Chapter 9 Contents

Introduction

In this chapter, you will find information regarding Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS) benefit categories, the Durable Medical Equipment Medicare Administrative Contractor (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 Centers for Medicare and Medicaid Services (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/jb/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, 50.5.3, 50.5.4, 50.6, 100-140, & 145

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 legs, arms, and eyes, including replacement (prostheses)
4. Surgical dressings
5. Immunosuppressive drugs
6. Therapeutic shoes for persons with diabetes
7. Oral anticancer drugs
8. Oral antiemetic drugs (replacement for intravenous antiemetics)

9. Intravenous immune globulin for primary immune deficiency
10. Lymphedema compression treatment items
11. Additional preventive services (specifically, pre-exposure prophylaxis [PrEP] for prevention of Human Immunodeficiency Virus [HIV])

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

Note: The home infusion services temporary transitional payment ended on December 31, 2020. The permanent Home Infusion Therapy services benefit went into effect the following day, on January 1, 2021.

The Part B Home Infusion Therapy services benefit (established at SSA §1861(s)(2)(GG)) was developed pursuant to section 5012 of the 21st Century Cures Act. This benefit is separate from the Part B DME benefit.

Durable infusion pumps and supplies (including home infusion drugs) remain under the Part B DME benefit. Items and services covered under the separate Home Infusion Therapy services benefit include professional services (such as nursing services), training and education (not otherwise paid for under DME), and remote (and other types) of monitoring services.

Effective January 1, 2021, home infusion therapy items and services provided under the Home Infusion Therapy services benefit are not processed by DME MACs. Claims for these items and services (that are represented by specified Level II HCPCS "G" codes) are processed by the A/B MACs.

Durable Medical Equipment (DME)

Durable medical equipment is equipment which (a) can withstand repeated use (i.e., can be rented), (b) for items classified as DME after January 1, 2012, has an expected life of at least three years, (c) is primarily and customarily used to serve a medical purpose, (d) generally is not useful to a person in the absence of an illness or injury, and (e) 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 treating practitioner, 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 Persons with Diabetes

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. As of January 1, 2024, this benefit has been amended to include coverage of services and supplies utilized in the provision of the intravenous immune globulin.

Lymphedema Compression Treatment Items

Lymphedema compression treatment items are standard and custom-fitted gradient compression garments and other items used to treat lymphedema. Professional services, including lymphedema treatment services, are not eligible for coverage under this benefit.

Additional Preventive Services (specifically PrEP for prevention of HIV)

Pre-exposure prophylaxis (PrEP) for the prevention of HIV involves the use of antiretroviral drugs approved by the Food and Drug Administration (FDA). The drugs and supplying of such drugs are covered for individuals at increased risk of HIV acquisition.

Note: DME MACs and A/B MACs process claims for HIV PrEP. The contractor to which these claims must be submitted depends on the type of supplier. Pharmacies enrolled as DMEPOS suppliers submit the claims to the DME MACs. Pharmacies enrolled as Part B pharmacy suppliers do not submit the claims to the DME MACs and should contact the A/B MAC contractor for guidance on billing of the claims.

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 medical directors (physicians), a research team, 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, identify and address 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
- Conduct Advance Determination of Medicare Coverage (ADMC) reviews
- Conduct Condition of Payment Prior Authorization Program reviews
- 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,* Chapter 1
CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 13

General Information

Medical policies may be either national or local. Local policies are termed Local Coverage Determinations (LCDs) and national policies are National Coverage Determinations (NCDs).

National Coverage Determinations 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. The DME MACs, CERT, and Unified Program Integrity Contractors (UPICs) follow, and Administrative Law Judges (ALJs) are bound by, national policy when it exists.

Local Coverage Determinations are developed jointly by the DME MACs. The DME MACs have the authority and responsibility to establish LCDs when there is no national policy on a subject or when there is a need to further define an NCD. The LCDs are identical for all DME MACs.

Local medical policies consist of three separate, though closely related, documents: an LCD, an LCD-related Policy Article, and the LCD-related Standard Documentation Requirements for All Claims Submitted to DME MACs Article. All LCD-related articles are referenced as links in the Associated Documents section of each LCD. A link to the CMS Medicare Coverage Database and the LCDs can be found on the home page of CGS's DME MAC Jurisdiction B website, listed under Local Coverage Determinations (https://www.cgsmedicare.com/jb/coverage/LCDinfo.html).

Major Sections of an LCD

Issue Description

This field appears in final LCDs published after June 23, 2022. The field, when displayed in a final LCD published as a result of a proposed LCD, provides a summary of coverage information presented in the proposed LCD. This field, when displayed in a final LCD that is not published as a result of a proposed LCD (such as a final LCD published with non-substantive revisions or with non-discretionary coverage updates to reflect changes in NCDs), provides a summary pertinent to the coverage information and/or relevant updates presented in the final LCD. (Note: This field

is also displayed in proposed LCDs as of June 23, 2022, and provides a summary of coverage information presented in the proposed LCD.)

Issue - Explanation of Change Between Proposed LCD and Final LCD

This field appears in final LCDs published after June 23, 2022. This field, when displayed in a final LCD published as a result of a proposed LCD, provides a summary of coverage information as it appears in the final LCD, including a description of changes between the proposed LCD and the resulting final LCD. This field, when displayed in a final LCD that is not published as a result of a proposed LCD (such as a final LCD published with non-substantive revisions or with non-discretionary coverage updates to reflect changes in NCDs), provides information which conveys that a proposed LCD was not published in connection with the final LCD publication.

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 the 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 a specific policy. Refer to the LCD-related Standard Documentation Requirements article for additional information regarding these requirements.

*Bibliography**

List of all evidentiary 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, for claims with dates of service on or before January 1, 2023)

Other suggested forms (if applicable)

Related Local Coverage Documents

Links to other related LCDs and Policy Articles

Related National Coverage Documents

Links to related NCDs

**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.

Requirements for Specific DMEPOS Items Pursuant to Final Rule 1713 (84 Fed. Reg Vol 217)

Provides information regarding the requirement for standard written orders (SWOs), face-to-face encounters and written order prior to delivery (WOPD) for certain HCPCS codes, as specified in CMS' Final Rule CMS-1713-F.

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

Provides detailed information about the characteristics and features of products that qualify for inclusion under specific HCPCS codes.

Modifiers

Contains billing and coding information specific to modifier usage when submitting claims for specified items/services. The presence of a modifier in this section does not necessarily indicate coverage.

ICD-10-CM Codes that Support Medical Necessity

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).

ICD-10-CM Codes that DO NOT Support Medical Necessity

Diagnosis codes listed in this section are not covered as specified.

Revision History Information

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

Related Local Coverage Documents

Links to related LCDs and Policy Articles

Related National Coverage Documents

Links to related NCDs

Posting of new and revised policies will be announced in an electronic mailing list message from CGS and on our website at https://www.cgsmedicare.com/jb.

The Local Coverage Determinations page on our website includes links to current/active LCDs and Policy Articles, Future LCDs and Policy Articles, Proposed LCDs, Archived LCDs and Policy Articles, and information related to New and Reconsideration LCD requests. This page can be viewed here: https://www.cgsmedicare.com/jb/coverage/LCDinfo.html.

Request for a New LCD Process

The New LCD Request process is a mechanism by which interested parties within a contractor's jurisdiction may request a new LCD. This process has different requirements from an LCD Reconsideration Request, the path by which an interested party requests modification of an existing, active LCD. Information for requesting an LCD Reconsideration may be found on the LCD Reconsideration Process page (https://www.cgsmedicare.com/jb/coverage/reconsideration.html). The process for developing a new LCD is described below.

Informal Teleconference (Optional):

Prior to submitting a formal LCD request, the DME MACs encourage requestors to schedule an informal conference call to review the requirements for a valid LCD request.

DME MAC participation in the call may include DME MAC medical policy ancillary staff, in addition to the DME MAC Medical Directors, on behalf of each DME MAC jurisdiction. The Pricing, Data Analysis, and Coding (PDAC) contractor Medical Director(s) and ancillary staff may also be invited to attend these calls. (If you prefer that the DME MACs solely attend the informal conference call, then please specify such in your call request.)

A request for a call may be submitted via email to LCDReconJB@cgsadmin.com and should include the following information:

1. "Request for New LCD Call – [**Topic for New LCD**]" in the subject line of the email.
2. Several options for dates and times for a call.
3. *(Required)* Teleconference number with enough lines to accommodate a minimum of 30 participants.
4. Summary information (1-2 paragraphs, maximum) for the LCD request.

5. *(Optional)* A web link for you to visually present materials during the call. (Note: If you provide a web link, please know it is still required that a teleconference number be provided, as some attendees may not have access to the link at the time of the meeting.)

Once the DME MAC has received your informal conference call request, the DME MAC will communicate with you to confirm the date and time for participation in the meeting.

At least one week in advance of the confirmed informal conference call date, the DME MACs and PDAC* will anticipate receipt of an agenda, presentation documents (if applicable), and an attendee list (including participants' names and titles who will attend on behalf of the informal conference call requestor). You should send these materials to each of the following email addresses:

Noridian Healthcare Solutions, DME MAC Jurisdictions A and D: DMERecon@noridian.com

CGS Administrators, LLC, DME MAC, Jurisdiction B: LCDRECONJB@cgsadmin.com

CGS Administrators, LLC, DME MAC, Jurisdiction C: LCDRECONJC@cgsadmin.com

Palmetto GBA, LLC, PDAC* Contractor: pdac.hcpcs@palmettogba.com

*If you specified in your informal conference call request that you prefer the DME MACs solely attend the call, then the PDAC will not attend the call and you may exclude the PDAC email address from the list of recipients to which you send the agenda, presentation documents (if applicable), and attendee list.

For your convenience, CGS has prepared an Informal Teleconference request form (https://www.cgsmedicare.com/jb/forms/pdf/lcd_informal_call.pdf) that you may fill out and submit with your informal conference call request. This form is optional.

New LCD Request Submission Criteria (Required):

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

1. Be submitted by one of the following:
   - 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.
2. Clearly identify the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under;
3. Provide a rationale justifying the proposed assignment of the Medicare benefit category;
4. Identify the language which the requestor wants in a new LCD;
5. Submission of all available evidence, as well as all related FDA approval correspondence, marketing designations, decision summaries pertinent to the product or service, 510(k)/PMA/De Novo notifications, SSED data sheet, FDA Panel Minutes and Post-Approval Study Result/Outcome Submissions.

   Submitted literature and references should be limited to published, full-text, peer-reviewed evidence, indexed in PubMed of the US National Library of Medicine, National Institutes of Health. The failure to include the specific literature with the request will render the LCD request incomplete.

6. Must include information which addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service in the Medicare-eligible population; and
7. Must include information which 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.

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

New LCD Request Letter Details*:*

Request letters sent to the DME MACs are subject to public disclosure. By sending the DME MACs a request letter, the sender is consenting to public posting of the letter. The following list provides request letter details to consider when submitting the request to the DME MACs:

1. Request letters sent to the DME MAC **must** be 508-compliant when submitted. If the request letter is not 508-compliant, it will be returned to the requestor for correction. The 508 compliance instructions and information on the technical standards can be reviewed on CMS' Section 508 webpage (https://www.cms.gov/research-statistics-data-and-systems/cms-information-technology/section508).
2. Request letters **must not** contain protected health information (PHI) or personally identifiable information (PII). If the request letter contains PHI and/or PII, the requestor will be required to resubmit the request letter with the PHI/PII removed or redacted.
3. Should the requestor include proprietary, privileged, or confidential information in the request, it is the requestor's responsibility to note such information. If proprietary, privileged, or confidential information is necessary for the validity of the new LCD request, the requestor is asked to submit two versions of the request, one with proprietary, privileged, or confidential information redacted and one without redaction. The redacted version will be posted to the public.
4. All valid request letters will be posted on the Medicare Coverage Database (MCD). Therefore, if a requestor provides personal contact information (such as phone numbers or email addresses), which the requestor does not wish to be publicly disclosed, then the requestor has the option to submit a redacted version of the request. The redacted version will be posted to the public.

If the requestor needs to submit a redacted version of the letter to the DME MAC, the requestor must provide the redacted version at the same time as providing the version without redaction.

How to Submit a New LCD Request*:*

For your convenience, CGS has prepared a New LCD Request form (https://www.cgsmedicare.com/jb/forms/pdf/new_lcd.pdf) that you may fill out and submit with your request. This form is optional; however, it will assist you in ensuring the requirements for a complete request are met.

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

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

- Electronic requests should be sent with "New LCD Request – **[Topic for New 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 LCDReconJB@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting a New LCD Request.

2. **Fax:** 615.660.5997
   - Please address your fax cover sheet to DME New LCD – **[Topic for New LCD]** – Attn: Dr. Sunil Lalla.
   - Note: This fax line is only for the LCD process described above. This is not the fax line for appealing individual claims (Redeterminations).
3. **Mail:**

   CGS Administrators, LLC
   Attn: Sunil V. Lalla, MD, FACS, CPC
   DME LCD Reconsiderations
   26 Century Blvd STE ST610
   Nashville, TN 37214-3685

Please note that this information is for NEW DME MAC LCD requests only. Information for submitting an LCD request for the Jurisdiction 15 A/B MAC may be found at the J15 website (https://www.cgsmedicare.com/partb/index.html).

Next Steps:

CGS will review the materials received to determine whether the request is valid. A valid request must meet criteria 1-7 listed above. CGS will respond to the request within 60 calendar days upon receipt.

If CGS determines that the request is not valid, CGS will notify the requestor in writing that the request is not valid and will provide the rationale for this decision.

If the request is valid, CGS will begin the LCD development process outlined in the *Program Integrity Manual*, Chapter 13 (Internet-only Manual Pub.100-08). The response to the requestor is an acknowledgement by CGS of the receipt of a valid, complete request. CGS' request response does not convey that a determination has been made in regard to the likelihood of coverage or non-coverage under 1862(a)(1)(A) of the Act, but is confirmation that CGS plans to proceed with development of a new LCD or place the requested LCD on the wait-list for development at a later time.

If the request is valid and a new LCD is developed, CGS 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.

**A proposed LCD will include the requestor's name and/or company information, along with a copy of the request. This information may also be included in other publicly available resources on the Medicare Coverage Database and/or the DME MAC websites.

Proposed 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/jb/coverage/lcd_request_process.html.

LCD Reconsideration Process

The Local Coverage Determination (LCD) Reconsideration process is a method by which interested parties may request a revision to an active LCD. CGS follows the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13 process for LCD Reconsiderations. The reconsideration process is available for final, effective LCDs only. The entire LCD or any part of it is subject to reconsideration. The process for LCD Reconsideration is outlined below.

Informal Teleconference (Optional):

Prior to submitting a formal LCD Reconsideration, the DME MACs encourage requestors to schedule an informal conference call to review the requirements for a valid LCD Reconsideration request.

DME MAC participation in the call may include DME MAC medical policy ancillary staff, in addition to the DME MAC Medical Directors, on behalf of each DME MAC jurisdiction. The Pricing, Data Analysis, and Coding (PDAC) contractor Medical Director(s) and ancillary staff may also be invited to attend these calls. (If you prefer that the DME MACs solely attend the informal conference call, then please specify such in your call request.)

A request for a call may be submitted via email to LCDReconJB@cgsadmin.com, and should include the following information:

1. "Request for LCD Reconsideration Call – [**Title of LCD**]" in the subject line of the email.
2. Several options for dates and times for a call.
3. *(Required)* Teleconference number with enough lines to accommodate a minimum of 30 participants.
4. Summary information (1-2 paragraphs, maximum) for the LCD reconsideration request.
5. *(Optional)* A web link for you to visually present materials during the call. (Note: If you provide a web link, please know it is still required that a teleconference number be provided, as some attendees may not have access to the link at the time of the meeting.)

Once the DME MAC has received your informal conference call request, the DME MAC will communicate with you to confirm the date and time for participation in the meeting.

At least one week in advance of the confirmed informal conference call date, the DME MACs and PDAC* will anticipate receipt of an agenda, presentation documents (if applicable), and an attendee list (including participants' names and titles who will attend on behalf of the informal conference call requestor). You should send these materials to each of the following email addresses:

Noridian Healthcare Solutions, DME MAC Jurisdictions A and D: DMERecon@noridian.com

CGS Administrators, LLC, DME MAC, Jurisdiction B: LCDRECONJB@cgsadmin.com

CGS Administrators, LLC, DME MAC, Jurisdiction C: LCDRECONJC@cgsadmin.com

Palmetto GBA, LLC, PDAC* Contractor: pdac.hcpcs@palmettogba.com

*If you specified in your informal conference call request that you prefer the DME MACs solely attend the call, then the PDAC will not attend the call and you may exclude the PDAC email address from the list of recipients to which you send the agenda, presentation documents (if applicable), and attendee list.

For your convenience, CGS has prepared an Informal Teleconference request form (https://www.cgsmedicare.com/jb/forms/pdf/lcd_informal_call.pdf) that you may fill out and submit with your informal conference call request. This form is optional.

LCD Reconsideration Request Submission Criteria (Required):

Following the informal discussion, should the requestor wish to continue with a formal LCD Reconsideration request, a valid request must meet all the following requirements:

1. Be submitted by one of the following:
    - 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.
2. Include the specific language that the requestor proposes to be added to or deleted from the LCD; and,
3. Submission of all available evidence, as well as all related FDA approval correspondence, marketing designations, decision summaries pertinent to the product or service, 510(k)/PMA/De Novo notifications, SSED data sheet, FDA Panel Minutes and Post-Approval Study Result/Outcome Submissions.

    Submitted literature and references should be limited to published, full-text, peer-reviewed evidence, indexed in PubMed of the US National Library of Medicine, National Institutes of Health. The failure to include the specific literature with the request will render the LCD request invalid.
4. Only request reconsideration of an LCD published in final form. Requests will not be accepted for other documents including:
    - National Coverage Determinations (NCDs);
    - 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 level of evidence required for LCD reconsideration is the same as that required for new LCD development (see the *Program Integrity Manual*, Chapter 13).

CGS 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.

CGS 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 Medicare Coverage Determination Process at https://www.cms.gov/DeterminationProcess/01_overview.asp. Information about requesting an NCD or an NCD revision is found under "How to Request an NCD" in the Coverage Process section.

***LCD Reconsideration Request Letter Details**:*

Request letters sent to the DME MACs are subject to public disclosure. By sending the DME MACs a request letter, the sender is consenting to public posting of the letter. The following list provides request letter details to consider when submitting the request to the DME MACs:

1. Request letters sent to the DME MACs **must** be 508-compliant when submitted. If the request letter is not 508-compliant, it will be returned to the requestor for correction. The 508 compliance instructions and information on the technical standards can be reviewed on CMS' Section 508 webpage (https://www.cms.gov/research-statistics-data-and-systems/cms-information-technology/section508).
2. Request letters **must not** contain protected health information (PHI) or personally identifiable information (PII). If the request letter contains PHI and/or PII, the requestor will be required to resubmit the request letter with the PHI/PII removed or redacted.
3. Should the requestor include proprietary, privileged, or confidential information in the request, it is the requestor's responsibility to note such information. If proprietary, privileged, or confidential information is necessary for the validity of the reconsideration request, the requestor is asked to submit two versions of the request, one with proprietary, privileged, or confidential information redacted and one without redaction. The redacted version will be posted to the public.
4. All valid request letters will be posted on the Medicare Coverage Database (MCD). Therefore, if a requestor provides personal contact information (such as phone numbers or email addresses), which the requestor does not wish to be publicly disclosed, then the requestor has the option to submit a redacted version of the request. The redacted version will be posted to the public.

If the requestor needs to submit a redacted version of the letter to the DME MACs, the requestor must provide the redacted version at the same time as providing the version without redaction.

How to Submit an LCD Reconsideration Request:

For your convenience, CGS has prepared an LCD Reconsideration request form (https://www.cgsmedicare.com/jb/pdf/lcd_reconsideration_form.pdf) that you may fill out and submit with your request. This form is optional; however, it will assist you in ensuring the requirements for a complete request are met.

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

1. **Email (Preferred Method):** LCDReconJB@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 LCDReconJB@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting an LCD Reconsideration request.
2. **Fax:** 615.660.5997
   - Please address your fax cover sheet to DME LCD Reconsideration – Attn: Dr. Sunil Lalla.
   - Note: This fax line is only for the LCD reconsideration process described above. This is not the fax line for appealing individual claims (Redeterminations).
3. **Mail:**

   CGS Administrators, LLC
   Attn: Sunil V. Lalla, MD, FACS, CPC
   DME LCD Reconsiderations
   26 Century Blvd STE ST610
   Nashville, TN 37214-3685

Please note that this information is for DME MAC LCD reconsiderations only. Information for submitting an LCD reconsideration request for the Jurisdiction 15 A/B MAC may be found at the J15 website (https://www.cgsmedicare.com/partb/index.html).

Next Steps:

CGS will review the materials received to determine whether the request is valid. A valid request must meet criteria 1-4 listed above. CGS will respond to the request within 60 calendar days upon receipt.

If CGS determines that the request is not valid, CGS will notify the requestor in writing that the request is not valid and will provide the rationale for this decision.

If the request is valid, CGS will begin the LCD development process outlined in the *Program Integrity Manual,* Chapter 13 (Internet-only Manual Pub.100-08). The response to the requestor is an acknowledgement by CGS of the receipt of a valid, complete request. A request response from CGS does not convey that a determination has been made in regard to the likelihood of coverage or non-coverage under 1862(a)(1)(A) of the Act, but is confirmation that CGS plans to proceed with reconsidering the LCD or place the requested LCD reconsideration on the wait-list for development at a later time.

If the request is valid and the LCD is accepted for reconsideration, CGS 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 the new policy at least 45 days in advance of the effective date.

**A proposed LCD will include the requestor's name and/or company information, along with a copy of the request. This information may also be included in other publicly available resources on the Medicare Coverage Database and/or the DME MAC websites.

Proposed LCDs will be finalized or retired within a rolling calendar year of the 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/jb/coverage/reconsideration.html.

LCD Tracking

When the DME MACs receive a valid request to revise an existing LCD, or to develop a new LCD, the DME MACs follow the LCD development process outlined in the CMS *Program Integrity Manual,* Chapter 13.

For up-to-date information on LCDs under reconsideration or development, please see CGS' LCD Tracking webpage at https://www.cgsmedicare.com/jb/coverage/tracking.html.

Claim Determination in the Absence of Medical Policy

Per the Social Security Act, §1862(a)(1)(A), all services billed to Medicare must be reasonable and necessary. Consequently, in addition, Social Security Act §1893(b)(1) authorizes the DME MACs 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 treating 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, §5.18

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 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 treating 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 ADMC requests must clearly indicate "ADMC" on the first page. For your convenience, an ADMC request form is provided on the DME MAC Jurisdiction B website. You can access and fill out the form online at https://www.cgsmedicare.com/jb/forms/pdf/JB_ADMC_request_form.pdf.

ADMC requests may be submitted by the following methods:

1. **Electronically:**
   - MyCGS Web Portal: https://mycgsportal.com/mycgs
   - esMD: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD
2. **Fax**: 615.660.5988

3. **Mail:**

   CGS
   Attn: ADMC
   P.O. Box 20007
   Nashville, TN 37202

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

- **Beneficiary information**
  - Name
  - Medicare Number
  - Address
  - Date of birth
  - Diagnosis code (narrative description is not sufficient)
  - Place of Service
- **Supplier information**
  - Company Name with a contact name
  - PTAN
  - Address
  - Phone number
- **Physician 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 B.
4. The request does not include the item codes (HCPCS) and/or item descriptions.
5. The request is missing demographic information (i.e., beneficiary's name, current address, date of birth, Medicare identification number, the supplier's PTAN and/or the provider's National Provider Identification [NPI] number).
6. It is the 2nd request, but no new information was submitted.
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

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

1. The **written order** (also referred to as the Standard Written Order [SWO]). The SWO must contain the following elements:
    i. Beneficiary's name or Medicare Beneficiary Identifier (MBI)
    ii. Order date
    iii. General description of the item
        - The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
        - For equipment—in addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately)
    iv. Quantity to be dispensed, if applicable
    v. Treating practitioner name or NPI
    vi. Treating practitioner's signature

    You may provide a template to the treating practitioner for their use in creating the order for the base item. The template may list the elements of an order, but you are prohibited from filling in or completing any of these elements. It is a statutory requirement that the treating practitioner who

conducted the face-to-face requirements write the SWO for the power mobility device (base item). The SWO for the power mobility device must be written within six months of the face-to-face encounter and be received by you, the supplier, prior to delivery of the power mobility device.

Refer to the Power Mobility Devices (PMD) LCD (https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33789) and Policy Article (PA) (https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52498) for information regarding the reasonable and necessary and statutory requirements for PMDs.

If you do not receive a written order containing all of these required elements prior to delivery, an EY modifier must be added to the HCPCS codes for the PMD and all accessories. The order must be available on request.

2. An SWO for related options and accessories (if not included on the SWO for the base item). Refer to the PMD Local Coverage Determination (LCD) and related Policy Article for additional information.

3. A report of the **examination**. The treating practitioner must conduct an examination of the beneficiary (via an in-person or Medicare-approved telehealth visit) before writing the order. Refer to the PMD LCD and related Policy Article for guidance about the type of information to be included in the in-person examination and specialty evaluation performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations and who documents the medical necessity for the wheelchair and its special features.

4. **Attestation of "no financial involvement."** The PMD LCD requires a signed and dated affirmation from the supplier that the LCMP or practitioner who performed the specialty evaluation has no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, the PT, OT, or practitioner working in the inpatient or outpatient hospital setting may perform the specialty evaluation.) CGS will also accept an attestation of no financial relationship from the LCMP or practitioner 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 LCMP's or practitioner's specialty evaluation identifying the ATP and their 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

For all manual wheelchair bases, the following items must be submitted with the ADMC request:

1. An SWO for the manual wheelchair base and related options/accessories.
2. Information from the beneficiary's medical record that documents that the coverage criteria defined in the Manual Wheelchair Bases LCD have been met.
3. A home assessment which establishes that the beneficiary or caregiver is able to use the wheelchair ordered to assist with ADLs in the home.

Additionally, for applicable HCPCS codes, the following must also be submitted:

4. A specialty evaluation performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations and who documents the medical necessity for the wheelchair and its special features.
5. The LCMP or practitioner who performed the specialty evaluation has no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, the PT, OT, or practitioner working in the inpatient or outpatient hospital setting may perform the specialty evaluation.) CGS will accept an attestation of no financial relationship from the LCMP or practitioner conducting the specialty evaluation.
6. Demonstration of an ATP in-person involvement in the wheelchair selection

Refer to the Manual Wheelchair Bases LCD (https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33788) and related Policy Article (https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=52497) for information regarding the reasonable and necessary and statutory requirements for manual wheelchairs.

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 standard written order.

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

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual,* Chapter 3, §§3.10, 3.10.1 & Chapter 5, §5.3
CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 1, §10.1.5.1

1. Medicare requires that all HCPCS codes that appear on the Required Prior Authorization List (https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/DMEPOS_PA_Required-Prior-Authorization-List.pdf) must be submitted for prior authorization prior to delivery and claim submission.

2. Claims to Medicare for a HCPCS code for which the required prior authorization applies must be associated with a prior authorization request as a condition of payment. Lack of a provisionally affirmed prior authorization request will result in the supplier of the HCPCS code receiving a claim denial.

3. Claims for HCPCS codes subject to the required prior authorization submitted without a prior authorization determination and a corresponding unique tracking number (UTN) will be automatically denied.

Exceptions to the above (1-3) are **only** for certain HCPCS codes and **only** for **acute situations**. For additional information, please see the "Braces (Orthotics)" section at: https://cgsmedicare.com/jb/pa/orthoses.html.

General Prior Authorization Request (PAR) Program Documentation

Submitters are encouraged to include the following data elements in all PARs to avoid potential delays in processing:

A. Beneficiary Information (as written on their Medicare card):

- Beneficiary Name
- Beneficiary Medicare Number (also known as the MBI)
- Beneficiary Date of Birth
- Beneficiary Address
- Place of Service
- Diagnosis Code

B. Supplier Information:

- Supplier Name
- Provider Transaction Access Number (PTAN)
- Supplier National Provider Enrollment (NPE) Number
- Supplier National Provider Identification
- Supplier Address
- Supplier Phone Number

C. Requestor Information:

- Requestor Name
- Requestor Phone Number

- NPI (if applicable)
- Requestor Address

D. Other Information:

- HCPCS Code
- Submission Date
- Indicate if the request is an initial or subsequent review
- Indicate if the request is expedited and the reason why
- Indicate if the request includes an upgrade

Submitters should note that the beneficiary and supplier addresses listed in the PAR will not be used by the DME MACs when sending review decision letters. The decision letters for suppliers and beneficiaries will be mailed to the supplier address on file with the NPE and the beneficiary address on file with the Social Security Administration. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address.

The Condition of Payment Prior Authorization Program requires all documentation to support a prior authorization request must meet all applicable rules, policies, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and LCD-related policy article requirements. For additional information visit: https://cgsmedicare.com/jb/mr/condition_of_payment_prior_auth.html.

Additional Required Documentation:

- Documentation from the medical record to support the medical necessity of the items
- Any other relevant documents as deemed necessary by the DME MAC to process the PAR

Submission of Prior Authorization Requests

Requests may be submitted by either the beneficiary or the supplier. The submitter is encouraged to complete, and include with their request, a Condition of Payment Prior Authorization Request Coversheet, which is available at: https://cgsmedicare.com/jb/mr/pdf/prior_authorization_coversheet.pdf.

Requesters/submitters have the option to submit a prior authorization request via the myCGS Web Portal, esMD (indicate document/content type 8.4), fax, or U.S. mail. The receipt date will be applied to all documents submitted using a Julian date format.

Prior authorization requests may be submitted by any of the following methods:

1. **Electronically:**
   - myCGS Web Portal: https://mycgsportal.com/mycgs
   - esMD: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD

2. **Fax:** 615.660.5992

3. **Mail:**

   CGS – **JUR B** DME Medical Review – Condition of Payment Program
   PO Box 23110
   Nashville, TN 37202-4890

Power Mobility Devices (PMDs)

As a condition of payment, Medicare requires a prior authorization for the following Power Operated Vehicle (POV) and Power Wheelchair (PWC) base HCPCS codes for all states and territories:

HCPCS Codes	Code Descriptions
K0800-K0802	Group 1 Power Operated Vehicles
*K0806-K0808	Group 2 Power Operated Vehicles
K0813–K0816	Group 1 Power Wheelchairs
K0820–K0829	Group 2 Power Wheelchairs
K0835–K0840	Group 2 Single Power Option Power Wheelchairs
K0841–K0843	Group 2 Multiple Power Option Power Wheelchairs
K0848–K0855	Group 3 No Power Option Power Wheelchairs
K0856–K0860	Group 3 Single Power Option Power Wheelchairs
K0861–K0864	Group 3 Multiple Power Option Power Wheelchairs

*NOTE: Group 2 POV HCPCS codes K0806, K0807, and K0808 are currently not covered as reasonable and necessary and will not be affirmed on prior authorization.

The LCD states that for PWC 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 PWC base, should also be submitted as part of the prior authorization request.

The Condition of Payment Prior Authorization Request for a POV or PWC HCPCS code must include the following documentation:

- WOPD for a POV or PWC base
- SWO for related options/accessories, if applicable
- Treating practitioner's face-to-face encounter
- Specialty evaluation performed by an LCMP or practitioner for Group 2 single and multiple power option bases and Group 3 bases
- Attestation of "no financial involvement" if the specialty evaluation, performed by the LCMP or practitioner, is to be considered part of the face-to-face encounter
- ATP in-person assessment for Group 2 single and multiple power option bases and Group 3 bases
- ATP's RESNA certification for Group 2 single and multiple power option bases and Group 3 bases
- Documentation from the medical record to support the medical necessity

Initial Submission:

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 five business days (not to exceed seven calendar days). 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. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. If the DME MAC exceeds the five business days (not to exceed seven calendar days from the postmarked date) requirement of the initial submission, the request is not automatically affirmed.

Resubmission:

For a resubmitted prior authorization request, the DME MAC will ensure that the written decision is faxed, postmarked, or delivered electronically to the supplier and/or the beneficiary (if specifically requested by the beneficiary) within five business days (not to exceed seven calendar days) of receipt of the resubmission. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. An unlimited number of resubmissions are allowed.

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 five business days (not to exceed seven calendar days) 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.

Expedited Review:

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 and weekends) of receipt of all applicable Medicare required documentation.

You, the supplier, should request an expedited review for replacement PMDs if the item is lost, stolen, or irreparably damaged within the 5-year reasonable lifetime. The PAR request must include supporting documentation that explains the circumstances leading to the need for the replacement, such as detailed reports of loss, theft, or damage and an SWO. The DME MAC will communicate the decisions within two business days (excluding federal holidays and weekends) of receipt of all applicable documentation.

An affirmative prior authorization determination for the HCPCS code is only valid for items delivered within six months following the date of the determination.

Power Mobility Device (PMD) Accessory Voluntary Prior Authorization

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual,* Chapter 3, §§3.10, 3.10.1 & Chapter 5, §5.3
CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 1, §10.1.5.1

Medicare has implemented a voluntary prior authorization program for certain power mobility device accessories.

The following accessories are available for voluntary prior authorization for all US states and territories:

HCPCS Code	Code Description
E0950	Wheelchair accessory, tray, each
E0955	Wheelchair accessory, headrest, cushioned, any type, includes fixed mounting hardware, each
E1002	Wheelchair accessory, power seating system, tilt only
E1003	Wheelchair accessory, power seating system, recline only, without shear reduction
E1004	Wheelchair accessory, power seating system, recline only, with mechanical shear reduction
E1005	Wheelchair accessory, power seating system, recline only, with power shear reduction
E1006	Wheelchair accessory, power seating system, combination tilt and recline, without shear reduction
E1007	Wheelchair accessory, power seating system, combination tilt and recline,

	with mechanical shear reduction
E1008	Wheelchair accessory, power seating system, combination tilt and recline, with power shear reduction
E1009	Wheelchair accessory, addition to power seating system, mechanically linked leg elevation system, including pushrod and leg rest, each
E1010	Wheelchair accessory, addition to power seating system, power leg elevation system, including leg rest, pair
E1012	Wheelchair accessory, addition to power seating system, center mount power elevating leg rest/platform, complete system, any type, each
E1029	Wheelchair accessory, ventilator tray, fixed
E1030	Wheelchair accessory, ventilator tray, gimbaled
E2310	Power wheelchair accessory, electronic connection between wheelchair controller and one power seating system motor, including all related electronics, indicator feature, mechanical function selection switch, and fixed mounting hardware
E2311	Power wheelchair accessory, electronic connection between wheelchair controller and two or more power seating system motors, including all related electronics, indicator feature, mechanical function selection switch, and fixed mounting hardware
E2312	Power wheelchair accessory, hand or chin control interface, mini-proportional remote joystick, proportional, including fixed mounting hardware
E2313	Power wheelchair accessory, harness for upgrade to expandable controller, including all fasteners, connectors, and mounting hardware, each
E2321	Power wheelchair accessory, hand control interface, remote joystick, nonproportional, including all related electronics, mechanical stop switch, and fixed mounting hardware
E2322	Power wheelchair accessory, hand control interface, multiple mechanical switches, nonproportional, including all related electronics, mechanical stop switch, and fixed mounting hardware

E2323	Power wheelchair accessory, specialty joystick handle for hand control interface, prefabricated
E2324	Power wheelchair accessory, chin cup for chin control interface
E2325	Power wheelchair accessory, sip and puff interface, nonproportional, including all related electronics, mechanical stop switch, and manual swing away mounting hardware
E2326	Power wheelchair accessory, breath tube kit for sip and puff interface
E2327	Power wheelchair accessory, head control interface, mechanical, proportional, including all related electronics, mechanical direction change switch, and fixed mounting hardware
E2328	Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware
E2329	Power wheelchair accessory, head control interface, contact switch mechanism, nonproportional, including all related electronics, mechanical stop switch, mechanical direction change switch, head array, and fixed mounting hardware
E2330	Power wheelchair accessory, head control interface, proximity switch mechanism, nonproportional, including all related electronics, mechanical stop switch, mechanical direction change switch, head array, and fixed mounting hardware
E2351	Power wheelchair accessory, electronic interface to operate speech generating device using power wheelchair control interface
E2373	Power wheelchair accessory, hand or chin control interface, compact remote joystick, proportional, including fixed mounting hardware
E2377	Power wheelchair accessory, expandable controller, including all related electronics and mounting hardware, upgrade provided at initial issue
E2601	General use wheelchair seat cushion width, less than 22 inches, any depth
E2602	General use wheelchair seat cushion, width 22 inches or greater, any depth

E2603	Skin protection wheelchair seat cushion, width less than 22 inches, any depth
E2604	Skin protection wheelchair seat cushion, width 22 inches or greater, any depth
E2605	Positioning wheelchair seat cushion, width less than 22 inches, any depth
E2606	Positioning wheelchair seat cushion, width 22 inches or greater, any depth
E2607	Skin protection and positioning wheelchair seat cushion, width less than 22 inches, any depth
E2608	Skin protection and positioning wheelchair seat cushion, width 22 inches or greater, any depth
E2611	General use wheelchair back cushion, width less than 22 inches, any height, including any type mounting hardware
E2612	General use wheelchair back cushion, width 22 inches or greater, any height, including any type mounting hardware
E2613	Positioning wheelchair back cushion, posterior, width less than 22 inches, any height, including any type mounting hardware
E2614	Positioning wheelchair back cushion, posterior, width 22 inches or greater, any height, including any type mounting hardware
E2615	Positioning wheelchair back cushion, posterior-lateral, width less than 22 inches, any height, including any type mounting hardware
E2616	Positioning wheelchair back cushion, posterior-lateral, width 22 inches or greater, any height, including any type mounting hardware
E2620	Positioning wheelchair back cushion, planar back with lateral supports, width less than 22 inches, any height, including any type mounting hardware
E2621	Positioning wheelchair back cushion, planar back with lateral supports, width 22 inches or greater, any height, including any type mounting hardware

E2622	Skin protection wheelchair seat cushion, adjustable, width less than 22 inches, any depth
E2623	Skin protection wheelchair seat cushion, adjustable, width 22 inches or greater, any depth
E2624	Skin protection and positioning wheelchair seat cushion, adjustable, width less than 22 inches, any depth
E2625	Skin protection and positioning wheelchair seat cushion, adjustable, width 22 inches or greater, any depth
K0020	Fixed, adjustable height armrest, pair
K0195	Elevating leg rests, pair (for use with capped rental wheelchair base)

Submitting a voluntary PAR for a PMD accessory is not mandatory and does not create a condition of payment. Prior authorization requests (PARs) submitted for a PMD accessory must include the related PMD base item. If the PAR request does not include a required PMD base, the PAR will be rejected. If the base item on the PAR is non-affirmed, the accessory will also be non-affirmed.

A prior authorization decision will be rendered for both the PMD base and the PMD accessory item(s). If the PMD base is affirmed, but the accessory item(s) is non-affirmed, you may not resubmit a prior authorization request solely for the non-affirmed accessory item(s).

An SWO for related options and accessories (if not included on the SWO for the base item) is required. For additional information regarding accessory requirements, refer to the Wheelchair Options/Accessories LCD (L33792) (https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33792) and LCD-related PA (A52504) (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52504), as well as the Wheelchair Seating LCD (L33312) (https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33312) and LCD-related PA (A52505) (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52505) for the specific coverage criteria and documentation requirements to support medical necessary for the item.
Additional information regarding PAR and the PMD accessories eligible for voluntary prior authorization can be located in the Prior Authorization Process for Certain DMEPOS Items Operational Guide at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/Operational-Guide-for-DMEPOS-PA-current.pdf.

Group 2 Pressure Reducing Support Surfaces (PRSSs)

As a condition of payment, Medicare requires a prior authorization for the following Group 2 PRSS HCPCS codes for all states and territories.

The following Group 2 PRSS HCPCS codes are subject to the Required Prior Authorization program:

HCPCS Code	Code Description
E0193	Powered air flotation bed (low air loss therapy)
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width
E0373	Nonpowered advanced pressure reducing mattress

The Condition of Payment Prior Authorization Request for a Group 2 PRSS HCPCS code must include the following documentation:

- SWO
- Documentation from the medical record to support the medical necessity

Initial Submission:

For the initial submission of the Group 2 PRSS prior authorization request(s), the DME MAC will be required to make the decision(s) and notify each requester within five business days (not to exceed seven calendar days). 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. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. If the DME MAC exceeds the five business days (not to exceed seven calendar days from the postmarked date) requirement of the initial submission, the request is not automatically affirmed.

Resubmission:

For a resubmitted Group 2 PRSS prior authorization request, the DME MAC will ensure that the written decision is faxed, postmarked, or delivered electronically to the supplier and/or the beneficiary (if specifically requested by the beneficiary) within five business days (not to exceed seven calendar days) of receipt of the resubmission. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. An unlimited number of resubmissions are allowed.

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 five business days (not to exceed seven calendar days) 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.

Expedited Review:

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 and weekends) of receipt of all applicable Medicare required documentation.

An affirmative prior authorization determination for the Group 2 PRSS HCPCS code is only valid for items delivered within one month following the date of the determination.

Lower Limb Prosthetics (LLPs)

As a condition of payment, Medicare requires a prior authorization for the following LLP HCPCS codes, for all states and territories.

The following LLP HCPCS codes are subject to the Required Prior Authorization program:

HCPCS Code	Code Description
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source
L5980	All lower extremity prostheses, flex foot system
L5987	All lower extremity prosthesis, shank foot system with vertical loading pylon

The Condition of Payment Prior Authorization Request for an LLP HCPCS code must include the following documentation:

- SWO
- Documentation from the medical record to support the medical necessity

Note: Based on Social Security Act §1834(h)(5), for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by the treating practitioner.

Initial Submission:

For the initial submission of the LLP prior authorization request(s), the DME MAC will be required to make the decision(s) and notify each requester within five business days (not to exceed seven calendar days). 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. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. If the DME MAC exceeds the five business days (not to exceed seven calendar days from the postmarked date) requirement of the initial submission, the request is not automatically affirmed.

Resubmission:

For a resubmitted LLP prior authorization request, the DME MAC will ensure that the written decision is faxed, postmarked, or delivered electronically to the supplier and/or the beneficiary (if specifically requested by the beneficiary) within five business days (not to exceed seven calendar days) of receipt of the resubmission. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. An unlimited number of resubmissions are allowed.

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 five business days (not to exceed seven calendar days) 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.

Expedited Review:

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 and weekends) of receipt of all applicable Medicare required documentation. For expedited review requests, utilize the myCGS Web Portal, esMD, or fax to avoid delays with mailing.

An affirmative prior authorization determination for the LLP HCPCS code is only valid for items delivered within 120 days following the date of the determination.

Braces (Orthotics)

As a condition of payment, Medicare requires a prior authorization for the following brace HCPCS codes for all states and territories.

The following brace HCPCS codes are subject to the Required Prior Authorization program:

HCPCS Code	Code Description
L0631	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to T-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0637	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panels, posterior extends from sacrococcygeal junction to T-9 vertebra, lateral strength provided by rigid lateral frame/panels, produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0639	Lumbar-sacral orthosis, sagittal-coronal control, rigid shell(s)/panel(s), posterior extends from sacrococcygeal junction to T-9 vertebra, anterior extends from symphysis pubis to xyphoid, produces intracavitary pressure to reduce load on the intervertebral discs, overall strength is provided by overlapping rigid material and stabilizing closures, includes straps, closures, may include soft interface, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L0648	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to t-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0650	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L1832	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an Individual with expertise

L1843	Knee orthosis, single upright, thigh, and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1845	Knee orthosis, double upright, thigh, and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1851	Knee orthosis (ko), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1951	Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise

Exceptions to claims submitted that may otherwise be subject to prior authorization requirements are for HCPCS codes L0631, L0637, L0639, L0648, L0650, L1832, L1843, L1845, L1851, and L1951, and **only** for **acute situations**:

- **Acute situations –** When the two-day review would delay care and risk the health or life of certain beneficiaries in need of an orthoses, prior authorization requirements are suspended.

Claims with dates of service on or before December 31, 2023, for these HCPCS codes are to be billed using modifier ST and will be subject to 100% prepayment review. Claims with dates of service on or after January 1, 2024, for these HCPCS codes are to be billed using modifier ST and will be subject to a 50% prepayment review.

The Condition of Payment Prior Authorization Request for a brace HCPCS code must include the following documentation:

- WOPD
- Treating practitioner's face-to-face encounter
- Documentation from the medical record to support the medical necessity

Note: Based on Social Security Act §1834(h)(5), for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by the treating practitioner.

Initial Submission:

For the initial submission of the brace prior authorization request(s), the DME MAC will be required to

make the decision(s) and notify each requester within five business days (not to exceed seven calendar days). 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. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. If the DME MAC exceeds the five business days (not to exceed seven calendar days from the postmarked date) requirement of the initial submission, the request is not automatically affirmed.

Resubmission:

For a resubmitted brace prior authorization request, the DME MAC will ensure that the written decision is faxed, postmarked, or delivered electronically to the supplier and/or the beneficiary (if specifically requested by the beneficiary) within five business days (not to exceed seven calendar days) of receipt of the resubmission. A physician/practitioner letter will be sent on request if there is a form, signed by the physician/practitioner, that includes the address. An unlimited number of resubmissions are allowed.

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 five business days (not to exceed seven calendar days) 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.

Expedited Review:

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 and weekends) of receipt of all applicable Medicare required documentation. For expedited review requests, utilize the myCGS Web Portal, esMD, or fax to avoid delays with mailing.

An affirmative prior authorization determination for the brace HCPCS code is only valid for items delivered within 60 days following the date of the determination.

6. Denial Categories

The Medicare Program provides coverage for a wide range of services to improve the health of persons with Medicare. 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, supplies required for the effective use of DME or prosthetic devices, or supplies necessary for the administration of intravenous immune globulin in the home when used to treat primary immune deficiency disease

2. Equipment that does not primarily and customarily serve a medically therapeutic function

3. Most oral and injectable medications

Medical Necessity Denials

Section 1862(a)(1)(A) 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.

Items and services that are considered investigational or experimental may be denied under this exclusion.

Other Statutory Exclusion Denials

Sections 1862(a)(2)–1862(a)(25) 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 persons with diabetes.

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. An example scenario, for claims denied as duplicate, appears below.

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 practitioner's name/NPI, or billing supplier information will be rejected as unprocessable claims. These claims will be considered for payment when the missing information is supplied on a resubmitted claim.