



<b>DEPARTMENT:</b> Regulatory Compliance Support	<b>POLICY DESCRIPTION:</b> Medicare National and Local Coverage Determinations for Physician Professional Services and Non-Hospital Entities
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<b>EFFECTIVE DATE:</b> December 1, 2021	<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:

Administration	Independent Diagnostic Testing Facilities (IDTFs)
Advanced Practice Professionals (APPs)	Nursing Staff
Ambulatory Surgery Division (ASD)	Office Staff
Coding/Billing	Ordering/Referring/Rendering Physicians
Employed and Managed Physicians	Parallon
Ethics and Compliance Officers (ECOs)	Physician Services Group (PSG)
Freestanding Imaging Centers	Practice Management
Freestanding Radiation Oncology Centers	

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

**National Coverage Determinations (NCDs)** are developed by the Centers for Medicare & 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 Administrative Contractors (MACs), Quality Improvement Organizations (QIOs), Administrative Law Judges (ALJs) and the Medicare Appeals Council.

**Local Coverage Determinations (LCDs)** are decisions by a local MAC, and are applicable only within the issuing MAC’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.

**Local Coverage Articles (LCAs)** are typically published by a MAC to provide coding/billing guidelines or other provider education that is complementary to an existing NCD or LCD. In some cases LCAs may be issued by MACs as independent policies. Similar to LCDs, LCAs apply only to the MAC that issued the Article.

CMS sets forth specific processes for periodically reconsidering, revising and updating NCDs, LCDs and LCAs. Typically, LCDs/LCAs are updated more frequently, and more subject to challenge, than are NCDs. If you have a question regarding NCDs, LCDs or LCAs, or if you wish to challenge an LCD/LCA, 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/LCA process.
2. Identify the NCDs/LCDs/LCAs that apply to the entity’s services, procedures, items and/or devices.



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3. Educate and disseminate the information in the NCDs/LCDs/LCAs 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/LCDs/LCAs, including but not limited to ensuring compliance with:
  - a. clinical indications or contraindications for the service, procedure, item or device,
  - 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/LCA criteria are met before performing a service or using a device, or, when applicable, that an Advance Beneficiary Notice of Noncoverage (ABN) is given before such services are rendered.
6. Bill appropriately for services, procedures or devices associated with an NCD/LCD/LCA.
7. Periodically assess compliance with this policy, including the identification of root causes for non-compliance with the NCD/LCD/LCA 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/LCA requirements.

Entities must work with their physicians and clinical staff in order to implement the following processes to facilitate compliance with NCD/LCD/LCA 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/LCA 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/LCAs 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/LCAs 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/LCA activities should be reported to entity administration and operational support teams.

**Identification, Education and Dissemination**

1. The individual responsible for the NCD/LCD/LCA process must:

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- a. Identify the NCDs/LCDs/LCAs that apply to the entity's services, procedures and devices. These NCDs/LCDs/LCAs must be organized and readily available to the applicable Clinical staff, Scheduling, Patient Registration, Coding and Billing Staff, as well as physicians and Advanced Practice Professionals. Tools and resources pertaining to NCDs/LCDs/LCAs are available on the Regulatory Compliance Support (Regs) website. In addition, CMS NCDs/LCDs/LCAs are available on the [Medicare Coverage Database](#) website.
- 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/LCAs.
2. All applicable office, clinical and medical staff must be provided with a summary of the following information:
  - a. National and Local Coverage Determinations and Local Coverage Articles.
  - b. Advance Beneficiary Notice (ABN) Policy (REGS.OSG.002).
  - c. Other mandated corporate tools and references related to NCDs/LCDs/LCAs (e.g. NCDs, LCDs, and LCAs Implementation and Compliance Guidance for Non-Hospital Entities).
  - d. Physician Pamphlet regarding National and Local Coverage Decisions and Local Coverage Articles (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/LCA Requirements**

NCDs/LCDs/LCAs range in the level of requirements for coverage. Some NCDs/LCDs/LCAs are rather general, and permit coverage with sufficient clinical documentation. Other NCDs/LCDs/LCAs 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/LCD/LCA should be met, particular attention should be paid to the following elements:

**Certification or Accreditation**

1. Determine if the NCD/LCD/LCA 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/LCA requires individuals, including physicians and clinical staff, to have specific licensure or credentials. For example, some LCDs for non-invasive vascular

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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.

**Data collection requirements**

1. Determine if the NCD/LCD/LCA 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/LCA requires special medical record documentation and/or billing requirements. For example:
  - a. The NCD on Hyperbaric Oxygen Therapy contains very specific documentation requirements.
  - b. The NCD and many LCDs/LCAs 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/LCA 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/LCD/LCA 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/LCDs/LCAs, 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/LCD/LCA applies.
2. If the service, procedure or device is included in an NCD/LCD/LCA, the pertinent information, including ICD-10-CM and HCPCS codes if applicable, must be gathered to determine if the requirements specified in the NCD/LCD/LCA have been met.

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3. Many LCDs/LCAs 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/LCD/LCA does not clearly articulate the pertinent ICD-10-CM or HCPCS codes and/or there are other specific NCD/LCD/LCA requirements, e.g., 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/LCA requirements are met. Appropriate staff may include personnel such as nursing, coding, and medical staff. The physician/APP should be consulted if assistance is needed to determine whether the service, procedure, item or device meets the NCD/LCD/LCA 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/LCA requirements, or if the ordering physician/APP did not clearly articulate the diagnosis, sign, symptom or ICD-10-CM code, entities should contact the ordering physician/APP for additional clinical information.
6. If no additional information is provided, or if the additional information provided does not meet the NCD/LCD/LCA 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/LCDs/LCAs 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/LCA, but was not performed, entities must review these cases prior to billing to ensure compliance with the NCD/LCD/LCA.
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](#)



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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](#)
6. [NCD LCD LCA Implementation Guidance for Non-Hospital Entities](#)
7. [Attachment A: Physician Notice Regarding Medicare National and Local Coverage Determinations](#)