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 of Power Mobility Equipment. 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 http://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 http://www.cgsmedicare.com/jc/coverage/LCDinfo.html. See the “Medical Policies” section below for more specific information.

1. DMEPOS Benefit Categories

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

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. 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 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.

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

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 probe reviews and audits to determine supplier compliance
• 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)
• Prior Authorization of Power Mobility Equipment
• 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. 100-08, Medicare Program Integrity Manual, Chapter 13

General Information
Medical policies may be either national or local.


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: a Local Coverage Determination (LCD), a related Policy Article, and the LCD-related Standard Documentation Requirements 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.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.”
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.

Diagnoses Codes that Support Medical Necessity

Lists the diagnosis codes that relate to coverage criteria described in the Coverage Indications, Limitations, and/or Medical Necessity section.

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.

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

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.
Diagnosis Codes that are covered

Lists the diagnosis codes that relate to statutory or regulatory coverage issues, as described in the Non-Medical Necessity Coverage and Payment Rules section.

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 http://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 http://www.cgsmedicare.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. A summary of the evidence, the sources of that evidence and an analysis of the evidence are also presented in conjunction with the draft policy.

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.cgsmedicare.com/jc/coverage/LCDinfo.html. The DME MAC website lists both a mail address and an email 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 Local Coverage Determinations (LCDs) page of the DME MAC Jurisdiction C website: [http://www.cgsmedicare.com/jc/coverage/LCDinfo.html](http://www.cgsmedicare.com/jc/coverage/LCDinfo.html).

**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/practitioner and supplier supporting the medical necessity of the item.

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**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 2: K0835-K0843

Group 3: K0848-K0855 [only if an alternative drive control interface (E2321-E2322, E2325, E2327-E2330) will be provided at the time of initial issue]
- K0856-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 [http://www.cgsmedicare.com/jc/forms/pdf/JC_ADMC_request_form.pdf](http://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
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
- **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

**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 [HICN], the supplier’s National Supplier Clearinghouse [NSC] number and/or the provider’s National Provider Identification [NPI] number).
5. It is the 2\textsuperscript{nd} 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 prior authorization demonstration or Condition of Payment Prior Authorization (PA) Program for PMDs (see sections 5 and 6 below).

**Power Wheelchair Documentation**

**NOTE:** Section 6407 of the Affordable Care Act requirements do 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 of physician/practitioner signature (refer to Chapter 3 of this manual for signature requirements)

You must document the date in 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 patient 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
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 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.

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 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. Prior Authorization of Power Mobility Devices (PMD)

On September 1, 2012, the Medicare Fee-for-Service Program began a prior authorization demonstration for certain PMDs. The new prior authorization process is for orders written on or after September 1, 2012, and applies to beneficiaries who permanently reside in the Jurisdiction C states of North Carolina, Florida, and Texas.
On October 1, 2014, the demonstration was expanded to include beneficiaries permanently residing in the states of Georgia, Louisiana, and Tennessee and is available for orders written on or after October 1, 2014.

The prior authorization process under this demonstration is available for the following HCPCS codes for Medicare payment:

- Group 1 Power Operated Vehicles (K0800–K0802 and K0812)
- All standard power wheelchairs (K0813–K0829)
- All Group 2 complex rehabilitative power wheelchairs (K0835–K0843)
- All Group 3 complex rehabilitative power wheelchairs without power options (K0848–K0855)
- Pediatric power wheelchairs (K0890–K0891)
- Miscellaneous power wheelchairs (K0898)

Note: Group 3 complex rehabilitative power wheelchairs with power options (K0856–K0864) are excluded from the prior authorization demonstration.

The goal of this program is to develop and demonstrate improved methods for the investigation and prosecution of fraud in the provision of PMDs. The CMS plans to test this process and compare the results to traditional pre-payment review in order to evaluate whether, and to what extent, the two processes are effective in investigating and prosecuting fraud. Letters have been sent to suppliers and physicians/practitioners who have provided a PMD for a Medicare beneficiary residing in one of the demonstration states within the past three years.

It is important to keep in mind that the prior authorization demonstration does not create new documentation requirements for physicians/practitioners or suppliers—it simply requires them to provide the information earlier in the claims process. The prior authorization request can be submitted by either the physician/practitioner or the supplier (referred to as a “submitter”).

For beneficiaries residing in GA, FL, LA, NC, TN, or TX, mail or fax the prior authorization request with accompanying documentation to the address or fax number below.

CGS – DME Medical Review – Prior Authorization
PO Box 24890
Nashville, TN 37202-4890
Fax: 615.664.5960

A Prior Authorization Request (PAR) coversheet is available on our website at http://www.cgsmedicare.com/jc/forms/pdf/prior_authorization_coversheet.pdf. Use of the coversheet will help to ensure that you have included all relevant documentation with your request.

The submitter of a prior authorization request must include all relevant documentation to support Medicare coverage of the PMD item. This includes:

1. The seven element written order for the PMD,
2. Documentation of the face-to-face examination where the physician/practitioner evaluated the patient's need for the PMD,
3. The report of a licensed/certified medical professional (LCMP) examination, if the exam is to be considered as part of the face-to-face examination,

4. A signed and dated attestation by the supplier or LCMP stating that the LCMP has no financial relationship with the supplier (if the exam is to be considered as part of the face-to-face examination),

5. For Group 2 Single Power or Multiple Power Options PWCs and Group 3 PWCs with no power options, documentation of the specialty evaluation which provides detailed information explaining why each specific option or accessory is needed to address the beneficiary’s mobility limitation, and

6. The detailed product description.

The Local Coverage Determination requires physicians/practitioners to originate the seven element order, face-to-face encounter documentation, and any other clinical documentation such as progress notes that are necessary to support the medical necessity of the item. In addition, you (the supplier) are required to complete the detailed product description.

After receipt of all relevant documentation from the submitter, the DME MAC will review and communicate a decision within 10 business days on whether the PMD meets all Medicare coverage requirements. In rare cases the physician/practitioner may seek an expedited review of the prior authorization request—under an emergency situation we will attempt to review and communicate within 48 hours a decision on the prior authorization request. The DME MAC will send the decision letter regarding prior authorization (affirmative or non-affirmative) to the physician/practitioner, the supplier, and the Medicare beneficiary. The decision letter will also contain information about why the prior authorization request is non-affirmative. In addition, a prior authorization unique tracking number will be provided when a decision is made. This number should be submitted on the claim for the PMD.

If the prior authorization is non-affirmed by the DME MAC, you may send subsequent prior authorization requests. The DME MAC will make every effort to conduct a review and communicate a decision within 20 business days for each subsequent prior authorization request. If a claim, with a non-affirmative decision, is still submitted to the DME MAC for payment, it will be denied. The supplier and/or beneficiary can use the claim appeal process for a claim denial but not a non-affirmative prior authorization decision from the DME MAC.

CMS will assess a 25 percent payment reduction on your payable claim when the first claim was not preceded by a prior authorization request. To avoid the payment reduction, you must include the prior authorization tracking number on the claim. This 25 percent reduction in the Medicare payment is for each covered claim not preceded by a prior authorization request, with one important exception: If a competitive bidding contract supplier submits a payable claim for a beneficiary with a permanent residence in a competitive bidding area, the competitive bid supplier will receive the contractual single payment amount under their contract. You must still adhere to all other requirements of the demonstration.

Additional information about the demonstration is available on our website at https://cgsmedicare.com/jc/mr/prior_auth.html and on the CMS website at http://go.cms.gov/PADemo.

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. The Condition of Payment Prior Authorization Program is eligible for Medicare beneficiaries residing in New York (Jurisdiction A), Illinois (Jurisdiction B), West Virginia (Jurisdiction C), and Missouri (Jurisdiction D).

A Condition of Payment Prior Authorization 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 http://cgsmedicare.com/jc/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)
- 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.

The request may be mailed or faxed as follows.

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: http://cgsmedicare.com/jc/mr/condition_of_payment_prior_auth.html.

7. 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 patients 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 HICN;
- 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 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.