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Introduction

In this chapter, you will find information regarding DMEPOS benefit categories, the DME MAC Medical Review Department, medical policies, Advance Determination of Medicare Coverage (ADMC) process, and Prior Authorization. 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 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>. The local policies can be found in Local Coverage Determinations (LCDs), which are available at <https://www.cgsmedicare.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. Surgical dressings
5. Immunosuppressive drugs
6. Therapeutic shoes for diabetics
7. Oral anticancer drugs
8. Oral antiemetic drugs (replacement for intravenous antiemetics)
9. Intravenous immune globulin

10. Home Infusion Services Temporary Transitional Payments

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 beneficiaries with permanent urinary incontinence, and glasses or contact lenses in beneficiaries with aphakia or pseudophakia.

Enteral and Parenteral Nutrition therapy is covered under the prosthetic device benefit provision, which requires that the beneficiary 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. The orthotic benefit for braces is limited to leg, arm, back, and neck, and used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. Accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable medical equipment benefit. You must not use L-codes or miscellaneous codes to bill for items that are components of, or used in conjunction with, wheelchairs. These items are correctly billed using the appropriate wheelchair accessory codes.

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

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 beneficiaries 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.

Therapeutic Shoes for Diabetics

Custom molded or extra-depth shoes and inserts for use by beneficiaries 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.

Home Infusion Temporary Transitional Payments

Effective for claims with dates of service on or after January 1, 2019, Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L 115-123) amended Section 1834(u) of the Social Security Act (the Act) by adding paragraph (7), which requires a temporary, transitional payment be made to eligible home infusion suppliers for home infusion therapy services furnished on or after January 1, 2019 until the implementation of the full home infusion therapy benefit, as required by section 5012(d) of the 21st Century Cures Act (Pub. L. 144-255).

2. Medical Review Program

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 1, §1.3.8

The goal of the medical review program is to reduce payment errors by preventing the initial payment of claims that do not comply with Medicare's coverage, coding, payment, and billing policies. The medical review staff at 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)
- Publish educational articles
- Analyze claim data, identifying and addressing billing errors and take action to correct future billing
- Perform reviews and audits to determine supplier compliance using Targeted Probe & Educate
- Notify suppliers of review findings
- Perform corrective actions to correct the behavior in need of change in order to prevent future inappropriate billing
- Advance Determination of Medicare Coverage (ADMC)
- Condition of Payment Prior Authorization Program
- Develop an annual Medical Review Strategy, based on data analysis, that details the problems and interventions in the jurisdiction
- Partner with the Provider Outreach & Education team to provide 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 <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>. You can search for National Coverage Determinations (NCDs) using the Medicare Coverage Database at <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. The DME MACs, CERT, Unified Program Integrity Contractors (UPICs), 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 three separate, though closely related, documents: an LCD, a related Policy Article, and the LCD-related Standard Documentation Requirements Article. A link to the CMS Medicare Coverage Database and the LCDs can be found on the home page of CGS's DME MAC Jurisdiction C website, listed under Local Coverage Determinations (<https://www.cgsmedicare.com/jc/coverage/LCDinfo.html>).

Major Sections of an LCD*Coverage Indications, Limitations, and/or Medical Necessity*

Defines coverage criteria based on a determination of whether an item is eligible for a defined Medicare benefit category, reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and meets all other applicable Medicare statutory and regulatory requirements. Items addressed in this section are based on Social Security Act §1862(a)(1)(A) provisions. When an item does not meet these criteria, it will be denied as “not reasonable and necessary.”

*Summary of the Evidence**

Summary of the evidence used for coverage determinations.

*Analysis of Evidence (Rationale for Determination)**

Explanation of the rationale that supports determination.

HCPCS Codes and Modifiers

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

Documentation Requirements

States the necessary documentation requirements that you must have on file and/or submit with your claim for this specific policy. Refer to the LCD-related Standard Documentation Requirements article for additional information regarding these requirements.

*Bibliography**

List of the sources used in determination.

Revision History Information

Explanation of revisions along with an effective date and reason for change are listed here.

Attachments

CMN or DIF (if applicable)

Other suggested forms (if applicable)

Related Local Coverage Documents

A link(s) to other related LCDs and Policy Articles

**For LCDs published for comment and notice on or after June 11, 2017, as required by the 21st Century Cures Act.*

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.

Policy Specific Documentation Requirements

States the necessary documentation requirements that you must have on file and/or submit with your claim for this specific policy. Refer to the LCD-related Standard Documentation Requirements article for additional information regarding these requirements.

Coding Guidelines

HCPCS Codes and Modifiers

Lists the HCPCS codes and modifiers that are applicable to the Policy Article. The presence of a code in this section does not necessarily indicate coverage.

ICD-10 Codes that are Covered

Diagnosis codes listed in this section relate to: coverage criteria (described in the Coverage Indications, Limitations, and/or Medical Necessity section of the LCD) and/or statutory or regulatory coverage (as described in the Non-Medical Necessity Coverage and Payment Rules section of the LCD-related PA).

Revision History Information

Explanation of revisions along with an effective date are listed here.

Related Local Coverage Documents

A link(s) to other related LCDs and Policy Articles.

Posting of new and revised policies will be announced in a ListServ message from CGS and on our website at <https://www.cgsmedicare.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 <https://www.cgsmedicare.com/jc/coverage/LCDinfo.html>.

New LCD Request Process

The New LCD Request process is a mechanism by which interested parties within a contractor's jurisdiction can request the development of a new LCD. This process is different from the LCD Reconsideration Process.

Informal Meeting (Optional):

The process for requesting a New LCD *may* begin with an informal meeting in which interested parties (in the DME MAC's jurisdiction) can request to informally discuss potential New LCD Requests. These meetings are permitted but **not** required, are for educational purposes only, and

allow requestors the opportunity to communicate with the DME MACs via conference call or in-person meeting before submitting a formal LCD request. During these meetings, the requirements for valid LCD requests are reviewed. Requests for these optional, informal meetings may be submitted via email to LCDReconJC@cgsadmin.com. In the request for an informal discussion, requestors should include the following information:

1. Include the following in the subject line of the email: "Request for New LCD Call – [Title of LCD]"
2. Several options for dates and times for a one (1) hour conference call
3. Teleconference number with enough lines to accommodate 15 participants
4. Agenda for the call, including requestor participants and titles
5. Summary information (1-2 paragraphs, maximum) for the LCD request

Request Submission Criteria (Required):

The DME MAC will consider all New LCD Requests from interested parties within the contractor's jurisdiction. This includes requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction;
- Health care professionals doing business in a contractor's jurisdiction; and,
- Any interested party doing business in a contractor's jurisdiction.

Following the voluntary informal discussion, should the requestor wish to continue with submission of a New LCD Request, the requestor must submit to the DME MAC a formal New LCD Request that is valid. New LCD Requests are considered valid if the following are met:

1. The request is in writing and is sent to the MAC via e-mail, facsimile or written letter;
2. The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under
3. Rationale is provided which justifies the proposed assignment of Medicare benefit category;
4. The language that the requestor wants in a new LCD is identified in the request;
5. The request includes justification for the new LCD supported by peer-reviewed evidence. Full text copies (i.e., not abstracts, meeting poster presentations, manuscripts or embargoed documents) of published evidence from peer-reviewed literature must accompany the request. Failure to include full-text clinical literature invalidates the request;
6. Information is included that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service in the Medicare-eligible population; and,
7. The request includes information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

The level of evidence required for LCD development may be found in the CMS Program Integrity Manual, Chapter 13.

How to Submit New LCD Requests:

New LCD requests may be sent via one of three methods: email (preferred), hard copy by mail, or fax. Below lists pertinent information for each of the three methods:

1. **Email (Preferred Method):** LCDReconJC@cgsadmin.com

- Electronic requests should be sent with "New LCD Request – **[Name of LCD]**" in the subject line.
- If the attachment size for clinical citations exceeds 15 MB, the requestor must send the articles and supporting documents via multiple, smaller emails.
- Please contact LCDreconJC@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting an LCD Reconsideration request.

2. **Fax:** 615.664.5955

- Please address your fax cover sheet to DME New LCD – **[Name of Proposed LCD]** – Attn: Dr. Robert Hoover

3. **Mail:**

CGS Administrators, LLC
Attn: Robert D. Hoover, Jr., MD, MPH
DME LCD Reconsiderations
Two Vantage Way
Nashville, TN 37228

Next Steps:

The DME MAC will review materials received within 60 calendar days upon receipt and determine whether the request is valid or invalid. If the request is invalid, the DME MAC will respond, in writing, to the requestor explaining why the request was invalid.

If the request is valid, the DME MAC will follow the process outlined in the Program Integrity Manual, Chapter 13. A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement to the requestor of the receipt of a complete, valid request.

If the request is valid and a new LCD is developed, the DME MAC will follow the process outlined in the Program Integrity Manual, Chapter 13. This involves:

1. Consultation with the requestor or subject matter experts (if necessary);
2. Contractor Advisory Committee (CAC) meeting (if necessary);
3. Publication of a proposed LCD;
4. Open meeting to solicit comments from the public on the proposed LCD;

5. Opportunity for public comment in writing (minimum of 45 days following posting of proposed LCD);
6. Publication of a final LCD, including:
 - a. A response to public comments received;
 - b. Notice to public of new policy at least 45 days in advance of the effective date.

Final LCDs will be finalized or retired within a rolling calendar year of publication date on the Medicare Coverage Database (365 days).

For additional information on the New LCD Request process, please see CGS' Request New LCD Process webpage at https://cgsmedicare.com/jc/coverage/lcd_request_process.html.

LCD Reconsideration Process

The LCD Reconsideration process is a method by which interested parties can request a revision to an active LCD. The reconsideration process is available for final, effective LCDs only. The entire LCD or any part of it is subject to reconsideration.

Informal Meeting (Optional):

Prior to submitting a formal request for LCD Reconsideration, interested parties are encouraged to schedule an informal conference call to review the requirements for a valid LCD Reconsideration request. Request for a conference call may be submitted via email to LCDReconJC@cgsadmin.com. In the request for an informal discussion, requestors should include the following information:

1. Include in the subject line of the email: "Request for LCD Reconsideration Call – [Title of LCD]"
2. Several options for dates and times for a one (1) hour conference call
3. Teleconference number with enough lines to accommodate 15 participants
4. Agenda for the call, including requestor participants and titles
5. Summary information (1-2 paragraphs, maximum) for the reconsideration request.

Request Submission Criteria (Required):

The DME MAC will consider all LCD Reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction;
- Providers doing business in a contractor's jurisdiction; and,
- Any interested party doing business in a contractor's jurisdiction.

Reconsideration requests are only accepted for LCDs published in final form. Requests will not be accepted for other documents including:

- National coverage Decisions (NCD);
- Coverage provisions in interpretive manuals;

- Proposed LCDs;
- Template LCDs, unless or until they are adopted by the contractor;
- Retired LCDs;
- Individual claim determinations;
- Bulletins, articles, training materials; and
- Any instance in which no LCD exists, i.e., requests for development of an LCD.

The DME MAC has the discretion to consolidate valid requests if similar requests are received. Any request for LCD reconsideration that, in the judgment of the contractor, does not meet these criteria is invalid.

The DME MAC may revise or retire their LCDs at any time on their own initiatives.

If modification of the final LCD would conflict with an NCD, the request will not be valid.

For information about the NCD reconsideration process, reference http://www.cms.gov/DeterminationProcess/01_overview.asp#regs. Information about requesting an NCD or an NCD revision is found under "How to Request an NCD" in the Coverage Process section.

Following the informal discussion, should the requestor wish to continue with a formal LCD Reconsideration request, a valid request must include:

1. The specific language that the requestor proposes added to or deleted from an LCD; and,
2. Justification for the proposed change supported by new evidence in the medical literature which will materially affect the LCDs content or basis. Full-text copies (i.e., not abstracts, meeting poster presentations, manuscripts or embargoed documents) of published evidence from peer-reviewed literature must accompany the request. Failure to include full-text clinical literature invalidates the request.

The level of evidence required for LCD reconsideration is the same as that required for new/revised LCD development (see Program Integrity Manual, Chapter 13).

How to Submit LCD Reconsideration Requests:

LCD Reconsideration requests may be sent via one of three methods: email (preferred), hard copy by mail, or fax. Below lists pertinent information for each of the three methods:

1. **Email (Preferred Method): LCDReconJC@cgsadmin.com**
 - Electronic requests should be sent with "LCD Reconsideration Request – **[Name of LCD]**" in the subject line.
 - If the attachment size for clinical citations exceeds 15 MB, the requestor must send the articles and supporting documents via multiple, smaller emails.
 - Please contact LCDreconJC@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting an LCD Reconsideration request.

2. Fax: 615.664.5955

- Please address your fax cover sheet to DME LCD Reconsideration – Attn: Dr. Robert Hoover.
- Note: This fax line for the LCD reconsideration process described above. This is not the fax line for appealing individual claims (Redeterminations).

3. Mail:

CGS Administrators, LLC
Attn: Robert D. Hoover, Jr., MD, MPH
DME LCD Reconsiderations
Two Vantage Way
Nashville, TN 37228

Next Steps

The DME MAC will review materials received within 60 calendar days upon receipt and determine whether the request is valid or invalid. If the request is invalid the DME MAC will respond, in writing, to the requestor explaining why the request was invalid.

A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement to the requestor of the receipt of a complete, valid request.

If the request is valid, the DME MACs will follow the process for LCD Reconsiderations detailed in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only manual 100-08), Chapter 13. Once the submitted material is reviewed, the requestor will be contacted should the Medical Directors have additional questions. If there are no additional questions from the Medical Directors, the requestor should monitor the DME MAC web sites and listservs for the posting of a proposed LCD, date and time for a public meeting, and timeline for completion of the reconsideration request. This information can be found under the Local Coverage Determinations link on each DME MACs website.

Final LCDs will be finalized or retired within a rolling calendar year of publication date on the Medicare Coverage Database (365 days).

For additional information on the LCD Reconsideration process, please see CGS' LCD Reconsideration Process webpage at <https://cgsmedicare.com/jc/coverage/reconsideration.html>.

Claim Determination in the Absence of Medical Policy

The DME MACs and UPICs 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 beneficiary. This may include a review of pertinent medical literature. It also includes review of detailed documentation from the ordering physician/practitioner and supplier supporting the medical necessity of the item.

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:

Manual Wheelchairs

E1161

E1231–E1234

K0005

K0008

K0009

Power Wheelchairs

Group 3: K0857–K0860 and K0862–K0864

Group 5: K0890–K0891

Custom Motorized/Power Wheelchair: K0013

When a particular wheelchair base is eligible for ADMC, all wheelchair options and accessories ordered by the physician/practitioner 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 CGS. **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 https://www.cgsmedicare.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 requests can be submitted electronically.

CGS – Jurisdiction C
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

- Medicare ID
- Address
- Date of birth
- **Diagnosis code** (narrative description is not sufficient)
- **Place of Service**
- **Supplier information**
 - Company Name with a contact name
 - NSC number
 - Address
 - Phone number
- **Physician's information**
 - Name
 - NPI
 - Address
 - Phone number

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. The request is missing demographic information (i.e., beneficiary's name, current address, date of birth, Medicare identification number, the supplier's National Supplier Clearinghouse [NSC] number and/or the provider's National Provider Identification [NPI] number).
5. It is the 2nd request, but no new information was submitted.
6. The place of service is a hospital or skilled nursing facility.
7. Two different wheelchair base item codes (HCPCS) are listed on the request and it cannot be determined which base is to be reviewed for medical necessity.

8. A faxing error has occurred which resulted in missing, blackened, partial and/or incomplete documentation.
9. A duplicate request is submitted.
10. A request is submitted for an advance determination on previously denied accessories and/or additional accessories when the base was previously approved.
11. The item that is being submitted for advanced determination is NOT a wheelchair.
12. The base is covered under **the Condition of Payment Required Prior Authorization Program for PMDs** (see **section 5** below).

Power Wheelchair Documentation

NOTE: Section 6407 of the Affordable Care Act requirements does not apply to Power Mobility Devices.

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

1. The **written order** (also referred to as the 7-element order) that you received within 45 days following the completion of the in-person examination. This order must be written by the treating physician/practitioner and contain the following elements:
 - i. Beneficiary name
 - ii. Description of the item. This may be general – e.g., “power wheelchair” or “power mobility device” – or may be more specific.
 - iii. Date of the in-person examination. If the evaluation involved multiple visits, enter the date of the last visit. Refer to the Power Mobility Devices policy for additional information.
 - iv. Pertinent diagnoses/conditions that relate to the need for the power wheelchair.
 - v. Length of need
 - vi. Physician’s/practitioner’s signature (refer to Chapter 3 of this manual for signature requirements)
 - vii. Date the prescription was written.

You must document the date on which you received the physician’s/practitioner’s order – there must be a clear date stamp or equivalent.

You may provide a template order listing the seven required elements, but you are prohibited from completing any part of it. It is a statutory requirement that the treating physician/practitioner who conducted the face-to-face requirements write the 7-element order. The 7-element order may only be written after the completion of the face-to-face exam requirements. Refer to the Power Mobility Devices (PMD) Policy Article, Nonmedical Necessity Coverage and Payment Rules section for information regarding the statutory requirements for PMDs.

If you do not receive a written order containing all of these required elements within 45 days after completion of the face-to-face examination, an EY modifier must be added to the HCPCS codes for the PMD and all accessories. The order must be available on request.

2. A **detailed product description**. Once you have determined the specific power mobility device that is appropriate for the beneficiary based on the physician's/practitioner's 7-element order, you must prepare a written document (termed a detailed product description). **This detailed product description (DPD) must comply with the requirements for a detailed written order as outlined in Chapter 3 of this manual** and the CMS Program Integrity Manual (CMS Manual System, Pub. 100-8), Chapter 5. Regardless of the form of the description, there must be sufficient detail to identify the item(s) in order to determine that the item(s) dispensed is properly coded.

The physician/practitioner must sign and date the detailed product description and you must receive it prior to delivery of the power wheelchair or power operated vehicle. A date stamp or equivalent must be used to document the supplier receipt date. The detailed product description must be available on request.

3. A report of the **in-person examination**. The treating physician/practitioner must conduct an in-person examination of the beneficiary before writing the order. Refer to the Power Mobility Devices Policy Article 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).** A copy of a RESNA certificate or screen print from the RESNA website is acceptable proof, but other documentation to show the supplier employs an ATP is acceptable. Examples of acceptable documentation include, but are not limited to, beneficiary evaluation and/or home assessment signed by the supplier's ATP (must be able to identify supplier); signed statement from the supplier that they employ the specific ATP involved in the in-person wheelchair selection process; narrative statement in the licensed/certified medical professional's (LCMP's) evaluation identifying the ATP and his/her employer. 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 beneficiary 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. 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 ADMC request:

1. A 5-Element Order (5EO) that must be completed within six (6) months after the required ACA 6407 face-to-face examination for manual wheelchair bases and received prior to delivery of the item (refer to Chapter 3 of this manual for 5EO requirements). Also, a detailed written order that lists each option/accessory that will be separately billed. This information may be entered by the supplier but the order must be signed and dated by the physician/practitioner (refer to Chapter 3 of this manual for signature requirements).

2. As a condition for payment, Section 6407 of the Affordable Care Act (ACA) requires that a face-to-face encounter occurs between the beneficiary and the treating practitioner. The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
3. Information from the beneficiary's medical record that documents that the coverage criteria defined in the LCD on Manual Wheelchairs have been met.
4. 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.

Even if the majority of the in-person examination for a power wheelchair (PWC) is performed by an LCMP, the ADMC request must also include the report of the in-person examination with the physician/practitioner.

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 ADMC 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 ADMC request must indicate the reason why it is being replaced.

ADMC Process

Upon receipt of an ADMC request, the DME MAC will make a determination within 30 calendar days. The DME MAC will provide you and the 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 ADMC 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 ADMC request (prior to providing the item) or filing a claim (after providing the item).

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

A negative ADMC 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 ADMC request for the wheelchair base is denied and if you obtain additional medical documentation, an ADMC request may be resubmitted. ADMC 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 ADMC 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.

5. Condition of Payment Required Prior Authorization Program

Effective March 6, 2017, Durable Medical Equipment Medicare Administrative Contractors (DME MACs) began accepting Prior Authorization Requests (PAR) for the K0856 – Group 3 standard, single power option and K0861 – Group 3 standard multiple power option wheelchairs for dates-of-delivery on or after March 20, 2017, in four states. This program was expanded nationally for dates of delivery on or after July 17, 2017.

For dates of delivery on or after September 1, 2018, an additional 31 Power Mobility Devices have been selected to be subject to required prior authorization. All new rental series claims for these PMDs with a date of delivery on or after September 1, 2018 must be associated with a prior authorization request as a condition of payment. Therefore, lack of a provisionally affirmed prior authorization request will result in a claim denial. All US states and territories are included in this mandatory program.

Following are the PMD bases included in the Required Prior Authorization program:

HCPCS Code	Type of Base
K0813-K0816	Group 1 Power Wheelchair
K0820-K0829	Group 2 Power Wheelchair
K0835-K0840	Group 2 Single Power Option Power Wheelchair
K0841-K0843	Group 2 Multiple Power Option Power Wheelchair
K0848-K0855	Group 3 Power Wheelchair, No Power Option

K0856	Group 3 Single Power Option sling/solid seat/back, patient weight capacity up to and including 300 pounds
K0861	Group 3 Multiple Power Option sling/solid seat/back, patient weight capacity up to and including 300 pounds

NOTE: This review is for the wheelchair base only. Accessories will not be reviewed.

- All documentation to support a prior authorization request must meet all applicable rules, policy, and NCD/LCD requirements.
- The LCD states that for these bases, the coverage criteria for certain accessories/options must be met to meet coverage criteria for the base. Therefore, the appropriate supporting documentation, as outlined in the LCD to support the base, should also be submitted as part of the prior authorization request.
- Requesters/ submitters have the option to submit a prior authorization request via esMD (content type 8.4), fax, or U.S. mail. The receipt date will be applied to all documents submitted using a Julian date format.
- CGS continued to honor all valid ADMC and PAR requests for HCPCS codes K0813–K0829, K0835–K0843, and K0848–K0855 that **were** received up to and including August 17, 2018.

The request may be submitted by either the beneficiary or the supplier. Before sending the request, the submitter should complete a Condition of Payment Prior Authorization Request Coversheet, which is available at https://cgsmedicare.com/ic/mr/pdf/condition_of_payment_prior_auth.pdf. The PAR must include the following documentation:

- Completed PAR coversheet
- 7-element written order
- Treating physician/practitioner face-to-face assessment
- Detailed product description
- Specialty evaluation performed by Licensed/Certified Medical Professional (LCMP) for Group 2 and Group 3 bases
- ATP in person assessment for Group 2 and Group 3 bases
- RESNA certification for Group 2 and Group 3 bases
- Other relevant medical documentation

NOTE: A provisional affirmation prior authorization decision is a condition of payment. CMS is finalizing the provision to automatically deny payment for a claim for an item on the Required Prior Authorization List that is submitted without a provisional affirmation prior authorization decision.

When faxing or mailing the request:

Fax the Condition of Payment Program Coversheet to:

615-664-5960

Mail the Condition of Payment Program Coversheet to:

CGS – **JUR C** DME Medical Review – Condition of Payment Program
PO Box 24890
Nashville, TN 37202-4890

For the initial submission of the prior authorization request(s), the DME MAC will be required to make the decision(s) and notify each requester within 10 business days (excluding federal holidays). The requesters will be notified of the decision, which will include specific reasons for the decision. The DME MAC will notify the beneficiary of the decision if the beneficiary was the prior authorization requester or if the beneficiary asked to be notified. If the DME MAC exceeds the 10 business day (postmarked) requirement of the initial submission, the request is not automatically affirmed.

A claim which has received an affirmed prior authorization decision will be paid so long as all other technical and Medicare requirements are met upon claim submission. If a prior authorization request receives a non-affirmed decision, the DME MAC will make the requester(s) aware that one or more Medicare requirements have not been met and provide a detailed explanation of which requirements have not been met. Upon receipt of a non-affirmed decision, the requester(s) may make changes and resubmit the prior authorization request. The DME MAC will have an additional 20 business days (excluding federal holidays) to conduct the medical review, make the decision(s), and notify the requester(s) of the decision(s). An unlimited number of resubmissions are allowed.

You, the supplier, may request an expedited review process where applying the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. In these situations the DME MAC will communicate the decisions within two business days (excluding federal holidays) of receipt of all applicable Medicare required documentation.

For more information, please visit the Condition of Payment Prior Authorization page on our website at: https://cgsmedicare.com/jc/mr/condition_of_payment_prior_auth.html.

6. Denial Categories

The Medicare Program provides coverage for a wide range of services that improve the health of the elderly and disabled. Medicare, however, does not cover every service that is related to the health care of its beneficiaries. Coverage and exclusion of services are defined in the Social Security Act, which in turn are implemented through federal regulations, Medicare manuals, instructions from CMS, and decisions by the individual DME MACs.

This section provides an overview of the denial categories for services billed to Medicare. It is important to understand the basic concepts for proper submission, as well as supplier and beneficiary liability issues. This section is a general summary; there are occasional exceptions to some of the statements made below. Specific coverage guidelines are published in the individual medical policies on our website.

Benefit Denials

Section 1861(s) of the Social Security Act defines the medical and other health services that are covered by Medicare. Items or services that are not included in the benefit category definitions are considered benefit category denials. While these services may be reasonable and important health care services, they are just not included in the benefit package specified by the law.

Examples (not all-inclusive) of items in this category include:

1. Disposable supplies other than surgical dressings or supplies required for the effective use of DME or prosthetic devices
2. Equipment that does not serve an exclusively medically therapeutic function
3. Most oral and injectable medications

Medical Necessity Denials

Section 1862(a)(1) of the Social Security Act excludes services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” CMS issues NCDs that are binding on all Medicare jurisdictions. In addition, the DME MAC has the authority and responsibility to make medical necessity determinations on all aspects of medical practice not defined nationally.

Services that are considered investigational or experimental are denied under this exclusion. Preventive services are excluded from coverage under this section of the Act because they do not diagnose or treat an established condition (not because they are inherently unreasonable or unnecessary).

Other Statutory Exclusion Denials

Sections 1862(a)(2)–1862(a)(16) of the Social Security Act list other categories of services that are excluded from coverage by Medicare. Those that may be related to DMEPOS items are as follows:

1. Routine services and appliances (Section 1862[a][7]). Some examples of items excluded from coverage under this section are:
 - a. Eyeglasses and contact lenses except in those beneficiaries who have had cataract extraction or have had their lens removed for other indications
 - b. Hearing aids
2. Orthopedic shoes or other supportive devices for the feet. An exception is a shoe that is an integral part of a leg brace. Another exception is a special shoe and inserts used for the prevention or management of foot ulcers in diabetics.
3. Personal comfort items.
4. Services received outside of the United States.
5. Services for which another government program is primary (e.g., Veteran’s Administration).
6. Services provided to an immediate relative or members of the household.
7. Services relating to war injuries received after the beneficiary is eligible for Medicare coverage.
8. Services for which the beneficiary has no legal obligation to pay.
9. Services paid under Workers’ Compensation.

Fragmented Coding

The Medicare allowance for an individual HCPCS code often includes several component items. An individual HCPCS code will be denied if it is determined that the item described by that code is included in the allowance for another code that has also been billed. In this case, even though the item provided may be covered—the payment for the code is being denied.

Duplicate Claims

If a claim is received for a service that has been previously processed, and a Medicare allowed amount has been established, the second claim will be denied as a duplicate.

When a second supplier submits a diabetic test strip claim for a span date already approved for the same beneficiary for a different supplier, the DME MAC will deny the second supplier's claim as a duplicate claim, when the following conditions are met:

- Same beneficiary Medicare ID;
- Overlapping span DOS (From DOS and through DOS);
- Same HCPCS code;
- Same type of service on the incoming claim matches a previously approved claim in history; and
- The item is a diabetic testing supply.

Incomplete Claims

You are required to submit complete claims for items provided to Medicare beneficiaries. Claims lacking beneficiary information, diagnosis codes, procedure codes, ordering physician's/practitioner's name/NPI, or billing supplier information will be denied as incomplete claims. These claims will be considered for payment when the missing information is supplied on a resubmitted claim.