

DEPARTMENT: Regulatory Compliance Support	POLICY DESCRIPTION: Medicare - National and Local Coverage Determinations
PAGE: 1 of 6	REPLACES POLICY DATED: REGS.GEN.002, Medicare – Medical Necessity Guidelines (7/1/09); 10/11/10, 12/1/14, 4/1/16, 1/1/18
EFFECTIVE DATE: May 1, 2019	REFERENCE NUMBER: REGS.GEN.011
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated hospitals performing and/or billing Medicare inpatient and/or outpatient services. Specifically, the following departments:

Nursing	Patient Access
Admitting/Registration	Parallon HIM Shared Services Centers (HSC)
Medical Staff	Physician Office Staff
Medical Directors	Physician Advisors
Central Scheduling	Ancillary Departments
Revenue Integrity	Case Management
Reimbursement	Non-physician Practitioners
Parallon Shared Services Centers	

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 Medicare Administrative Contractor 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 local Medicare Administrative Contractor 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 and LCDs. 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, please contact Regs.

POLICY:

Hospitals must:

1. Designate an individual who will be responsible for the facility’s NCD/LCD/LCA process.

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2. Identify the NCDs, LCDs, and LCAs that apply to the hospital's services, procedures and devices.
3. Educate and disseminate the information in the NCDs/LCDs/LCAs to all applicable hospital and medical staff.
4. Develop processes and 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 or device,
 - b. qualifications, licensure or certification of individuals,
 - c. special certification of the hospital or a department of a hospital,
 - d. data collection and submission, and
 - e. documentation requirements.
5. Ensure that NCD/LCD/LCA criteria are met before performing a service, procedure or device, or that a Hospital Issued Notice of Non-Coverage (HINN) or 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/LCA.
7. Follow established monitoring processes to assess compliance with this policy and identify the root causes of any identified issues.

PROCEDURE:

The hospital administrative team, including but not limited to, the Medical Director, CEO, COO, CFO and CNO, shall work together to understand the clinical and financial aspects of NCD/LCD/LCA requirements.

Hospitals 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 hospital must design a mechanism to retrospectively review these cases in order to bill the claim appropriately.

Designation of Responsible Individual

1. The hospital CEO shall appoint an individual who will be responsible for the facility's NCD/LCD/LCA process. This individual should have a clinical background and be able to communicate effectively with the hospital and medical staffs.
2. This individual is responsible for identifying those NCDs/LCDs/LCAs that apply to the hospital'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 hospital departments and medical staff.
4. This individual will also be responsible for monitoring compliance with this policy.

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5. Key NCD/LCD/LCA activities should be reported to hospital administration, applicable medical staff committees and departments, and the Facility Ethics and Compliance Committee.

Identification, Education and Dissemination

1. The individual responsible for the NCD/LCD/LCA process must:
 - a. Identify the NCDs, LCDs and LCAs that apply to the hospital's services, procedures and devices. These NCDs, LCDs, and LCAs must be organized and readily available to the applicable Ancillary Departments, Case Management, Quality Management, Health Information Management, Scheduling, Patient Registration, and Service Center staff, as well as physicians and non-physician practitioners. Tools and resources pertaining to NCDs/LCDs/LCAs are available on the Regulatory Compliance Support (Regs) website. In addition, CMS NCDs are available on the [Medicare Coverage Center](#) website.
 - b. Work with other hospital staff, such as Ancillary Department Directors, Case Management, Health Information Management, Physician Advisors, Medical Director, Schedulers and/or Patient Access Director 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 hospital and medical staff personnel 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.GEN.003)
 - c. Hospital Issued Notice of Non-Coverage (HINN) Policy (REGS.GEN.010)
 - d. Other mandated corporate tools and references related to NCDs/LCDs
 - e. Physician Pamphlet regarding National and Local Coverage Determinations (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 during the credentialing process.

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 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:

Hospital certification or accreditation

1. Determine if the NCD/LCD/LCA requires the hospital to be specifically certified by CMS or another accrediting body to provide that service, procedure or device. For example:
 - a. The NCD on Percutaneous Transluminal Angioplasty includes a requirement for all hospitals performing carotid artery stenting to be certified by CMS.

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- b. The NCD on Artificial Hearts and Related Devices includes a requirement for hospitals providing VAD destination therapy to be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.
2. If it is determined that a special hospital certification or accreditation is required, and the hospital is not already certified or accredited, the hospital must take steps to become certified and/or accredited in order to provide the service, procedure or device.
3. Documentation of the certification or accreditation must be maintained and made available upon request.

Individual qualifications, training, licensure or certification

1. Determine if the NCD/LCD/LCA requires individuals, including physicians and hospital staff, to have specific qualifications, training, 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, hospitals must ensure that all relevant staff, including physicians, are appropriately qualified, trained, licensed and/or credentialed in order to provide the service, procedure or device.
3. Documentation of the qualifications, training, 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. For example, the NCD on Transcatheter Aortic Valve Replacement contains a requirement that the hospital participate in a qualified data collection system.
2. If it is determined that participation in a data collection system or submission of data is required, hospitals must ensure that this requirement is met in order to provide the service, procedure 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 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, hospitals 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

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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 or device to be provided, hospitals must ensure that these requirements are met prior to providing the service, procedure or device. For certain NCDs/LCDs/LCAs, corporate headquarters may provide tools and resources to assist hospitals 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. Hospitals 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 diagnosis and HCPCS codes if applicable, must be gathered to determine if the requirements specified in the NCD/LCD/LCA have been met.
3. Many LCDs/LCAs contain 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, the front-end medical necessity software system can be used to screen the case prior to delivery.
4. If the NCD/LCD/LCA does not clearly articulate the pertinent diagnosis or HCPCS codes and/or there are other specific NCD/LCD/LCA 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/LCA requirements are met. Appropriate staff may include clinical personnel such as nursing, revenue integrity, case management and ancillary department staff. The physician advisor or Medical Director should be consulted if assistance is needed to determine whether the service, procedure or device meets the NCD/LCD/LCA requirements or the service, procedure or device needs to be provided.
5. If it is determined that the service, procedure or device does not meet the NCD/LCD/LCA requirements, or if the ordering physician did not clearly articulate the diagnosis, sign, symptom or diagnosis code, hospitals 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/LCA requirements, the hospital must proceed in issuing an ABN for outpatients or a HINN for inpatients to the patient prior to providing the service, procedure or device. See the Advance Beneficiary Notice Policy (REGS.GEN.003) and the Hospital Issued Notice of Non-Coverage Policy (REGS.GEN.010) for more information on the ABN and HINN processes. The hospital should follow its normal procedures after the issuance of the ABN or HINN as to any prepayment obligations, processing of any patient request for financial concession, or any other financial matters related to the service, procedure or device and the patient's personal financial responsibility arising from the Medicare non-coverage.

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Billing edits and review

1. When NCDs/LCDs/LCAs contain diagnosis and/or HCPCS codes that delineate when a service, procedure or device is covered, Regulatory Compliance Support, in conjunction with Parallon, 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, hospitals must review these cases prior to billing to ensure compliance with the NCD/LCD/LCA.
3. Hospitals must establish processes for communicating this information to their PAD or Patient Access department to ensure appropriate billing codes are added to the claim.

Audit and monitoring

Regulatory Compliance Support and the Parallon will develop an audit and monitoring process that the hospitals, SSCs and MSCs can use to assess compliance with this policy.

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. CMS Manual System Transmittal 829, Medicare Program Integrity (Pub 100.08), October 3, 2018
6. Advance Beneficiary Notice of Noncoverage – Outpatient Services Policy, [REGS.GEN.003](#)
7. Hospital Issued Notice of Non-Coverage Policy, [REGS.GEN.010](#)

Physician Notice Regarding Medicare National and Local Coverage Determinations

What is a Medicare Coverage Determination?

Coverage determinations:

- Describe the criteria and coverage limitations that apply to particular services, procedures 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 hospitals 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)/Local Coverage Articles (LCAs)**
 - Developed by a local Medicare Contractor, e.g., Fiscal Intermediary (FI), Carrier or Medicare Administrative Contractor (MAC)
 - Applied locally
 - 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/LCDs/LCAs address?

NCDs/LCDs/LCAs

- 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 hospital and physician?

- Procedures or services subject to an NCD/LCD/LCA must meet the NCD/LCD/LCA 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 diagnosis 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/LCA applies or what criteria are contained in an NCD/LCD/LCA?

Contact the appropriate ancillary department. They maintain a current list of applicable NCDs/LCDs/LCAs 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/LCA requirements?

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

What does this mean to the patient?

- If the service or procedure, as documented, does not meet the NCD/LCD/LCA criteria, the patient will be so informed but may still choose to have the service or procedure.
- If they choose to proceed with the service or procedure, they will be asked to sign an Advance Beneficiary Notice of Noncoverage (ABN) (for outpatient services) or Hospital Issued Notice of Non-Coverage (HINN) (for inpatient services).
 - o The purpose of the ABN and HINN is to give the patient advance notice that Medicare may not pay for the test, procedure or service ordered. If Medicare does not pay, the patient will be liable for payment.
 - o The guiding principle in obtaining an ABN or HINN 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/LCA requirements.
- The patient may be able to appeal Medicare's decision not to pay for the service or procedure. The hospital can assist the patient with the appeal.

How can we work together?

- The hospital will keep physicians informed of key NCD/LCD/LCA requirements.
- Physicians should become familiar with the NCD/LCD/LCA requirements that pertain to the services they order and/or provide.
- Physicians must provide the hospital with the information it needs to determine Medicare coverage.
- If a service or procedure does not meet an NCD/LCD/LCA, physicians must decide whether to reschedule or to proceed as planned with the service or procedure.
 - o They should explain these options to the patient including their potential financial liability if they receive services that Medicare does not cover.
 - o They should also work with the hospital to obtain and/or explain the ABN or HINN to the patient, including why Medicare may not pay.