

<b>DEPARTMENT:</b> Regulatory Compliance Support	<b>POLICY DESCRIPTION:</b> Medicare - National and Local Coverage Determinations for Physician Professional Services and Non-Hospital Entities
<b>PAGE:</b> 1 of 5	<b>REPLACES POLICY:</b> 10/1/11, 10/1/15
<b>EFFECTIVE DATE:</b> February 1, 2017	<b>REFERENCE NUMBER:</b> REGS.OSG.007
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

**SCOPE:** All non-hospital entities and personnel responsible for providing and/or billing for services. Including but not limited to:

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| Ambulatory Surgery Centers (ASCs)                 | Registration                            |
| HCA Physician Services Group (PSG)                | Coding and Billing                      |
| Independent Diagnostic Testing Facilities (IDTFs) | Ordering/Referring/Rendering Physicians |
| Freestanding Imaging Centers                      | Nursing Staff                           |
| Employed and Managed Physicians                   | Hospitalists                            |
| Freestanding Radiation Oncology Centers           | Non-Physician Practitioners             |
| Administration/Practice Management                | Service Centers                         |
| Office Staff                                      |   |

**PURPOSE:** To define the requirements for complying with Medicare's National and/or Local Coverage Determinations.

National Coverage Determinations (NCDs) are developed by the Centers for Medicare and Medicaid Services (CMS) and applied on a nationwide basis. NCDs generally describe the criteria and coverage limitations that apply to particular services, procedures or devices for coverage and payment purposes. NCDs are binding on all Medicare Contractors, (e.g., Medicare Administrative Contractors (MACs) and Quality Improvement Organizations (QIOs) nationwide, and Administrative Law Judges (ALJs)).

Local Coverage Determinations (LCDs) are decisions by a local MAC, and are applicable only within that issuing Medicare Contractor's jurisdiction(s). Like NCDs, LCDs generally describe the criteria and coverage limitations that apply to particular services, procedures or devices for coverage and payment purposes. Unlike NCDs, however, an LCD is binding only on the Medicare Contractor that issued the LCD and on the jurisdiction's QIO; it is not binding on other Medicare Contractors, QIOs or ALJs.

CMS sets forth specific processes for periodically reconsidering, revising and updating NCDs and LCDs. Typically, LCDs are updated more frequently, and more subject to challenge, than are NCDs. If you have a question regarding NCDs or LCDs, or if you wish to challenge an LCD, please contact Regs.

**POLICY:** Each entity must implement the necessary processes to ensure the following key requirements are met:

1. Designate an individual who will be responsible for the local entity's NCD/LCD process.
2. Identify the NCDs and LCDs that apply to the entity's services, procedures, items and/or devices.
3. Educate and disseminate the information in the NCDs/LCDs to all applicable office, clinical, and medical staff.
4. Structure operational processes to establish clear areas of responsibility and accountability for personnel to ensure compliance with the NCDs and/or LCDs, including but not limited to ensuring compliance with:
  - a. clinical indications or contraindications for the service, procedure, item or device,

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- b. qualifications, licensure or certification of individuals,
  - c. special certification of an entity or a department of an entity,
  - d. data collection and submission, and
  - e. documentation requirements.
5. Ensure that NCD/LCD criteria are met before performing a service or using a device, or, when applicable, that an Advance Beneficiary Notice of Non-coverage (ABN) is given before such services are rendered.
  6. Bill appropriately for services, procedures or devices associated with an NCD/LCD.
  7. Periodically assess compliance with this policy, including the identification of root causes for non-compliance with the NCD/LCD and corrective actions taken.

**PROCEDURE:**

The entity's administrative and operational support team, including but not limited to, the Medical Director, Administrator, Area Practice Manager, Practice Manager, and regional/divisional personnel shall work together to understand the clinical and financial aspects of NCD/LCD requirements.

Entities must work with their physicians and clinical staff in order to implement the following processes to facilitate compliance with NCD/LCD requirements. These processes are not intended to apply in emergent situations or where the physician certifies that the beneficiary's health or safety is at risk; In these situations, the entity must design a mechanism to retrospectively review the cases in order to bill the claims appropriately.

**Designation of Responsible Individual**

1. Within each entity, an individual will be appointed who will be responsible for the entity's NCD/LCD process. This individual would preferably have a clinical background and be able to communicate effectively with the office, clinical, and medical staffs.
2. This individual is responsible for identifying those NCDs/LCDs that apply to the entity's services, procedures and devices.
3. This individual is also responsible for coordinating the education and dissemination of the information in the NCDs/LCDs to the relevant office, clinical, and medical staff.
4. This individual will also be responsible for monitoring compliance with this policy.
5. Key NCD/LCD activities should be reported to entity administration and operational support teams.

**Identification, Education and Dissemination**

1. The individual responsible for the NCD/LCD process must:
  - a. Identify the NCDs and LCDs that apply to the entity's services, procedures and devices. These NCDs and LCDs must be organized and readily available to the applicable Clinical staff, Scheduling, Patient Registration, Coding and Billing Staff, as well as physicians and non-physician practitioners. Tools and resources pertaining to NCDs/LCDs are available on the Regulatory Compliance Support (Regs) website. In addition, CMS NCDs are available on the [Medicare Coverage Database](#) website.

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- b. Work with other staff, such as Coders, Billers, Medical Director, and Schedulers to ensure that physicians and staff responsible for ordering, referring, performing, registering, charging, coding or billing are educated on the requirements of the NCDs/LCDs.
2. All applicable office, clinical and medical staff must be provided with a summary of the following information:
  - a. National and Local Coverage Determinations.
  - b. Advance Beneficiary Notice (ABN) Policy (REGS.OSG.002).
  - c. Other mandated corporate tools and references related to NCDs/LCDs.
  - d. Physician Pamphlet regarding National and Local Coverage Decisions (Attachment A). The Pamphlet will be provided to each ordering physician/non-physician practitioner upon issuance of this policy and at least once every two years.

**Development of Process to Comply with NCD/LCD Requirements**

NCDs/LCDs range in the level of requirements for coverage. Some NCDs and LCDs are rather general, and permit coverage with sufficient clinical documentation. Other NCDs and LCDs provide more specific requirements for coverage or specify situations in which a service, procedure, item or device would not be covered. Although all elements of an NCD and LCD should be met, particular attention should be paid to the following elements:

**Certification or Accreditation**

1. Determine if the NCD/LCD requires the entity to be specifically certified by CMS or another accrediting body to provide that service, procedure or device. For example: The NCD on Diabetes Outpatient Self-Management Training (DSMT) includes a requirement for all programs to be accredited as meeting quality standards by a CMS approved national accreditation organization.
2. If it is determined that a special entity certification or accreditation is required, and the entity is not already certified or accredited, the entity must take steps to become certified and/or accredited in order to provide the service, procedure, item or device.
3. Documentation of the certification or accreditation must be maintained and made available upon request.

**Individual licensure or certification**

1. Determine if the NCD/LCD requires individuals, including physicians and clinical staff, to have specific licensure or credentials. For example, some LCDs for non-invasive vascular studies require technicians to have one of the following credentials in vascular ultrasound technology: RVS, RVT, ARRT (VS).
2. If it is determined that special staff or physician credentials are required, entities must ensure that all relevant staff, including physicians, are appropriately licensed or credentialed in order to provide the service, procedure or device.
3. Documentation of the license or certification must be maintained and made available upon request.

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**Data collection requirements**

1. Determine if the NCD/LCD requires participation in a qualified data collection system and/or submission of data to CMS.
2. If it is determined that participation in a data collection system or submission of data is required, entities must ensure that this requirement is met in order to provide the service, procedure, item or device.

**Medical record documentation and billing requirements**

1. Determine if the NCD/LCD requires special medical record documentation and/or billing requirements. For example:
  - a. The NCD and many LCDs on Hyperbaric Oxygen Therapy contain very specific documentation requirements.
  - b. The NCD and many LCDs on Erythropoiesis Stimulating Agents require the most current hemoglobin or hematocrit to be reported on the claim.
2. If it is determined that special medical record documentation and/or billing requirements are required, entities must take the appropriate steps to incorporate them.

**Clinical indications and/or contraindications**

1. Determine if the NCD/LCD contains specific clinical indications or contraindications for performing the service, procedure or device. For example, the NCD on Implantable Cardiac Defibrillators defines specific indications and contraindications for performing the procedure.
2. **If it is determined that an NCD or LCD requires specific criteria to be met in order for the service, procedure, item or device to be provided, then entities and their physicians must ensure that these requirements are met prior to providing the service, procedure, item or device. For certain NCDs or LCDs, corporate headquarters may provide tools and resources to assist in accomplishing this process. This process may be analogous to the preauthorization practices employed by other payers.**

**Screening for and determining if clinical indications are met**

1. Entities must implement a screening process prior to performing a service, procedure or device to determine if an NCD and/or LCD applies.
2. If the service, procedure or device is included in an NCD or LCD, the pertinent information, including ICD-10-CM and HCPCS codes if applicable, must be gathered to determine if the requirements specified in the NCD and/or LCD have been met.
3. Many LCDs contain ICD-10-CM diagnosis and procedure codes, as well as HCPCS procedure codes, that delineate when a service, procedure or device is covered. When this is the case, front-end systems/processes can be used to screen the case prior to delivery.
4. If the NCD or LCD does not clearly articulate the pertinent ICD-10-CM or HCPCS codes and/or there are other specific NCD/LCD requirements, *i.e.*, documentation of symptoms or prior procedures, a manual review of the required elements must be completed by appropriate staff to determine if the NCD/LCD requirements are met. Appropriate staff may include personnel such as nursing, coding, and medical staff. The physician should be consulted if assistance is needed to determine whether the service, procedure, item or device

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meets the NCD/ LCD requirements or the service, procedure, item or device needs to be provided at all.

5. If it is determined that the service, procedure, item or device does not meet the NCD/LCD requirements, or if the ordering physician did not clearly articulate the diagnosis, sign, symptom or ICD-10-CM code, entities should contact the ordering physician for additional clinical information.
6. If no additional information is provided, or if the additional information provided does not meet the NCD/LCD requirements, the entity must proceed in issuing an ABN to the patient prior to providing the service, procedure or device. See the Advance Beneficiary Notice Policy (REGS.OSG.002) for more information on the ABN processes. The entity should follow its normal procedures after the issuance of the ABN as to: a.) any prepayment obligations, b.) processing of any patient request for charge adjustments, or c.) any other financial matters related to the service, procedure, item or device and the patient's personal financial responsibility arising from the Medicare non-coverage.

**Billing edits and review**

1. When NCDs and LCDs contain ICD-10-CM and/or HCPCS codes that delineate when a service, procedure or device is covered, Medicare contractors may develop edits to facilitate appropriate billing.
2. In cases where screening was required due to the clinical criteria contained in an NCD/LCD, but was not performed, entities must review these cases prior to billing to ensure compliance with the NCD/LCD.
3. Entities must establish processes for communicating this information to their billing departments to ensure appropriate billing codes are added to the claims.

**Audit and monitoring**

Entities should periodically review their processes to assess compliance and make improvements, where necessary. Applicable tools from Regulatory Compliance Support and/or Parallon Business Solutions may be used in this process.

**REFERENCES:**

1. Medicare National Coverage Determinations Manual (100-03)
2. Medicare Claims Processing Manual (100-04), Chapter 30
3. Medicare Claims Processing Manual (100-04), Chapter 32
4. Medicare Program Integrity Manual (100-08), Chapter 13
5. Advance Beneficiary Notice of Noncoverage for Physician Professional Services and Non-Hospital Entities, REGS.OSG.002

## Physician Notice Regarding Medicare National and Local Coverage Determinations

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### What is a Medicare Coverage Determination?

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#### **Coverage determinations:**

- Describe the criteria and coverage limitations that apply to particular services, procedures, items or devices for coverage and payment purposes
- Are based on clinical evidence, intended to reflect accepted current consensus and defined by Medicare as being reasonable and necessary
- Apply to both facilities and physicians, although there may be instances where the coverage criteria differ

#### **Two types of coverage determinations**

- **National Coverage Determinations (NCDs)**
  - Developed by the Centers for Medicare and Medicaid Services (CMS)
  - Applied on a nationwide basis
- **Local Coverage Determinations (LCDs)**
  - Developed by a local Medicare Administrative Contractor (MAC)
  - Applied locally, *i.e.*, jurisdiction of the Contractor
  - Established for services and procedures not articulated in an NCD
  - Can be based on an NCD, but cannot conflict or be less restrictive than an NCD

### What do NCDs and LCDs address?

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#### **NCDs and LCDs**

- Cover services ranging from the simple, *e.g.*, CBC, to the complex, *e.g.*, heart transplants
- Vary in the level of requirements for coverage
- Some are rather general and allow coverage with sufficient clinical documentation
- Others provide more specific clinical requirements for coverage, including situations in which a service or procedure would not be covered

### What does this mean to the facility and physician?

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- Procedures or services subject to an NCD/LCD must meet the NCD/LCD requirements in order to be covered and paid.
- When ordering services, such as lab or imaging tests, physicians must provide a diagnosis, sign, symptom, or ICD-10-CM code.
- When scheduling certain surgical or interventional procedures, such as implantable cardiac defibrillators, bariatric surgery or HBO therapy, physicians may be asked to provide additional clinical information and/or documentation.

### What assistance is available in determining whether an NCD/LCD applies or what criteria are contained in an NCD/LCD?

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Contact your operational support team. They maintain a current list of applicable NCDs/LCDs and can make available a clinical contact to assist with any questions.

### **What happens when a service or procedure does not meet the NCD/LCD requirements?**

- Medicare coverage and payment are at risk if the service, procedure, item or device does not meet the NCD/LCD requirements.
- Physicians will be notified. The facility will request the physician to provide additional information or to reschedule the procedure, if appropriate. With sufficient, appropriate additional information, the NCD/LCD requirements may be met.

### **What does this mean to the patient?**

- If the service, procedure, item or device as documented, does not meet the NCD/LCD criteria, the patient will be so informed but may still choose to have the service/procedure or receive the item/device.
- If the patient chooses to proceed, s/he will be asked to sign an Advance Beneficiary Notice of Noncoverage (ABN)
  - The purpose of the ABN is to give the patient advance notice that Medicare may not pay for the test, service, procedure, item or device ordered. If Medicare does not pay, the patient will be liable for payment.
  - The guiding principle in obtaining an ABN is not whether you, as a physician, believe that the procedure or service is medically necessary. But rather, whether the patient's diagnosis, signs, or symptoms meet the NCD/LCD requirements.
- The patient may be able to appeal Medicare's decision not to pay for the service or procedure.