DME MAC Jurisdiction B **New LCD Request** **NEW 222**

Date

REQUESTOR INFORMATION

First and Last Name **Title**

Organization

Email Address

Phone Number

Requestor Type (choose one)

- ☐ Medicare Beneficiary
- ☐ Individual Physician/Non-Physician Practitioner
- ☐ Health Care Professional* (if selected, complete Specify Requestor Type field to specify degree/credentials)
- ☐ Manufacturer
- ☐ Supplier/Provider
- ☐ Clinical Organization
- ☐ Industry Trade Organization/Coalition
- ☐ Consultant* (if selected, complete Specify Requestor Type field to specify client)
- ☐ Other* (if selected, complete Specify Requestor Type field to specify affiliation)

* Specify Requestor Type

NEW LCD REQUEST INFORMATION

The following fields must be completed in order for a new LCD request to be considered valid. Please include additional documentation if you exceed the character limit.

Clearly identify the statutorily-defined Medicare benefit category under which you believe the item or service falls: See the Social Security Act (SSA) Title XVIII and the CMS Benefit Policy Manual Chapter 15 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf) documents for more information.

- ☐ 1861(s)(2)(J) – Immunosuppressive drugs
- ☐ 1861(s)(2)(Q) – Oral anticancer drugs
- ☐ 1861(s)(2)(T) – Oral anti-emetic drugs
- ☐ 1861(s)(2)(Z) – Intravenous immunoglobulin (IVIG) for primary immune deficiency (Further described at 1861(zz))
- ☐ 1861(s)(2)(JJ) – Lymphedema compression treatment items
- ☐ 1861(s)(5) – Surgical dressings
- ☐ 1861(s)(6) – Durable medical equipment
- ☐ 1861(s)(8) – Prosthetic devices (other than dental) and colostomy bags and colostomy supplies; eyeglasses and contacts following cataract surgery
- ☐ 1861(s)(9) – Leg, arm, back and neck braces (i.e., orthotics) and artificial legs, arms and eyes (i.e., prosthetic limbs)
- ☐ 1861(s)(12) – Therapeutic shoes for persons with diabetes
- ☐ Other** (if selected, complete the “Specify Benefit Category” field to specify the statutorily-defined Medicare benefit category)

** Specify Benefit Category

Provide a rationale for the benefit category selected above.

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What specific coverage or non-coverage language are you requesting in the new LCD?

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 must be submitted.

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.

The level of evidence required for LCD development may be found in the *CMS Program Integrity Manual*, Chapter 13 (https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/Downloads/pim83c13.pdf).

Please provide information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service in the Medicare-eligible population that the new LCD will address.

Please provide information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

(Optional) Please provide the ICD-10 codes that you believe would apply to this request and the rationale for their inclusion.

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METHODS FOR SUBMISSION OF NEW LCD REQUEST

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

Email to (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 an LCD request.

Fax to: 1.615.660.5997

Please address your fax cover sheet to:
DME New LCD – [Topic for New LCD] – Attn: Dr. Sunil Lalla

Mail to: CGS Administrators, LLC
Attn: Sunil V. Lalla, MD, FACS, CPC
DME New LCD Request
26 Century Blvd, Suite NT600
Nashville, TN 37214

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