials are current. The RESNA website is www.resna.org.
6. **Evidence of “direct, in-person involvement” in the selection of the product.** Documentation of direct in-person interaction with the patient by the ATP in the wheelchair selection process must be complete and detailed enough so a third party can understand the nature of the ATP involvement. Just "signing off" on a form completed by another individual does not adequately document direct, in-person involvement. Also, merely signing a statement such as, "I am a RESNA-certified professional specializing in wheelchairs and had direct, in-person involvement in the wheelchair selection for this patient" does not sufficiently verify that this policy requirement was met. Finally, a home assessment completed by a supplier-employed ATP does not meet the requirement unless the documentation shows how the ATP applied the assessments and measurements to the wheelchair selection process.
7. A report of the **on-site home assessment** which establishes that the beneficiary is able to use the wheelchair ordered to assist with Activities of Daily Living (ADLs) in the home.

Manual Wheelchair Documentation

Include **all** of the following items with the ADCM request:

1. Detailed written order that lists the specific wheelchair base that is to be provided and each option/accessory that will be separately billed. The order must also specify which HCPCS code is associated with each item on the order. This information may be entered by the supplier but the order must be signed and dated by the physician (hand written or electronic only – stamped signature and dates are not acceptable).
2. Information from the beneficiary’s medical record that documents that the coverage criteria defined in the LCD on Manual Wheelchairs have been met.
3. A home assessment which establishes that the beneficiary or caregiver is able to use the wheelchair ordered to assist with ADLs in the home.

Additional Guidance on Documentation

Any information that is provided that explains the medical necessity for separately-billed options and accessories must use the same short description for the item that is used in the detailed product description or detailed written order.

If the beneficiary’s weight and/or height are needed to support the medical necessity for items that are ordered, that information should be included on the first page of the ADCM request.

Even if the majority of the in-person examination is performed by an LCMP, the ADCM request must also include the report of the in-person examination with the physician.

For wheelchair cushions, include the manufacturer, product name, model number, and the width of the wheelchair cushion(s) that is provided. Make certain that the product is listed on the Pricing, Data Analysis and Coding (PDAC) Contractor Product Classification List and that the HCPCS code

on the ADCM is the one specified by the PDAC (consult the PDAC website at <https://www.dmepdac.com/>). See Chapter 16 of this manual for information about the PDAC.

If the beneficiary currently has a wheelchair or a power operated vehicle (POV), the ADCM request must indicate the reason why it is being replaced.

ADMC Process

Upon receipt of an ADCM request, the DME MAC will make a determination within 30 calendar days. The DME MAC will provide you and beneficiary with its determination, either affirmative or negative, in writing. If it is a negative determination, the letter will indicate why the request was denied - e.g., not medically necessary, insufficient information submitted to determine coverage, statutorily non-covered.

If a wheelchair base receives a negative determination, all accessories will also receive a negative determination. If a wheelchair base receives an affirmative determination, each accessory will receive an individual determination.

An affirmative determination only relates to whether the item is reasonable and necessary based on the information submitted. An affirmative determination does not provide assurance that the beneficiary meets Medicare eligibility requirements nor does it provide assurance that any other Medicare requirements (e.g., place of service, Medicare Secondary Payer) have been met. Only upon submission of a complete claim can the DME MAC make a full and complete determination. An affirmative determination does not extend to the price that Medicare will pay for the item.

An affirmative ADCM is only valid for items delivered within six months following the date of the determination. If the wheelchair is not delivered within that time, you have the option of either submitting a new ADCM request (prior to providing the item) or filing a claim (after providing the item).

When submitting a claim with HCPCS code K0108 for the ADCM approved options/accessories, the narrative description on the claim must be the same description used in the ADCM request.

A negative ADCM may not be appealed because it does not meet the regulatory definition of an initial determination since no request for payment is being made. However, if the ADCM request for the wheelchair base is denied and if you obtain additional medical documentation, an ADCM request may be resubmitted. ADCM requests may only be resubmitted once during the six-month period following a negative determination. If the wheelchair base is approved, but one or more accessories are denied, an ADCM request may not be resubmitted for those accessories. If you provide a wheelchair and/or accessories following a negative determination, a claim for the item should be submitted. If new information is provided with the claim, coverage will be considered. If the claim is denied, it may be appealed through the usual process (see Chapter 13 of this manual for information about appeals).

Finally, the DME MAC may review selected claims on a pre-payment or post-payment basis and may deny a claim or request an overpayment if it determines that an affirmative determination was made based on incorrect information.