



Medicare Utilization Review Version

KEY CONCEPTS OUTLINE

Module 2: Medical Necessity Rules and Policies

I. Overview of Medicare Coverage

A. To be covered by Medicare, items and services must:

1. Fall into a Medicare benefit category;
2. Not be statutorily excluded;
3. Be reasonable and necessary; and
4. Meet other Medicare program requirements for payment. <Medicare Program Integrity Manual, Chapter 3 § 3.6.2.1>

B. Coverage guidance:

1. The Social Security Act defines Medicare benefit categories and exclusions, supplemented by regulatory guidance (e.g., 42 C.F.R. §§ 409, 410) and sub-regulatory guidance (e.g., the *Medicare Benefit Policy Manual*) published by CMS.
2. In some cases, CMS publishes National Coverage Determinations (NCDs), discussed later in this module, specifying the circumstances under which an item or service is reasonable and necessary. <Medicare Program Integrity Manual, Chapter 3 § 3.6.2.2>
3. If there is no NCD, MACs may publish Local Coverage Determinations (LCDs), discussed later in this module, specifying the circumstances under which an item or service is reasonable and necessary. <Medicare Program Integrity Manual, Chapter 3 § 3.6.2.2>
4. If there is no NCD or LCD applicable to an item or service, contractors determine if it is reasonable and necessary based on the following criteria:
 - a. It is safe and effective;
 - b. It is not experimental or investigational;

- c. It is appropriate, including duration and frequency;
- d. It is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
- e. It is furnished in a setting appropriate to the beneficiary's medical needs and condition;
- f. It is ordered and furnished by qualified personnel; and
- g. It meets, but does not exceed, the beneficiary's medical need. <Medicare Program Integrity Manual, Chapter 3 § 3.6.2.2>

II. National and Local Coverage Policies

- A. Course note: Advanced Beneficiary Notices of Non-coverage (ABNs) and Hospital Issued Notices of Non-coverage (HINNs) are discussed in later modules.
- B. Medicare Coverage Database

Link: Coverage Database (NCDs, NCAs, LCDs) under Medicare-Related Sites – General

- 1. CMS hosts a comprehensive coverage website entitled the Medicare Coverage Database where they publish National and Local Coverage Determinations and related documents.
- 2. Types of Documents on the Medicare Coverage Database
 - a. National Coverage Determinations (NCDs)
 - i. NCDs describe national Medicare coverage policy and generally provide the conditions under which an item or service is considered to be covered. <Medicare Program Integrity Manual, Chapter 13 § 13.1.1>
 - ii. NCDs are binding on all Medicare contractors and in most cases on ALJs in the appeals process. <42 C.F.R. 405.1060; Medicare Program Integrity Manual, Chapter 13 § 13.1.1>
 - b. National Coverage Analyses (NCAs) and Decision Memoranda

CMS publishes NCAs and Decision Memoranda describing CMS coverage decisions and providing the **clinical basis and rationale** of the decisions, including **clinical evidence and studies**.

- i. NCAs and Coverage Decision Memoranda are not binding on Medicare Contractors or ALJs, but CMS directs contractors to consider them in their medical review activities. <Medicare Program Integrity Manual, Chapter 12 § 13.1.1>
- c. Local Coverage Determination (LCDs)
 - i. MACs publish LCDs to describe local coverage policy and as educational tools to assist and furnish guidance to providers within their jurisdiction. <Medicare Program Integrity Manual, Chapter 13 § 13.1.3>
 - ii. LCDs are not binding on Medicare contractors or ALJs, beyond the contractor that established them. Regulations require contractors and ALJs give substantial deference to LCDs applicable to a case and if they do not follow an LCD, explain why in their decision letter. <42 C.F.R. 405.1062>
- d. Local Coverage Articles
 - i. MACs publish coverage articles addressing local coverage, coding, billing, medical review, and claims considerations. The articles may include newly developed educational materials, coding instructions, or clarification of existing billing or claims policy.

C. Coverage with Evidence Development (CED)

1. CED policies cover items or services on the condition they are furnished in the context of approved clinical studies or with the collection of additional clinical data. <See *Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document*, Issued on November 20, 2014>

Link: Coverage with Evidence Development (CED) under Medicare-Related Sites – General

Use links on the left navigation to access an information page for each item or service covered under CED.

2. The routine costs of items and services, associated with services covered under CED, are also covered if the items or services are generally covered for Medicare beneficiaries. <See *Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document*, Issued on November 20, 2014>

III. Prior Authorization

- A. For specified services, CMS requires a prior authorization as a condition of payment. The provider must submit a request for and receive a provisional affirmation of coverage for the specified service to be covered and paid. <See 42 C.F.R. 419.82; 84 Fed. Reg. 61447, 85 Fed. Reg. 86236-248>

Although CMS refers to this process as the “prior authorization” process in regulations and other guidance, they refer to the actual approval as a “provisional affirmation”.

1. CMS has published a “Prior Authorization (PA) Program for Certain Hospital Outpatient Department (OPD) Services Operational Guide”, referred to in this section as the Operational Guide, available on the CMS website.

Link: Prior Authorization for Certain Hospital Outpatient Department Services under Medicare -Related Sites - General

- B. The prior authorization process only applies to services paid through Medicare Fee-for-Service and provided in hospital outpatient departments. <84 Fed. Reg. 61453>
- C. The prior authorization process does not apply to:
1. Services provided outside a hospital outpatient department (e.g., ASC or physician office) <84 Fed. Reg. 61453>;
 2. Services paid through a Medicare Advantage plan or Medicare Advantage IME only claims <84 Fed. Reg. 61453; Operational Guide, Section 9.2>;
 3. Critical Access Hospital (CAH) outpatient departments <Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services, Frequently Asked Questions, Q12>;
 4. Part A/B rebilling claims (presumably 12X with CCW2) <Operational Guide, Section 9.2>;
 5. Emergency department claims with modifier ET or revenue code 45X <Operational Guide, Section 9.2>;
 6. Part A and Part B Demonstration claims <Operational Guide, Section 9.2>; and
 7. Veterans Affairs and Indian Health Services <Operational Guide, Section 9.5>.

D. The list of CPT/HCPCS codes which will require prior authorization can be found in Appendix A of the Operational Guide and Table 103 of the CY2023 OPPS Final Rule, included in the materials behind the outline. <See Operational Guide, Appendix A; 87 *Fed. Reg.* 72230-233>

1. CMS finalized five categories of services requiring prior authorization, effective July 1, 2020:
 - a. Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair;
 - i. Effective January 7, 2022, CMS removed 67911 (Correction of lid retraction) from the list of applicable blepharoplasty codes.
 - b. Rhinoplasty;
 - c. Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy);
 - d. Botulinum toxin injections;
 - i. Prior authorization is only required when one of the listed Botulinum Toxin codes is billed with one of the listed injection codes. Botulinum Toxin billed with other procedure codes will not require prior authorization. <Operational Guide, Section 6.2.2>
 - e. Vein ablation. <84 *Fed. Reg.* 61448, 42 *C.F.R.* 419.83(a)(1)>
2. CMS finalized two additional categories of services requiring prior authorization, effective July 1, 2021:
 - a. Cervical Fusion with Disc Removal; and
 - b. Implanted Spinal Neurostimulators. <85 *Fed. Reg.* 86246-248, 42 *C.F.R.* 419.83(a)(2)>
 - i. In May 2021, CMS announced that two codes (63688 and 63685), which were finalized as requiring prior authorization July 1, 2021, were temporarily removed from the list, presumably because they can be used to code revision, removal, or replacement procedures. <See Operational Guide, Appendix A>
 - ii. If a trial and permanent implantation are performed, a PAR should be request for the trial and the Unique Tracking Number (UTN) for the trial should be reported for both the trial and permanent implantation. <Operational Guide, Section 6.3.2.2>

3. CMS finalized one additional category of services requiring prior authorization, effective July 1, 2023:

- a. Facet Joint Interventions <87 *Fed. Reg.* 72230, 42 *C.F.R.* 419.83(a)(3)>

E. Prior Authorization Process

1. Responsibility for Obtaining Prior Authorization

- a. CMS has determined that the hospital is ultimately responsible for obtaining prior authorization as a condition of payment, although they allow for either physicians or hospitals to obtain the prior authorization. <84 *Fed. Reg.* 61453>
2. The provider must submit a prior authorization request (PAR) to the MAC before the service is provided to the beneficiary, including all documentation necessary to show the service meets all applicable Medicare coverage, coding, and payment rules. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61454; see Operational Guide, Section 3>
 - a. The prior authorization Operational Guide provides general documentation requirements for each service requiring prior authorization and refers providers to their MAC's LCDs and LCAs for more detailed requirements. <See Operational Guide, Section 6.2>
 - b. For services requiring prior authorization that do not have specific NCDs or LCDs, contractors may make individual claim determinations to assess whether the services are reasonable and necessary. <84 *Fed. Reg.* 61459>
3. The MAC reviews the PAR, assigns a UTN and makes a provisional affirmation or non-affirmation decision and issues a decision to the provider within 10 business days. <See Operational Guide, Section 4>
 - a. A provider may request an expedited review, with a decision in 2 business days, if a delay in the service may jeopardize the beneficiary's life, health, or ability to regain maximum function. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61454; see Operational Guide, Section 4.2>
 - b. If the MAC makes a provisional affirmation decision, the MAC will issue a decision letter to the provider and the beneficiary. <See Operational Guide, Section 4.3>
 - i. A provisional affirmation is valid for 120 days from the date of the decision. <See Operational Guide, Section 7.1>

- ii. Claims receiving a provisional affirmation may later be denied based on technical requirements that can only be evaluated after the claim has been submitted or information not available at the time of the PAR. <84 Fed. Reg. 61447; see Operational Guide, Section 8.1>
- c. If the MAC makes a provisional non-affirmation decision, the MAC will provide detailed information about all missing or non-compliant information. <See Operational Guide, Section 4; 84 Fed. Reg. 61461>
 - i. The provider may resubmit the PAR with additional or updated documentation any number of times until a provisional affirmation is received. <Operational Guide, Section 4.1.2>
 - ii. A provisional non-affirmation is not an initial claim determination and cannot be appealed. <See Operational Guide, Section 11>
 - iii. If the provider receives a non-affirmation and believes the service is not medically necessary, the provider should issue an Advanced Beneficiary Notice (ABN) to transfer liability to the patient for the non-covered service. <Operational Guide, 9.1>
 - a) CMS also “encourages” providers to issue an ABN to the patient if the provider believes the service will be denied under the statutory exclusion for purely cosmetic services. <Operational Guide, 9.1>

F. Claims Submission

1. To be paid, the provider must submit a Unique Tracking Number (UTN) corresponding to a provisional affirmation on any claim submitted for a service requiring prior authorization. <84 Fed. Reg. 61453>
 - a. For electronic claims, the UTN is submitted in positions 1-18 of the Treatment Authorization field and moved to positions 19-32 by the FISS for processing. For other claims, the provider tabs to the second field (positions 19-32) to enter the UTN. <See Operational Guide, Section 8.1>
2. Claims for services requiring prior authorization submitted without a UTN or a UTN corresponding to a provisional non-affirmation will be automatically denied. <84 Fed. Reg. 61447; see Operational Guide, Section 8.3>
 - a. When a service that requires prior authorization is denied, CMS “intends” to deny claims for codes associated with or related to the service (e.g., anesthesiologist’s or surgeon’s services). <84 Fed. Reg. 61453, see Operational Guide, Section 8.4.1>

- i. CMS published a list of codes associated with the services requiring prior authorization in Appendix B of the Operational Guide.
- b. The denial of a claim for lack of prior authorization (i.e., submitted without a UTN corresponding to a provisional affirmation) is considered an initial claim determination and may be appealed by the provider. <See Operational Guide, Section 11>
- i. CMS has instructed MACs to review appealed claims to determine if a prior authorization request was submitted and deny payment if no prior authorization request was made due to the provider's failure to comply with a mandatory condition of payment, even if the item or service is otherwise covered. <Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services, Frequently Asked Questions, Q28>
- c. If the provider issued an ABN to transfer liability to the patient, the claim should be submitted with modifier -GA if the provider believes the denial is based on medical necessity or modifier -GZ if the provider believes the denial is based on the statutory exclusion for purely cosmetic services. <See Operational Guide, Section 9.1>
- i. Claims for services requiring prior authorization reported with an ABN modifier will be stopped by the MAC for an additional documentation request and review of the validity of the ABN. < See Operational Guide, Section 9.1>
- ii. If the beneficiary has secondary insurance, including Medicaid, this process can be used to obtain a denial from Medicare for submission to secondary insurance. For more information see the Operational Guide, Section 10.1.

G. Exemption from Prior Authorization Requirements

- 1. CMS may exempt a provider from the prior authorization process when a provider demonstrates compliance by achieving a 90% provisional affirmation rate with at least 10 submitted claims. <42 C.F.R. 419.83(c); 84 Fed. Reg. 61448; Medicare Program Integrity Manual, Chapter 3 § 3.10.2, Operational Guide, Section 5>
- a. The exemption applies for the full calendar year and applies to all services requiring prior authorization, regardless of whether they were part of the sample used to determine compliance and grant the exemption. <Operational Guide, Section 5.1>

- b. PARs submitted by exempt providers will be rejected. <Operational Guide, Section 5.1>
- c. Providers will receive a notification of continued exemption or withdraw of exemption 60 days prior to the effective date, generally by November 1. <Operational Guide, Section 5.1; 42 C.F.R. 419.83(c)(2)>
 - i. Providers may opt out of the exemption by submitting a request to their MAC no later than November 30. <Operational Guide, Section 5.1>
- d. Retaining exemption from the prior year:
 - i. A provider with an exemption must have 10 claims submitted by June 30. The MAC will sample 10 claims beginning August 1. Providers must demonstrate a 90% claim approval rate on the 10-claim review to retain their exemption. <Operational Guide, Section 5.1>
- e. Gaining exemption if not exempt in prior year:
 - i. The MAC will calculate the affirmation rate of initial PARs beginning in January and notify providers in October if they have achieved the required 90% affirmation rate to qualify for an exemption for the following year. <Operational Guide, Section 5.1>
- f. See the Operational Guide, Section 5.1 for details on timeframes and the process for exemption for calendar year 2024.

Case Study 1

Facts: A Medicare patient is scheduled for a first diagnostic joint injection procedure described by HCPCS code 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint) at a pain clinic that is an outpatient department of a PPS hospital.

The following documentation is in the pain clinic electronic record for the patient:

1. Pain clinic nursing assessment showing pain level 6/10.
2. Bilateral hip, sacroiliac (SI) joint, and lower back x-rays.
3. H&P signed by the pain clinic physician detailing the intended procedure, referencing x-rays, and referencing the nursing pain assessment.

Turn to the *LCD – Facet Joint Interventions for Pain Management L34892*) and *Article – Billing and Coding: Facet Joint Interventions for Pain Management (A56670)* in the materials behind the outline and review the requirements for coverage of the procedure. What additional documentation is needed to demonstrate coverage?

CASE STUDY WITH ANALYSIS

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Analysis: The pain clinic physician must document that there is no untreated radiculopathy or neurogenic claudication and no non-facet pathology that could explain the source of the patient's pain, as required by the LCD.

In addition to the pain assessment, the LCD requires a disability scale at baseline for functional assessment. The billing and coding article lists some acceptable disability scales in the "Documentation Requirements" section.

The patient's history of pain and conservative care that has been tried must also be documented. The LCD requires the patient has had pain for a minimum of 3 months with documented failure of conservative management, defined in the policy as use of NSAIDs, acetaminophen, physical therapy, acupuncture, or spinal manipulation.

The provider must also document that the patient has a covered diagnosis, supported by the medical record. The Article contains a list of covered diagnosis codes.

Note: This procedure will require a prior authorization when performed in a PPS hospital outpatient department beginning July 1, 2023.

Note: This case study is based on a Novitas LCD, and billing and coding Article provided for illustrative purposes only. The LCDs and billing and coding Articles for facet joint injections vary by jurisdiction, including the documentation required to demonstrate coverage. Verify coverage, including documentation requirements, with the LCD for the applicable jurisdiction and timeframe when determining coverage.

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Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development

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Date:

11/20/2014

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**Guidance for the Public, Industry, and CMS Staff
Coverage with Evidence Development
Document Issued on November 20, 2014**

This guidance represents the Centers for Medicare & Medicaid Services' (CMS') current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind CMS or the public. Where warranted by unique circumstances, CMS may consider a modified approach if it satisfies the requirements of the applicable statutes and regulations. Individuals interested in discussing an alternative approach are encouraged to contact the CMS staff responsible for this guidance.

Contact: Rosemarie Hakim, PhD
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For information regarding national coverage determinations (NCDs), local coverage determinations (LCDs), or other coverage materials, including those referenced throughout this guidance document, please see the Medicare Coverage Center website at <http://www.cms.hhs.gov/center/coverage.asp.%20>

I. Purpose of this Guidance Document

While CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS' implementation of coverage with evidence development (CED) through the national coverage determination process. The guidance describes the history of CED, its statutory basis, and reflects public comments received on a draft guidance document published on November 12, 2012. We received comments representing medical technology trade associations, individual drug and device manufacturing companies, physician professional societies, and the general public, which are addressed in a separate document.

II. Background

CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.

History

Although Medicare generally does not cover experimental or investigational items and services as reasonable and necessary under section 1862(a)(1)(A) of the Act (and regulations at 42 CFR 411.15(o)), the Medicare program has adopted coverage policies that relate to clinical studies before the formal articulation in 2006 of the CED paradigm. In 1995, CMS (then known as the Health Care Financing Administration (HCFA)) established coverage for certain items furnished in FDA-approved IDE trials (42 CFR 405 Subpart B). CMS updated the coverage criteria for certain items and services in IDE trials effective January 1, 2015 (78 FR 74429-74437). In response to a June 7, 2000 Executive Memorandum, CMS (then HCFA) issued an NCD for coverage under the authority of section 1862(a)(1)(E) of routine costs in clinical trials, commonly referred to as the Clinical Trial Policy (Section 310.1 of the NCD Manual). The Clinical Trial Policy was revised in 2007 through the NCD reconsideration process.

In 2005, CMS began to implement NCDs requiring study participation (for example: NCD Manual §50.3 Cochlear Implantation Moderate Hearing Loss; NCD Manual §220.6.13 FDG PET for Dementia and Neurodegenerative Diseases). Subsequently, CMS issued guidance on the CED paradigm in the 2006 guidance document entitled *National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development*. The 2006 document introduced two arms of CED which included Clinical Study Participation (CSP) and Coverage with Appropriateness Determination (CAD). While the concepts behind both arms are described in this document, we are no longer using this terminology to distinguish the two.

While CMS has embraced an evidence-based medicine coverage paradigm, CMS is increasingly challenged to respond to requests for coverage of certain items and services when we find that the expectations of interested parties are disproportionate to the existing evidence base. At the same time, we believe that CMS should support evidence development for certain innovative technologies that are likely to show benefit for the Medicare population, but where the available evidence base does not provide a sufficiently persuasive basis for coverage outside the context of a clinical study, which may be the case for new technologies, or for existing technologies for which the evidence is incomplete.

Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies.

III. Statutory Basis

Sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Social Security Act (42 U.S.C. 1395v)

Sections 1862(a)(1)(A) and 1862(a)(1)(E) of the Act read:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, **except** for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section. (Emphasis added.)

Two of the earliest CED decisions were made under section 1862(a)(1)(A) of the Act. In 2005, CMS made two national coverage determinations, the NCD for automatic implantable cardioverter-defibrillators (ICDs) (NCD Manual §20.4) and the NCD for 18F-fludeoxyglucose positron emission tomography (FDG PET) for oncologic conditions (NCD Manual §220.6.17). In both NCDs, data were submitted to CMS-approved registries. While the intent of these CED NCDs was to monitor the appropriateness of use of these items and services, we recognized that the data could also be used to generate useful clinical evidence. More recent NCDs have tended to rely on section 1862(a)(1)(E) of the Act, in which CED is used to support clinical research.

Section 1142 of the Act

Section 1142 of the Act describes the authority of the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research on outcomes, effectiveness, and appropriateness of services and procedures to identify the most effective and appropriate means to prevent, diagnose, treat, and manage diseases, disorders, and other health conditions. That section includes a requirement that the Secretary assure that AHRQ research priorities under Section 1142 appropriately reflect the needs and priorities of the Medicare program.

Section 1142(b)(3) states: Relationship with Medicare program - In establishing priorities under paragraph (1) for research and evaluation... the Secretary shall assure that such priorities appropriately reflect the needs and priorities of the program under title XVIII, as set forth by the Administrator of the Centers for Medicare and Medicaid Services.

The coordination of AHRQ priorities under section 1142 with the needs and priorities of the Medicare program is accomplished through direct collaboration between the AHRQ and CMS. AHRQ reviews all CED NCDs established under Section 1862(a)(1)(E) of the Act. Consistent with section 1142, AHRQ also indicates its support for clinical research studies that CMS determines address the CED questions and meet the general standards for CED studies.

IV. Principles governing the application of CED:

- CED will occur within the coverage determination process, which is transparent and open to public comment.
- CED will not be used when less restricted coverage is justified by the available evidence.
- CED will generally expand access to medical technologies for beneficiaries.
- CED will lead to the production of evidence complementary to existing medical evidence.
- CED will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products, and devices.
- CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials.
- CED will be consistent with federal laws, regulations, and patient protections.

V. CED under Section 1862(a)(1)(A)

In some cases CMS requires as a condition of coverage for certain items and services under section 1862(a)(1)(A) the collection of additional clinical data, which allows CMS to ensure that items and services are provided appropriately to patients meeting specific characteristics as described in an NCD.

VI. Requirements for CED under Section 1862(a)(1)(E)

As CMS and AHRQ have gained experience with CED under section 1862(a)(1)(E), we have developed the following list of general requirements for clinical studies supported by AHRQ. We expect that all CED clinical studies under section 1862(a)(1)(E) will demonstrate adherence to these requirements, which will be included (with occasional minor modifications) in the applicable coverage determination. We would not anticipate approving a study that does not meet these requirements.

- a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.

- b. The rationale for the study is well supported by available scientific and medical evidence.
- c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
- d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
- e. The study is sponsored by an organization or individual capable of completing it successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
- g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
- h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
- l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

VII. Coverage of Control Groups in CED Studies under 1862(a)(1)(E): Standard of Care and Placebo controls; and Blinding or Masking

In the most rigorous experimental designs, a new treatment is compared to something else for purposes of studying effectiveness and to control for the placebo effect or other observation biases. For example, a carotid stent procedure may be compared to the current best standard of medical care; in a drug trial, some subjects may be randomized to receive a placebo medication; or to study an orthopedic procedure for back pain, the control group may be randomized to receive a placebo procedure to preserve blinding. The purpose of a placebo control group is to account for the placebo effect; that is, to exclude from the study certain effects that do not depend on the treatment itself. Such factors can include participants' knowledge that they are receiving a treatment and receiving extra attention from health care professionals, and the expectations of a treatment's effectiveness by those running the research study. Without a placebo group to compare against, it is not possible to know or measure the effect of the treatment itself. These methods effectively blind or mask patients and investigators, if the trial is double blinded, to their treatment assignment. Placebo controls can be critical in evaluating endpoints that may be vulnerable to subjective interpretation, such as changes in pain levels or depression.

While the items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the statute because they have no health benefit, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these services can be covered under section 1862(a)(1)(E) when furnished in the context of a clinical study where coverage is necessary to preserve the scientific integrity of the study.

In section 184 of the Medicare Improvements for Patients and Providers of 2008 (MIPPA), Congress added a new subsection 1833(w) of the Act which allows the Secretary to develop alternative methods of payment under Medicare Part B for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health & Human Services: *"to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design."* We may use this authority, for example, to ensure that a placebo control group is not undermined by differences in Medicare payment methods that would otherwise reveal the group to which a patient has been assigned.

Under CED, routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) arm are paid. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, coverage is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.

VIII. Ending CED

We expect that the studies conducted under a CED NCD will produce evidence that will lead to revisions to Medicare coverage policies, such as to the NCD that included CED as a component of the decision (for example, NCDs for oncologic uses of FDG PET, and ventricular assist devices). Studies with a specific design, such as randomized clinical trials, have established start and end dates. When enrollment and follow up are complete, the data are to be analyzed and published in the peer reviewed medical literature.

When an NCD requires CED under 1862(a)(1)(E), it is because the available evidence about a particular item or service is insufficient to support coverage outside the context of a well-designed clinical research study. While CMS does not believe that beneficiaries should have broad access to these items or services when scientific results are unavailable, there are ways to avoid or minimize the gap between the end of clinical studies under a CED NCD and a revised coverage decision based on the results of CED studies. Sponsors should build interim analyses into their study design and communicate these results to CMS. If the results support consideration of a change in the coverage status of the item or service, a revised NCD could be expedited.

A CED cycle is considered completed when CMS completes a reconsideration of the CED coverage decision, and removes the requirement for study participation as a condition of coverage. As with any NCD, any member of the public may request to reopen the NCD that requires CED. In addition, CMS may internally generate a request to develop or reconsider an NCD. Once initiated, this process is similar to the externally-generated request process. CMS will review the evidence generated by the CED studies and any other available evidence. The NCD process is described in the Federal Register (78 FR 48164).

IX. Transparency of CED

The NCD process, in general, is a transparent one. Requesters may meet with CMS and frequent, informal contact is possible. A tracking sheet is posted on the CMS website that allows interested individuals to participate in and monitor the progress of the review. A proposed decision is issued for public comment within six months of opening the NCD review. The proposed decision generally includes details of CED study design, which are also open to public comment. Consistent with section 1862(l)(3)(B) of the Act, we provide 30 days for public comment on the proposal. There may be a Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting, which is open to the public. Not later than 60 days after the close of the 30-day public comment period, we issue a final NCD. The LCD process is also transparent. The MACs issue a draft LCD, receives public comments, and responds to those comments before finalizing an LCD.

CMS expects that results of all CED approved studies under 1862(a)(1)(E) will be analyzed and published in peer reviewed clinical journals. CMS has used and will continue to use the results of published CED studies to inform new or revised coverage decisions. CMS intends to maintain information on ongoing CED research studies via NCDs on its website along with links to the ClinicalTrials.gov website maintained by the National Library of Medicine and the Registry of Patient Registries (RoPR) maintained by AHRQ when appropriate. We also plan to include links on our website to CED study results.

All studies seeking Medicare coverage under CED should be registered with ClinicalTrials.gov and if the CED study is a registry, on AHRQ's Registry of Patient Registries (RoPR) (see standard j). Registrants at ClinicalTrials.gov must submit a standardized set of data elements to describe the study design, eligible populations, outcome measures, and other parameters and results. Registration on this site, for most studies, serves as a vehicle for Medicare beneficiaries to learn about, and identify studies in which they may want to participate. When reporting of results are required, it also offers an assurance of quality because, generally, public access to information enables a higher level of accountability in the accurate reporting of the clinical study protocol and results, and in the conduct of the trial itself. This accountability derives both from public access to information about studies and from the risk of penalty for submitting false or misleading clinical trial information. Registration with ClinicalTrials.gov also assures that Medicare beneficiaries and their treating healthcare professionals will have pertinent information about CED studies, and we expect this may facilitate better informed decision-making. Similarly, registry studies that registered at AHRQ's RoPR are advised to follow the set of best practices on methodologies and on the technical, legal, ethical, and analytical considerations for designing, operating, and utilizing registries and registry data as described in AHRQ's *Registries for Evaluating Patient Outcomes: A User's Guide*.

X. The role of Medicare Administrative Contractors (MACs) and Coverage with Evidence Development

Although the definition of local coverage determination (LCD) in the Social Security Act does not support the use of CED under 1862(a)(1)(E) of the Act, MACs may use LCDs to determine coverage of items and services to the extent that they do not conflict with national Medicare policy.

XI. Additional Information

We believe that CED can be applied to coverage of drugs and biologics. However, we do not contemplate the application of CED to drugs or biologics that have not been approved by FDA for at least one indication. Additionally, many drugs and biologics are self-administered, falling outside the scope of Medicare Part A and B, and therefore, outside the scope of CED. Self-administered drugs are usually addressed under the scope of Medicare Part D.

Appendix: [Summary of Public Comments \(received 11/29/12-1/28/13\) and Responses](#)

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the efficiency of our prior authorization processes, increase provider willingness to submit requests electronically, reduce provider burden, decrease delays in patient care, and promote high-quality, affordable health care.

In sum, we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding onerous new documentation requirements. A broad program integrity

strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary.

After consideration of the public comments we received, we are finalizing our proposal to add the Facet joint interventions service category to

the list of hospital outpatient department services requiring prior authorization with modification. In particular, we are finalizing an implementation date for prior authorization for the Facet joint interventions service category of July 1, 2023, rather than the March 1, 2023 implementation date we proposed and making this change in the proposed regulation text at § 419.83(a)(3). Other than this change in the implementation date, we are finalizing the proposed regulation text changes as proposed.

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TABLE 103: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair ³³⁰
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxin a, 1 unit
J0586	Injection, abobotulinumtoxin a, 5 units
J0587	Injection, rimabotulinumtoxin b, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit

Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(iv) Rhinoplasty, and related services ³³¹
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites

36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators ³³²
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 1, 2023	
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint

64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

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XXI. Overall Hospital Quality Star Rating**A. Background**

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars (85 FR 86193). The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016³³³ (now reported on its successor website at <https://www.medicare.gov/care-compare> and referred to as Care Compare) and has been refreshed multiple times, with the most current refresh planned for 2022.^{334 335 336 337 338 339 340} In the CY

2021 OPPTS/ASC final rule with comment period (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating. We refer readers to section XVI (Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years) of the CY 2021 OPPTS/ASC final rule with comment period and 42 CFR 412.190 for details.

In the CY 2023 OPPTS/ASC proposed rule (87 FR 44807–44809), we: (1) provided information on the previously finalized policy for inclusion of quality measure data from Veterans Health Administration (VHA) hospitals; (2) proposed to amend the language of § 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months; and (3) conveyed that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy if applicable.

B. Veterans Health Administration Hospitals

In the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86197 and 86198), we finalized a policy to include Veterans Health Administration hospitals' (VHA hospitals) quality measure data for the purpose of calculating the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. In that final rule, we also stated that we intended to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule (85 FR 48999). Since the publication of the CY 2021 OPPTS/ASC final rule, we conducted an internal analysis from February 28, 2022, through March 30, 2022, with

measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. The internal analysis included a period of confidential reporting and feedback during which VHA hospitals reviewed their Overall Hospital Quality Star Ratings internal analysis results, and in addition, further familiarized themselves with the Overall Hospital Quality Star Ratings methodology and had the opportunity to ask questions. All VHA hospitals were made aware of the internal analysis and were provided the opportunity to participate. For the internal analysis, the Overall Hospital Quality Star Ratings were calculated using VHA hospital measure data along with subsection (d) hospitals and CAHs. The internal analysis included the same measures used for the April 2021 refresh of Overall Hospital Quality Star Ratings on our public reporting website, Care Compare. At the time of the 2022 VHA internal analysis, VHA hospitals in each peer group reported a similar number of measures when compared to non-VHA hospitals for most measure groups. VHA hospitals in the five-measure group peer group reported a lower median number of Safety and Readmission measures. VHA hospitals in all three peer groups reported fewer measures in the Timely and Effective Care measure group. The measurement periods for VHA and non-VHA hospitals were the same, except for the HAI-1, HAI-2, PSI 04, PSI 90, and OP-22 measures. The specific performance periods for these measures were provided to VHA hospitals during the internal analysis. The reasons for the differing measure reporting periods are:

- The HAI-1 and HAI-2 measures were first publicly reported for VHA hospitals in July 2021, but only included one quarter of measure data. Therefore, we chose to use the next public reporting, April 2022, which included four quarters of these measures' data.

- For the PSI 04 and PSI 90 measures, we used measure data that were publicly reported in July 2021. VHA hospitals first publicly reported these measures in October 2020; however, a different software was used for the measure calculations than the software used to calculate subsection (d) hospitals and CAHs measure data. We

³³⁰CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

³³¹CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

³³²CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPTS/ASC final rule comment period.

³³³Centers for Medicare & Medicaid Services. (2016, July 27). First Release of the Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from CMS.gov newsroom at: <https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare>.

³³⁴Centers for Medicare & Medicaid Services. (2016, May). Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.

³³⁵Centers for Medicare & Medicaid Services. (2016, October). Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.

³³⁶Centers for Medicare & Medicaid Services. (2017, October). Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.

³³⁷Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from [qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

³³⁸Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from [qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

³³⁹Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from [www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources](https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources).

³⁴⁰Centers for Medicare & Medicaid Services. (2022, May 17). Overall Hospital Quality Star Rating on Hospital Compare: July 2022 Updates and Specifications Report. Retrieved from [qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES	2 - 21

LCD Information

Document Information

LCD ID

L34892

LCD Title

FACET JOINT Interventions for Pain Management

Proposed LCD in Comment Period

N/A

Source Proposed LCD

[DL34892](#)

Original Effective Date

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Revision Effective Date

For services performed on or after 04/25/2021

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

03/11/2021

Notice Period End Date

04/24/2021

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for FACET JOINT interventions for pain management. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or

Editor's note: This LCD was abbreviated for these materials. The full LCD with applicable jurisdictions and full Summary of Evidence is available in the Medicare Coverage Database.

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supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for FACET JOINT interventions for pain management and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
 - Chapter 15, Section 50 Drugs and Biologicals
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1,
 - Part 1, Section 30.3 for Acupuncture
 - Part 2, Section 150.7 for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents
 - Part 4, Section 220.1 for Computed Tomography (CT)
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
 - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1861(s)(2)(K), medical or surgical services provided by a physician, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)[14], which are other than physicians' services described by section 1861(s)(2)(K)
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Code of Federal Regulations (CFR) References:

- CFR, Title 42, Volume 2, Chapter IV, Part 410.74 Physician assistants' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.75 Nurse practitioners' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.76 Clinical nurse specialists' services.
- CFR, Title 42, Volume 3, Chapter IV, Part 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.
- FR, Volume 65, Number 68, Page 18543. April 7, 2000, non-physician providers services, as defined

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The spine is the most common source of chronic pain. Chronic axial spinal pain is one of the major causes of

disability and accounts for a substantial U.S. health burden. Chronic spine pain poses a peculiar diagnostic and therapeutic challenge due to multiple pain sources, overlapping clinical features, and nonspecific radiological findings.

The FACET JOINTs can cause axial spinal pain and referred pain in the extremities. The pathology of the pain source is due to FACET JOINTs being richly innervated by the nerve fibers from the medial branch of the dorsal ramus of spinal nerves. Each facet has a dual nerve supply. One exception is at the C2–C3 zygapophysial joint, which has a singular nerve supply from the third occipital nerve (the superficial medial branch of C3 dorsal ramus).¹

FACET JOINT interventions may be used in pain management for chronic cervical/thoracic and back pain arising from the paravertebral FACET JOINTs. The facet block procedure is an injection of a local anesthetic, with or without a steroid medication, either into the FACET JOINT (intra-articular) or outside the joint space around the nerve supply to the joint (the medial branch nerve) known as medial branch block (MBB). Imaging guidance (fluoroscopy or CT per code descriptor) is used to assure accurate placement of the needle for the injection. Paravertebral FACET JOINT denervation is a therapeutic intervention used to provide both long-term pain relief and reduce the likelihood of recurrence of chronic cervical/thoracic or back pain confirmed as originating in the FACET JOINT's medial branch nerve.¹

There are various methods that may be used in performing FACET JOINT denervation. Percutaneous radiofrequency ablation (RFA) is a minimally invasive procedure done with imaging guidance (fluoroscopy or CT per code descriptor) and involves using energy in the radiofrequency range to cause necrosis of specific nerves (medial branches of the dorsal rami), preventing the neural transmission of pain. Conventional radiofrequency ablation (non-pulsed or continuous) applies thermal energy of typically 80 to 85 degrees Celsius. The terms RFA and radiofrequency neurotomy are used interchangeably. Both terms refer to a procedure that destroys the functionality of the nerve using radiofrequency energy. Non-thermal methods of denervation include chemical (chemodenervation), low-grade thermal energy (less than 80 degrees Celsius), pulsed RFA, laser neurolysis, and cryoablation.¹

Throughout this document, societal recommendations with the grading of evidence are referenced. There are multiple systems to grade or rank the quality of medical evidence and develop evidence-based recommendations. Not all grading systems are equivalent, so while there are typically similarities in the grades or recommendations from various grading systems, they must be considered independent of the other. The references in this document refer to the following grading systems.

1. GRADE Guidelines used in some systematic reviews, the basis for NASS recommendations align with GRADE.
2. A Modified approach to the grading of evidence² and development of interventional pain management specific instrument³ used in American Society of Interventional Pain Physicians (ASIPP) Guidelines and some systematic reviews.
3. The U.S. Preventive Services Task Force grading of evidence guidelines used by 2020 Consensus Guidelines by Cohen et al⁴.
4. Levels of Evidence for Primary Research Question and Grades of Recommendation for Summaries or Review of Studies adopted by North American Spine Society (NASS).⁵


A Multi-MAC Subject Matter Expert (SME) Panel on FACET JOINT and Medial Nerve Branch Procedures meeting was held on 5/28/2020.




Covered Indications

A. FACET JOINT Interventions:

FACET JOINT Interventions generally consist of four types of procedures: Intraarticular (IA) FACET JOINT Injections, Medial Branch Blocks (MBB), Radiofrequency Ablations (RFA) and Facet cyst rupture/aspiration.

 FACET JOINT Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** of the following criteria:

1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale¹¹; **AND***
2. Pain that has been present for a minimum of 3 months with documented failure to respond to noninvasive conservative care management (as tolerated)^{4,12}; **AND**
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by FACET JOINT synovial cyst)^{4,7}; **AND**
4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.¹¹


 *Pain assessment must be performed and documented at baseline, after each diagnostic procedure using the same pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

B. Diagnostic FACET JOINT Injection Procedures (IA or MBB):

The primary indication of a diagnostic FACET JOINT procedure is to diagnose whether the patient has facet syndrome.^{1,4,7,12,16} Intraarticular (IA) facet block(s) are considered medically reasonable and necessary as a diagnostic test only if MBB cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, a RFA procedure would be considered the primary treatment goal at the diagnosed level(s).¹¹

A second diagnostic facet procedure is considered medically reasonable and necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure.⁷

-  1. An initial diagnostic FACET JOINT procedure will be considered medically reasonable and necessary when the patient meets the criteria outlined under the indications for FACET JOINT interventions.
2. A second confirmatory diagnostic FACET JOINT procedure is considered medically reasonable and necessary in patients who meet **BOTH** of the following criteria:
- The patient meets the criteria for the first diagnostic procedure; **AND**
 - After the first diagnostic FACET JOINT procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used).¹¹

Frequency limitation: For each covered spinal region no more than four (4) diagnostic joint sessions will be considered medically reasonable and necessary per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

C. Therapeutic FACET JOINT Injection Procedures (IA):

Therapeutic FACET JOINT procedures are considered medically reasonable and necessary for patients who meet **ALL** of the following criteria:

1. The patient has had two (2) medically reasonable and necessary diagnostic FACET JOINT procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); **AND**
2. Subsequent therapeutic FACET JOINT procedures at the same anatomic site result in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale¹¹; **AND**
3. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device) is in the medical record.^{5,42,43,44}

Frequency limitation: For each covered spinal region no more than four (4) therapeutic FACET JOINT injection (IA) sessions will be reimbursed per rolling 12 months.

D. FACET JOINT Denervation:

An initial thermal RFA of cervical, thoracic, or lumbar paravertebral FACET JOINT (medial branch) nerves is considered medically reasonable and necessary for patients who have had at least two (2) medically reasonable and necessary diagnostic MBBs, with each one providing a consistent minimum of 80% sustained relief of primary (index) pain (with the duration of relief being consistent with the agent used).

Repeat thermal¹¹ FACET JOINT RFA at the same anatomic site is considered medically reasonable and necessary provided the patient had a minimum of consistent 50% improvement in pain for at least six (6) months **or** at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale.

Frequency limitation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months.

E. Facet Cyst Aspiration/Rupture

Intra-articular FACET JOINT injection performed with synovial cyst aspiration is considered medically reasonable and necessary when **BOTH** of the following criteria are met:

1. Advanced diagnostic imaging study (e.g., MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a FACET JOINT synovial cyst; **AND**
2. Clinical and physical symptoms related to synovial facet cyst are documented in the medical record.

Frequency limitation: Cyst aspiration/rupture may be repeated once and only if there is 50% or more consistent improvement in pain for at least three (3) months.¹¹



Limitations

1. FACET JOINT interventions done without CT or fluoroscopic guidance are considered not medically reasonable and necessary. This includes FACET JOINT interventions done without any guidance,

performed under ultrasound guidance,^{4,11} or with Magnetic Resonance Imaging (MRI).⁴

2. General anesthesia is considered not medically reasonable and necessary for FACET JOINT interventions. Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for intraarticular FACET JOINT injections or medial branch blocks and are not routinely considered medically reasonable and necessary. Individual consideration may be given on redetermination (appeal) for payment in rare, unique circumstances if the medical necessity of sedation is unequivocal and clearly documented in the medical record. Frequent reporting of these services together may trigger focused medical review.⁴
3. It is not expected that patients will present with pain in both cervical/thoracic and lumbar spinal regions. Therefore, FACET JOINT interventions (both diagnostic and therapeutic) are limited to one spinal region per session.
4. It is not routinely necessary for multiple blocks (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) to be provided to a patient on the same day as FACET JOINT procedures. Multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be clearly documented in the medical record. For example, the performance of both paravertebral FACET JOINT procedures and a transforaminal epidural steroid injection (TFESI) at the same or close spinal level at the same encounter would not be expected unless a synovial cyst is compressing the nerve root. In this situation, TFESI may provide relief for the radicular pain, while the facet cyst rupture allows nerve root decompression. Frequent reporting of multiple blocks on the same day may trigger a focused medical review.
5. FACET JOINT intraarticular injections and medial branch blocks may involve the use of anesthetic, corticosteroids, anti-inflammatories and/or contrast agents and do not include injections of biologicals or other substances not FDA designated for this use.
6. One to two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) that are performed during the same day.
7. If there is an extended period of time, two years or more, since the last RFA and/or there is a question as to the source of the recurrent pain then diagnostic procedures must be repeated.
8. Therapeutic intraarticular facet injections are not considered medically reasonable and necessary unless there is documentation explaining why RFA cannot be performed.^{5,42,43,44}
9. FACET JOINT procedures in patients for the indication of generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes are considered not medically reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.⁵⁶
10. In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

The following are considered not medically reasonable and necessary:

1. Intraarticular and extraarticular FACET JOINT prolotherapy ^{5,42,43,44}
2. Non-thermal modalities for FACET JOINT denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation
3. Intra-facet implants⁵⁸
4. FACET JOINT procedure performed after anterior lumbar interbody fusion (ALIF)
5. Definitive clinical and/or imaging findings pointing to a specific diagnosis other than FACET JOINT syndrome
6. Diagnostic injections or MBB at the same level as the previously successful RFA procedure

Notice: Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS

national coverage determinations, and all Medicare payment rules.



Provider Qualifications

Patient safety and quality of care mandate that healthcare professionals who perform facet injections/procedures are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

In addition to the above requirements, non-physician providers, such as certified nurse anesthetist, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; FR Vol. 65, No. 68 page18543, April 7, 2000). Each practitioner must provide only those services within the scope of practice for each state.

Definitions

Acute Pain: The temporal definition of pain persisting for up to 4 weeks after the onset of the pain.

Axial: Relating to or situated in the central part of the body, in the head and trunk as distinguished from the limbs, e.g., axial skeleton.

Biopsychosocial Model: Interdisciplinary model that looks at the interconnection between biology, pathology and socioenvironmental factors.

Central Neuropathic Pain: Pain, which is causally related to a lesion or disease of the central somatosensory nerves.

Centralized Pain: A neurological chronic pain syndrome of the central nervous system (brain, brainstem, and spinal cord) which commonly presents with widespread generalized allodynia which is causally related to the increased responsiveness of nociceptive nerves in the central nervous system to the normal threshold or subthreshold stimulation from the afferent nerves. The condition has also been called "central sensitization," "central amplification," and "central pain syndrome." Fibromyalgia is considered one of the most common centralized pain syndromes.

Cervical Facet Pain: Pain located in the cervical spine, which may be characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Chronic Pain: The temporal definition of pain persisting for greater than or equal to 12 weeks after the onset of the pain.

Dual Diagnostic Blocks: The diagnostic technique of injecting the same spinal nerve on two separate occasions to be used as an efficacy comparison to increase diagnostic accuracy.

Epidural Steroid Injection: The administration via injection of steroid medicine into the potential epidural space in the spinal column to deliver steroids to the spinal nerves.

FACET JOINT Intraarticular Injections, Diagnostic: The placement of local anesthetic and possibly a corticosteroid into the FACET JOINT to diagnose FACET JOINT pain.

FACET JOINT Intraarticular Injections, Therapeutic: The placement of local anesthetic and possibly a corticosteroid into the FACET JOINT to produce the beneficial effect of pain reduction.

FACET JOINT: A diarthrodial joint in the spinal column (also called the zygapophysial joint or z-joint), producing the articulation of the posterior elements of one vertebra with its neighboring vertebra. There are bilateral superior and inferior articular surfaces at each spinal level. The terminology or nomenclature of the FACET JOINT is classified by the specific vertebrae level that forms it (e.g., C4-5 or L2-3). There are two (2) FACET JOINTs, right and left, at each spinal level.

Facet Injection: (also called facet block) A general term used to describe the injection of local anesthetic and possibly a corticosteroid in the FACET JOINT capsule or along the medial branch nerves supplying the FACET JOINTs.

FACET JOINT Denervation or Radiofrequency Ablation (RFA): A general term used to describe the minimally invasive procedure that uses thermal energy generated by the radiofrequency current to deprive the FACET JOINT of its nerve supply. The procedure is also known as a Medial Branch Radiofrequency Neurotomy (Ablation) because it is used to thermally remove the medial branch nerve by using electrical current to create thermal energy to coagulate the adjacent tissues around the targeted medial branch nerve.

FACET JOINT Syndrome: A set of concurrent signs or symptoms to describe FACET JOINT pain as the pain generator. The typical clinical signs or symptoms of a facet syndrome may include local paraspinal tenderness; pain that is brought about or increased on hyperextension, rotation, and lateral bending; low back stiffness; absence of neurologic deficit; absence of root tension signs (non-radiating below the knee, absence of paresthesia). Cervical facet pain is often characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Facet Level: Refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each level has a pair of FACET JOINTs: one on the right side and one of the left side of the spine.

Intra-Articular Injection (IA): The injection of local anesthetic and possibly a corticosteroid into the FACET JOINT capsule.

Medial Branch: The dorsal ramus is the dorsal branch of a spinal nerve that forms from the dorsal root of the nerve after it emerges from the spinal cord.

Medial Branch Block (MBB): The placement of local anesthetic and possibly a corticosteroid near the medial branch nerve which supplies the sensory innervation to a specific FACET JOINT.

Neuropathic Pain: The pain which is caused by a lesion or disease of the somatosensory nerves.

Neurogenic Claudication: Intermittent leg pain from impingement of the nerves emanating from the spinal cord

(also called pseudoclaudication).

New Onset of Spinal Pain: The new onset of the spinal pain must be materially and significantly different in location, type, duration and character from the previously treated spine pain.

Noninvasive Conservative Management: The use of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, physical therapy, acupuncture (applies to only chronic low back pain), or spinal manipulation. This management should include the application of a biopsychosocial treatment technique.

Non-Radicular Back Pain: The radiating non-neuropathic pain which is not causally related to a spinal nerve root irritation and does not produce reproducible neuropathic symptoms in an objective dermatomal pattern.

Peripheral Neuropathic Pain: Pain, which is causally related to a lesion or disease of the peripheral somatosensory nerves.

Radicular Back Pain: The radiating neuropathic pain causally related to the spinal nerve root irritation which extends into the distal distribution, typically the lower extremity, producing neuropathic pain in a dermatomal pattern.

Radiculopathy: Radiating neuropathic pain causally related to the spinal nerve root irritation, which extends distal producing neuropathic pain in a dermatomal pattern.

Region: The segments of the back involved will be defined in this policy as two regions:

1. Cervical/Thoracic region = C1-C7/T1-T12
2. Lumbar/Sacral region = L1-L5/S1-S5

Session: A time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) performed during one day.

Subacute Pain: The temporal definition of pain occurring during the 4-12-week time period.

Transforaminal Epidural Steroid Injection (TFESI): An epidural injection performed via a paramedian approach to enter the epidural space by placing the needle in the posterior-superior quadrant of the intervertebral foramen (neuroforamen) to inject near the dorsal root ganglion and exiting spinal nerve root (previously known as a selective nerve root block).

Summary of Evidence

Diagnostic FACET JOINT Injections

Due to the lack of reliable history, physical exam, or imaging to predict response, providers must rely on facet interventions diagnostic injections given for diagnostic purposes to determine if the FACET JOINT is the source of suspected spinal pain. There is controversy over optimal patient selection for diagnostic injections, which measures successful response and type and number of diagnostic injections performed.

Numerous investigations have been undertaken to correlate symptoms and physical exam findings with facet pathology and have concluded conventional clinical findings are unreliable in identifying FACET JOINT success.

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CMS National Coverage Policy

Internet-Only Manuals (IOMs)

- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,

- Chapter 12, Section 40.7 Claims for Bilateral Surgeries
- Chapter 13, Section 10.1 Billing Part B Radiology Services and Other Diagnostic Procedures, Section 20 Payment Conditions for Radiology Services, and Section 30 Computerized Axial Tomography (CT) Procedures

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Article Guidance

Article Text

This Billing and Coding Article provides billing and coding guidance for Local Coverage Determination (LCD) L34892, FACET JOINT Interventions for Pain Management. Please refer to the LCD for reasonable and necessary requirements.

Coding Guidance

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by the entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Diagnostic and Therapeutic Procedures:

Each paravertebral facet level refers to either the FACET JOINT, also called the zygapophyseal joint **OR** the two medial branch nerves that innervate each zygapophyseal joint.

Each facet level has a pair of FACET JOINTS (one on the right side and one on the left side of the spine). Unilateral or bilateral facet interventions may be performed during the FACET JOINT procedure (a diagnostic nerve block, a therapeutic FACET JOINT [intraarticular] injection, or a medial branch block injection, in one session. A bilateral facet nerve intervention is still considered a single level intervention.

For paravertebral spinal nerves and branch injections, image guidance (fluoroscopy or CT) is required for the performance of CPT codes 64490, 64491, 64493, and 64494 with any injection contrast, which is an included component of the code.

As defined by the Current Procedural Terminology (CPT) Professional edition code book, there are two distinct anatomic spinal regions for paravertebral facet injections: cervical /thoracic (codes 64490, 64491) and lumbar/sacral (codes 64493, 64494).

For each initial, single level injection, diagnostic or therapeutic, performed with image guidance (fluoroscopy or CT), use code 64490 (cervical or thoracic) or code 64493 (lumbar or sacral).

For any additional diagnostic or therapeutic procedures on the same day, use add-on codes 64491 (cervical/thoracic) or 64494 (lumbar/sacral) to report second level injections performed with image guidance (fluoroscopy or CT) in addition to the primary procedure codes 64490 or 64493.

Note: Each unilateral or bilateral intervention at any level should be reported as one unit of service (UOS).

If an initial (64490 or 64493) or second level add-on (64491 or 64494) paravertebral facet injection procedure is performed bilaterally, report the procedure with modifier -50 as a single line item using one UOS. Do not use modifier RT or LT when performing these procedures bilaterally (modifier -50).

For services performed in the Ambulatory Surgical Center (ASC), do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.

When an intraarticular FACET JOINT injection is used for facet cyst aspiration/rupture, it should be reported with CPT code 64999. Providers are required to indicate in block 19 of the 1500 claim form or the EMC Equivalent the date of the initial injection procedure and if the injection procedure is being repeated.

For CPT codes 64492 and 64495, the need for a three-level procedure may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.

KX modifier requirements:

The KX modifier should be appended to the line for all diagnostic injections. In most cases the KX modifier will only be used for the two initial diagnostic injections. If the initial diagnostic injections do not produce a positive response as defined by the LCD and are not indicative of identification of the pain generator, and it is necessary to perform additional diagnostic injections, at a different level, append the KX modifier to the line. Aberrant use of the KX modifier may trigger focused medical review.

Neurolytic Destruction Procedures (Radiofrequency Ablation):

For destruction of paravertebral FACET JOINT medial branch nerves, image guidance and localization (fluoroscopy or CT) are required and inclusive in codes 64633, 64634, 64635, and 64636.

Per the current CPT Professional edition code book, codes 64633, 64634, 64635, and 64636 are reported per joint, not per nerve. Although two nerves innervate each FACET JOINT, only one unit per code may be reported for each joint denervated, regardless of the number of nerves treated. There are two distinct anatomic spinal regions for paravertebral facet destruction: cervical/thoracic (codes 64633, 64634) and lumbar/sacral (codes 64635, 64636). For each initial, single level thermal radiofrequency destruction performed with image guidance (fluoroscopy or CT), use code 64633 (cervical or thoracic) or code 64635 (lumbar or sacral).

For any additional thermal radiofrequency destruction performed on the same day, use add-on codes 64634 (cervical/thoracic) or 64636 (lumbar/sacral) in addition to the primary procedure codes 64633 or 64635.

Note: Each unilateral or bilateral intervention at any level should be reported as one UOS.

If initial (64633 or 64635) or each additional add-on (64634 or 64636) paravertebral neurolytic destruction procedure is performed bilaterally, report the procedure with modifier -50 as a single line item using one UOS. Do not use modifier RT or LT when performing these services bilaterally (modifier -50).

For services performed in the Ambulatory Surgical Center (ASC), do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.

Non-thermal FACET JOINT denervation (including chemical, low grade thermal energy [<80 degrees Celsius] or any other form of pulsed radiofrequency) should not be reported with CPT codes 64633, 64634, 64635 or 64636. These services should be reported with CPT code 64999.

Note: Report CPT code 64999 when facet cyst aspiration/rupture is performed.

Note: CPT code 64999 is non covered when used to report non thermal FACET JOINT denervation including chemical, low grade thermal energy (less than 80 degrees Celsius) or any form of pulsed radiofrequency.

Note: When reporting CPT code 64999 ensure that the description of the service is included on the claim.

If FACET JOINTs are injected with biologicals or other substances not designated for this use the entire claim may deny per CMS IOM *Medicare Benefit Policy Manual*, Chapter 16, Section 180-Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.

Utilization Parameters

Note: A session is defined as all procedures (i.e., MBB, IA, facet cyst ruptures, and destruction by a neurolytic agent (e.g., RFA) performed on the same date of service.

CPT codes 64490 through 64494 will be limited to no more than four (4) sessions, per region, per rolling 12 months.

CPT code 64490 through 64494 with the KX modifier will be limited to no more than four (4) sessions, per region, per rolling 12 months.



CPT codes 64633 through 64636 will be limited to no more than two (2) sessions, per region, per rolling 12 months.

Consistent with the LCD, CPT code 64999 may only be reported twice for an intraarticular FACET JOINT injection for a facet cyst aspiration/rupture.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record must include the assessment of the patient by the performing provider as it relates to the complaint of the patient for that visit, relevant medical history, and the results of any pertinent tests/procedures.
5. Documentation of why the patient is not a candidate for radiofrequency ablation (RFA) must be submitted for therapeutic injection procedures.
6. The scales used to assess the measurement of pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to: verbal rating scales, Numerical Rating Scale (NRS), Visual Analog Scale (VAS) for pain assessment, Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OLBPDQ), Quebec Back Pain Disability Score (QBPDS), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the Patient-Reported Outcomes Measurement Information System (PROMIS) profile domains to assess function.

Coding Information

CPT/HCPCS Codes**Group 1 Paragraph:**

Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

Note: Report CPT code **64999** when facet cyst aspiration/rupture is performed.

The following CPT codes need to be listed separately in addition to a code for the primary procedure: **64491**, **64494**, **64634**, and **64636**.

Group 1 Codes: (9 Codes)

CODE	DESCRIPTION
64490	Inj paravert f jnt c/t 1 lev
64491	Inj paravert f jnt c/t 2 lev
64493	Inj paravert f jnt l/s 1 lev
64494	Inj paravert f jnt l/s 2 lev
64633	Destroy cerv/thor facet jnt
64634	Destroy c/th facet jnt addl
64635	Destroy lumb/sac facet jnt
64636	Destroy l/s facet jnt addl
64999	Nervous system surgery

Group 2 Paragraph:

Note: CPT code **64999** is non-covered when used to report non-thermal facet joint denervation including chemical, low grade thermal energy (less than 80 degrees Celsius), or any form of pulsed radiofrequency.

The following CPT/HCPCS codes do not support medical necessity and will not be covered by Medicare.

Group 2 Codes: (13 Codes)

CODE	DESCRIPTION
64492	Inj paravert f jnt c/t 3 lev
64495	Inj paravert f jnt l/s 3 lev
64999	Nervous system surgery
0213T	Njx paravert w/us cer/thor
0214T	Njx paravert w/us cer/thor
0215T	Njx paravert w/us cer/thor
0216T	Njx paravert w/us lumb/sac
0217T	Njx paravert w/us lumb/sac

CODE	DESCRIPTION
0218T	Njx paravert w/us lumb/sac
0219T	Plmt post facet implt cerv
0220T	Plmt post facet implt thor
0221T	Plmt post facet implt lumb
0222T	Plmt post facet implt addl

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes: (4 Codes)

CODE	DESCRIPTION
50	BILATERAL PROCEDURE: UNLESS OTHERWISE IDENTIFIED IN THE LISTINGS, BILATERAL PROCEDURES THAT ARE PERFORMED AT THE SAME OPERATIVE SESSION SHOULD BE IDENTIFIED BY ADDING THE MODIFIER -50 TO THE APPROPRIATE FIVE DIGIT CODE OR BY USE OF THE SEPARATE FIVE DIGIT MODIFIER CODE 09950
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET
LT	LEFT SIDE (USED TO IDENTIFY PROCEDURES PERFORMED ON THE LEFT SIDE OF THE BODY)
RT	RIGHT SIDE (USED TO IDENTIFY PROCEDURES PERFORMED ON THE RIGHT SIDE OF THE BODY)

ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.



The following ICD-10-CM codes support medical necessity and provide coverage for CPT codes: **64490, 64491, 64493, 64494, 64633, 64634, 64635, 64636, and 64999** (facet cyst aspiration/rupture).

Note: ICD-10 Codes **M71.30** or **M71.38** is allowed for facet cyst rupture procedures only.

Group 1 Codes: (20 Codes)

CODE	DESCRIPTION
M47.812	Spondylosis without myelopathy or radiculopathy, cervical region

CODE	DESCRIPTION
M47.813	Spondylosis without myelopathy or radiculopathy, cervicothoracic region
M47.814	Spondylosis without myelopathy or radiculopathy, thoracic region
M47.815	Spondylosis without myelopathy or radiculopathy, thoracolumbar region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.892	Other spondylosis, cervical region
M47.893	Other spondylosis, cervicothoracic region
M47.894	Other spondylosis, thoracic region
M47.895	Other spondylosis, thoracolumbar region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M48.12	Ankylosing hyperostosis [Forestier], cervical region
M48.13	Ankylosing hyperostosis [Forestier], cervicothoracic region
M48.14	Ankylosing hyperostosis [Forestier], thoracic region
M48.15	Ankylosing hyperostosis [Forestier], thoracolumbar region
M48.16	Ankylosing hyperostosis [Forestier], lumbar region
M48.17	Ankylosing hyperostosis [Forestier], lumbosacral region
M71.30	Other bursal cyst, unspecified site
M71.38	Other bursal cyst, other site

ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

All those not listed under the "ICD-10 Codes that Support Medical Necessity" section of this article.

Group 1 Codes: (1 Code)

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

CODE	DESCRIPTION
999x	Not Applicable

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

CODE	DESCRIPTION
99999	Not Applicable

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/25/2021	R4	Article revised and published on 05/27/2021 effective for dates of service on and after 04/25/2021. The "Diagnostic and Therapeutic Procedures:" and Neurolytic Destruction Procedures (Radiofrequency Ablation):" sections of the article were revised to clarify coding guidance for the add-on CPT codes 64491/64494 (second level) and 64634/64636 (each additional) when billing bilaterally. Also, the "Internet-Only Manuals" section of the article was updated to include Pub. 100-04, <i>Medicare Claims Processing Manual</i> , Chapter 12, Section 40.7 Claims for Bilateral Surgeries.
04/25/2021	R3	Article revised and published on 04/22/2021 effective for dates of service on and after 04/25/2021. This revision was to add clarifying language to the paragraph under the "KX modifier requirements:" section of the Article. Also, minor formatting change made