

National and Local Coverage Determination Appeals

I. Introduction

Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) are decisions as to whether and when certain medical services or treatments are medically necessary and should be covered by Medicare. Medicare's claims processing contractors--Fiscal Intermediaries, Carriers, and the new Medicare Administrative Contractors (MAC)--issue LCDs. The Center for Medicare and Medicaid Services (CMS) issues NCDs. Medicare beneficiaries whose requests for services or claim for payment have been denied as a result of a current LCD or NCD can:

- Seek reconsideration of their individual coverage denial through the coverage and payment [appeals process](#); and
- Challenge the validity of the LCD or NCD as it applies to all similarly situated Medicare beneficiaries through the LCD or NCD appeals process.

The beneficiary need not go through both of these processes. He or she may choose to appeal an LCD or NCD to avoid future denials for the same services.

See [42 CFR §426](#) et. seq.

II. National Coverage Determination Appeals

A. Overview

NCDs are rules on Medicare coverage that CMS issues. The process used by CMS in deciding what is and is not medically necessary is lengthy, involving a review of studies on the subject, expert opinion, and public comment. One result of this evidence-based process for determining Medicare coverage is that these determinations are often difficult to challenge.

See [42 CFR §426.500](#)

B. Stages of an NCD Appeal

Step One: Filing the NCD Complaint

- **Who:** A Medicare beneficiary who is:
 - entitled to benefits under Part A, enrolled under Part B, or both; and
 - is in need of coverage for a service that has been denied based on an applicable NCD; and
 - has obtained documentation of the need for the service by his or her treating physician.

- **When:**
 - **Parties Seeking Medical Treatment:** Within 6 months of the date of the beneficiary's treating physician's written statement in support of Medicare coverage
 - **Parties Seeking Payment for Medical Services Already Received:** Within 120 days of the initial denial notice.

- **How:** The complaint must be in writing, addressed and mailed to the [Department of Health and Human Services Departmental Appeals Board](#):

Departmental Appeals Board
U.S. Department of Health and Human Services
Attn: NCD Participation Request
Appellate Division - MS 6127
300 Independence Avenue, SW
Cohen Building, Room G-644
Washington, DC 20201

- **What:** The complaint must include the following:
 - **Beneficiary and/or Representative identifying information:** Name, address, telephone number, Medicare number, e-mail address (if available), and representative agreement form, if applicable.
 - **Treating physician written statement:** A copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the NCD. This statement may be in the form of a written order for the service or other documents from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.

- **NCD-identifying information:** Name of the contractor using the NCD, the title of the NCD being challenged, and the specific provision of the NCD that is adversely affecting the beneficiary. This information should be stated on the Medicare summary or denial of payment notice. A list of all LCDs and NCDs is available at: www.cms.hhs.gov/mcd. HAP's resource "[How to Find Specific Coverage Under Medicare](#)" explains how to find information in the CMS database.
- **Aggrieved party statement:** A statement from the beneficiary explaining what service is medically necessary and why the current NCD is incorrect. See "[How to Help on a Medicare Appeal](#)" for suggestions on what to include.
- **Clinical or scientific evidence:** Any clinical studies or medical literature supporting the medical need for the service or treatment at issue or showing that the current NCD is not reasonable. See "[How to Help on a Medicare Appeal](#)" for information on locating this data.
- **What Happens Next:** The Departmental Appeals Board sends a letter of acknowledgement to the Medicare beneficiary that states the docket number assigned to the case. The letter also states the date by which Medicare must provide all parties to the matter a copy of the NCD record at issue.

See [42 CFR §§426.500, 426.510](#)

Step Two: Review of the Record and Filing of Statements

Overview: Within 30 days of receiving the DAB docketing letter, Medicare sends the beneficiary a copy of the NCD record. This NCD record is very informative. It contains items such as the NCD rule being challenged, medical evidence considered on or before the date the NCD was issued, coverage decision memoranda, and comments that were made in response to early drafts of the rule.

Upon review of the record, the Medicare beneficiary may file a statement with the DAB and Medicare that explains why the NCD is invalid. Medicare may, in turn, submit a statement as to why the beneficiary is incorrect and the NCD is valid. Upon review of the statements and the evidence, the ALJ makes a determination of the validity of the NCD.

Beneficiary's Review and Statement

- **Who:** The beneficiary may review the NCD record and submit a statement as to why the NCD is invalid.
- **When:** The statement must be filed within 30 days of receiving the NCD record.

- **How:** The beneficiary must mail the DAB and Medicare a copy of the statement.
- **What:** The statement must explain why Medicare's NCD record is incomplete or is inadequate to support the validity of the NCD under the reasonableness standard. The DAB is required to uphold an NCD if, on review of the NCD record, the findings of fact, interpretations of law, and the way Medicare applied facts to the law in developing the LCD were reasonable.
- **What Happens Next:** Medicare reviews the beneficiary's statement and is given an opportunity to respond.

Medicare's Review and Statement

- **Who:** Medicare may review the beneficiary's statement and submit a response.
- **When:** The statement must be filed within 30 days of receiving the beneficiary's statement.
- **How:** Medicare must submit its response in writing to the DAB.
- **What:** Medicare must submit a response to the beneficiary's statement to defend the NCD.
- **What Happens Next:** The DAB applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD.

See [42 CFR §426.525](#)

Step Three: Departmental Appeal Board (DAB) Review

- **Who:** The DAB conducts a review of the NCD record and statements submitted by Medicare and the Medicare beneficiary.
- **When:** Within 90 days of closing the NCD review record to new evidence, the DAB must issue written notification of a decision or the approximate date the decision will issue. It must also place a copy of its decision on the CMS Web site (www.cms.hhs.gov).
- **What:** Under the reasonableness standard, the DAB must uphold a challenged NCD as valid if the findings of fact, interpretations of law, and applications of fact to law as determined by Medicare in creating the NCD were reasonable based upon the NCD record and the record as developed before the DAB.
- **What Happens Next:** If the DAB determines that the NCD is valid, it must issue this decision to the Medicare beneficiary along with information on how the beneficiary may file a federal judicial appeal.

If the DAB determines that the NCD is not valid, the DAB instructs Medicare to re-evaluate the beneficiary's claim for services or payment without relying on the invalid NCD provision. Additionally, within 30 days, Medicare must implement the DAB's decision as Medicare policy in determining subsequent similar claims.

See [42 CFR §§ 426.525](#), [426.547](#), [426.560](#)

III. Local Coverage Determination Appeals

A. Overview

LCDs are rules on Medicare coverage that are issued by regional contractors and fiscal intermediaries when an NCD rule has not addressed the policy at issue. Because individual regional contractors issue LCDs, a Medicare beneficiary with a particular illness may receive Medicare covered treatment under one contractor's LCD in a particular state, but find that she cannot receive the same treatment in a different state because the LCD does not apply. When beneficiaries believe that scientific and medical data supports the medical need for the treatment at issue, they may start an LCD appeal.

B. Stages of an LCD Appeal

Step One: Filing the LCD Complaint

- **Who:** A Medicare beneficiary who is:
 - entitled to benefits under Part A, enrolled under Part B, or both; and
 - is in need of coverage for a service that has been denied based on an applicable LCD; and
 - has obtained documentation of the need for the service by his or her treating physician.
- **When:**
 - **Parties Seeking Medical Treatment:** Within 6 months of the date of the treating doctor's written statement in support of Medicare coverage; or
 - **Parties Seeking Payment for Medical Services Already Received:** Within 120 days of the initial denial notice.
- **How:** The complaint must be in writing, addressed, and mailed to the following address:

Departmental Appeals Board
Civil Remedies Division, Mail Stop 6132
Cohen Building, Room G-644
330 Independence Avenue, S.W
Washington, DC 20201

- **What:** The complaint must include the following:
 - **Beneficiary and/or Representative identifying information:** Name, address, telephone number, Medicare number, e-mail address, and representative agreement form (if applicable).
 - **Treating physician written statement:** A copy of a written statement from the treating physician that the beneficiary has a medical necessity for the service that is the subject of the LCD. This statement may be in the form of a written order for the service or other documents from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service.
 - **LCD-identifying information:** Name of the contractor using the LCD, the title of the LCD being challenged, and the specific provision of the LCD that is adversely affecting the beneficiary. This information should be stated on the Medicare summary or denial of payment notice. CMS maintains an up to date [database](#) of all LCDs and NCDs. HAP's resource "[How to Find Specific Coverage Under Medicare](#)" explains how to find information in the CMS database.
 - **Aggrieved party statement:** A statement from the beneficiary explaining what service is medically needed and why the current LCD is incorrect. See "[How to Help on a Medicare Appeal](#)" for suggestions on deciding what to include.
 - **Clinical or scientific evidence:** Any clinical studies or medical literature supporting the medical need for the service or treatment at issue or showing that the current LCD is not reasonable. See "[How to Help on a Medicare Appeal](#)" for information on locating this data.
- **What Happens Next:** The Departmental Appeals Board assigns an Administrative Law Judge (ALJ) to review the case. The ALJ sends a letter of acknowledgement to the Medicare beneficiary that states the docket number assigned to the case and informs the beneficiary of his or her right to review the LCD record, the date by which the record should be made available to the beneficiary, and the right of the beneficiary to submit a statement in support of his or her position. This letter is also mailed to the Medicare contractor.

See [42 CFR § 426.400](#)

Step Two: Review of the Record and Filing of Statements

Overview: Following the filing of the complaint, the Medicare contractor sends the beneficiary a copy of the LCD record. This LCD record is very informative. It contains

items such as the LCD rule being challenged, medical evidence considered on or before the date the LCD was issued, and comments that were made in response to early drafts of the rule.

Upon review of the record, the Medicare beneficiary may file a statement with the ALJ indicating why the LCD is incorrect under Medicare's reasonable and necessary standard. The contractor may, in turn, submit a statement as to why the beneficiary is incorrect. Upon review of the statements and the evidence, the ALJ makes a determination.

Beneficiary's Review and Statement

- **Who:** The beneficiary may review the LCD record and submit a statement as to why the LCD is not supported under the reasonableness standard.
- **When:** The statement must be filed within 30 days of receiving the LCD record.
- **What:** The beneficiary must mail the contractor and the ALJ a copy of his or her statement. The statement must explain why the contractor's LCD record is incomplete or is inadequate to support the validity of the LCD under the reasonableness standard. The reasonableness standard requires that an ALJ uphold a LCD if, upon review of the LCD record, the findings of fact, interpretations of law, and applications of fact to law as made by the contractor in developing the LCD were reasonable.
- **What Happens Next:** The contractor reviews the beneficiary's statement and is given an opportunity to respond.

Contractor's Review and Statement

- **Who:** The Medicare contractor may review the beneficiary's statement and submit a response.
- **When:** The statement must be filed within 30 days of receiving the beneficiary's statement.
- **What:** The contractor must submit its response in writing to the ALJ.
- **What Happens Next:** The ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the LCD's validity.

See [42 CFR §426.425](#)

Step Three: Administrative Law Judge (ALJ) Review

- **Who:** The ALJ must review the LCD record and the statements submitted by the beneficiary and Medicare contractor and issue a determination.
- **When:** Within 90 days of closing the LCD review record to new evidence, the ALJ must issue written notification of a decision or the approximate date that the decision will issue.
- **What:** The decision must indicate whether the LCD is valid or invalid under the reasonableness standard. The ALJ must uphold a challenged LCD as valid if the findings of fact, interpretations of law, and applications of fact to law by the contractor are reasonable based on the LCD record and the record as developed before the ALJ.
- **What Happens Next:** If the ALJ determines that the LCD is valid, the beneficiary may appeal this decision to the Departmental Appeals Board (DAB). If the ALJ determines that the LCD is not valid and the Medicare contractor fails to appeal, the contractor must re-evaluate the beneficiary's claim for services or payment without relying on the invalid provision.

Additionally, within 30 days, the contractor must implement the ALJ's decision as policy in determining subsequent claims. If the Medicare contractor chooses to appeal the ALJ's determination, the LCD remains in force and the individual claim re-evaluation is stayed until the DAB issues a final decision.

See [42 CFR §§426.110](#), [426.450](#), [426.460](#)

Step Four: Departmental Appeal Board (DAB) Review

- **Who:** A Medicare beneficiary whose ALJ level LCD appeal was unsuccessful may file a request for DAB review.
- **When:** An appeal to the DAB must be filed within 30 days of the ALJ issuing its decision.
- **What:** The beneficiary must submit to the DAB an appeal that includes the full names and addresses of the parties, the name of the LCD, the date the ALJ's decision was issued, the docket number that appears on the ALJ's decision, a statement identifying the part(s) of the ALJ's decision that are being appealed, and a statement explaining why the ALJ's decision should be reversed.

- **What Happens Next:** The DAB reviews the LCD record and the arguments submitted by the parties to determine whether the ALJ made a material error in reaching its decision. The DAB may allow oral argument if it believes that it would be helpful in deciding the matter. The DAB then issues a written decision upholding, modifying, or reversing the ALJ decision. If the DAB decision remains adverse to the beneficiary's interests, the beneficiary may file a complaint for judicial review.

See [42 CFR §§426.300, 426.465](#)