



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. Coverage with Evidence (CED) policies are NCDs with a trial or registry component required for coverage. They 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 through a registry. <Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document, Issued on November 20, 2014; 88 Fed. Reg. 22258>

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. <Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document, Issued on November 20, 2014>

D. Routine Costs of Qualifying Clinical Trials under NCD 310.1

1. Medicare covers and pays routine costs of qualifying clinical trials under NCD 310.1 and for the diagnosis and treatment of complications related to the clinical trial. <NCD 310.1, *Medicare Claims Processing Manual*, Chapter 32 § 69.1>
 - a. Clinical trials deemed automatically qualified for coverage of their routine costs:
 - i. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
 - ii. Trials supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
 - iii. Trials conducted under an investigational new drug (IND) application reviewed by the FDA;
 - iv. Drug trials exempt from an IND and meeting specified criteria. <NCD 310.1>
 - b. Clinical trials qualify for coverage of routine costs when the lead principal investigator certifies that the trial meets the qualifying criteria set out by a multi-agency panel. <NCD 310.1>

E. Investigational Device Exemption (IDE) Studies

1. Medicare covers the routine care items and services furnished in CMS-approved Category A (Experimental) or B (Nonexperimental/investigational) IDE studies and the device in CMS-approved Category B IDE studies. <42 C.F.R. § 405.211; *Medicare Claims Processing Manual*, Chapter 32 § 68>
 - a. CMS-approved IDE studies can be verified on the CMS website.

Link: Approved IDE Studies under Medicare-Related Sites – General

III. Coverage by Medicare Advantage Plans (under Part C)

- A. Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F) published by CMS February 6, 2024, are included in the materials behind the outline and discuss many of the topics in this section in greater detail.

- B. When interpreting traditional Medicare coverage criteria for prior authorization, case management, or claim payment for basic benefits, MA plans must comply with:
1. National Coverage Determinations (NCDs);
 2. Local Coverage Determinations (LCDs) in the geographic area in which services are covered under the MA plan (the plan's service area); and
 3. Other general coverage and benefit conditions in traditional Medicare laws, including criteria for determining whether an item or service is a benefit. <42 C.F.R. § 422.101(b)(1)-(3)>
- C. Examples of coverage determinations that would not comply with the above requirements include:
1. Restricting access to a Medicare covered item or service unless another item or service is furnished first, if not specifically required in NCD or LCD (e.g., an x-ray prior to authorizing an MRI otherwise covered under an LCD that does not require a prior x-ray). <88 Fed. Reg. 22188>; or
 2. Denying ordered care based on considerations other than failure to meet coverage criteria, when care can be delivered in more than one setting or provider type (e.g., denying covered SNF care ordered by the attending physician and redirecting the patient to home health care). <88 Fed. Reg. 22190>
- D. MA plans may establish their own internal coverage criteria when coverage criteria are not fully established by Medicare statutes, regulations, NCDs, or LCDs. <42 C.F.R. § 422.101(b)(6)>
1. Coverage criteria is considered not fully established if:
 - a. There is no NCD, LCD, Medicare statute or regulation setting forth coverage criteria; or
 - b. The NCD or LCD explicitly allows for coverage in circumstances beyond the specific indications in the NCD or LCD; or
 - c. Additional, unspecified criteria are needed to interpret or supplement general coverage provisions consistently,
 - i. The plan must show the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harm, including from delay or decreased access. <42 C.F.R. § 422.101 (b)(6)(i)>

2. MA plan internal coverage policies must be publicly accessible and based on current evidence available in widely used treatment guidelines or clinical literature published in peer-reviewed journals. <42 C.F.R. § 422.101(b)(6)>
3. For internal coverage policies, the plan must provide, in a publicly accessible way, the following:
 - a. The coverage criteria used, and a summary of evidence considered in the development of the criteria;
 - b. A list of sources of the evidence;
 - c. An explanation of the rationale that supports adoption of the criteria, including the general provisions being supplemented or interpreted; and
 - d. An explanation of how the additional criteria provide clinical benefit highly likely to outweigh any clinical harm. <42 C.F.R. § 422.101(b)(6)(ii)>
- E. If an MA plan approves an item or service for coverage or payment through prior authorization, pre-service determination, or concurrent determination during a beneficiary's inpatient or outpatient service, the plan may not:
 1. Deny coverage later on the basis of a lack of medical necessity; and
 2. May not reopen the decision except for good cause or if there is reliable evidence of fraud or similar fault. <42 C.F.R. § 422.138>
- F. If an MA plan expects to make a partially or fully adverse medical necessity decision, the determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care at issue, including knowledge of Medicare coverage criteria. <42 C.F.R. § 422.566 (d)>
 1. The physician or health care professional need not be in the same specialty or subspecialty as the treating physician. <42 C.F.R. § 422.566 (d)>
- G. MA plan Coverage and Payment for Services Related to Clinical Trials, Registries and Studies
 1. MA plans are responsible for coverage and payment of services covered under CED, similar to any other NCD, subject to a "significant cost" determination for new NCDs with CED. <88 Fed. Reg. 22258-59>

- a. A “significant cost” determination is made for any new NCD or legislative change, and services that meet the “significant cost” criteria are paid by traditional Medicare until the contract/plan year in which payment adjustments takes into account the cost of the newly covered service. <42 C.F.R. § 422.109 (c), (d)>
- 2. Routine Costs of Qualifying Clinical Trials under NCD310.1
 - a. Traditional (fee-for-service) Medicare pays for the routine costs of qualifying clinical trials covered under NCD 310.1 for MA plan enrollees. <42 C.F.R. § 422.109(e); 88 Fed. Reg. 22257>
 - b. MA plan enrollees are not charged traditional Part A or B deductibles and only pay the plans in-network cost share for the qualifying clinical trial item (or item of the same category as the clinical trial item), which must be credited to their max-out-of-pocket (MOOP) spending. <42 C.F.R. § 433.109 (e)(2) and (3); 88 Fed. Reg. 22257>
 - i. MA plans must pay the difference between the plans in-network cost share and traditional Medicare cost share. <42 C.F.R. § 433.109 (e)(3); 88 Fed. Reg. 22257>
 - c. MA plan may not require prior authorization for participation in a Medicare-qualified clinical trial or create impediments to an enrollee’s participation in a clinical trial. <42 C.F.R. § 433.109(e)(5)>
 - d. MA plans must also pay for services necessary to diagnose a condition covered by a qualifying clinical trial, most follow-up care after the clinical trial, and services already covered by the plan. <42 C.F.R. § 422.109(c)(2); 88 Fed. Reg. 22257>
- 3. Category A and B IDE Studies
 - a. MA plans pay for the routine care items and services in CMS-approved Category A and B IDE studies and the devices in CMS-approved Category B IDE studies because they are covered Medicare services. <42 C.F.R. § 422.109 (f); 88 Fed. Reg. 22258>

IV. Prior Authorization by Medicare Advantage plans

A. Medicare Advantage plans may only use prior authorization for:

- 1. Verifying the presence of diagnoses or other medical criteria that are the basis for the coverage determination for the specific item or service;

2. For basic benefits, to ensure an item or service is medically necessary under NCDs, LCDs, traditional Medicare coverage and benefit conditions, or plan policies if coverage is not fully established under traditional Medicare policies; or
 3. For supplemental benefits, to ensure the service or benefit is clinically appropriate. <42 C.F.R. § 422.138>
- B. MA plans must make medical necessity determinations based on the circumstances of the specific individual, as opposed to using an algorithm or software that doesn't account for an individual's circumstances. <88 Fed. Reg. 22195>
- C. An MA plan that uses utilization management policies and procedures, including prior authorization, must establish a Utilization Management (UM) committee led by the plan's medical director. <42 C.F.R. § 422.137 (a).>
1. A plan may not use utilization management policies for either basic or supplemental benefits unless those policies and procedures have been reviewed and approved by the UM committee. <42 C.F.R. § 422.137 (b)>
 2. The utilization management policies and procedures, including for prior authorization, must be reviewing at least annually, considering the services and any coverage decisions and guidelines for traditional Medicare (e.g., NCDs, LCDs, regulations, and laws) and relevant clinical guidelines. <42 C.F.R. § 422.137 (d)>
- V. Prior Authorization for Hospital Outpatient Services under Part B
- 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 - Hospital](#)

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, included in the materials behind the outline. <See Operational Guide, Appendix A>

1. CMS has finalized eight categories of services requiring prior authorization:
 - 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)>
 - f. Cervical Fusion with Disc Removal; and
 - g. 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>
 - h. Facet Joint Interventions <87 *Fed. Reg.* 72230, 42 *C.F.R.* 419.83(a)(3)>
- E. 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>

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

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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.

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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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DATE: February 6, 2024

TO: All Medicare Advantage Organizations and Medicare-Medicaid Plans

SUBJECT: Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

On April 5, 2023, CMS issued the “[Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly](#)” final rule which included requirements and clarifications relating to Medicare Advantage (MA) coverage criteria for basic benefits, use of prior authorization, and the annual review of utilization management tools. The new regulatory provisions are applicable to coverage beginning January 1, 2024. Since the issuance of this rule, CMS has received questions about the application of these rules once they are effective. In this memo, we provide clarification about how we expect MA plans to comply with these new rules.

1. Question: When are MA organizations able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits?

Answer: For Medicare basic benefits, MA organizations must make medical necessity determinations in accordance with all medical necessity determination requirements, outlined at § 422.101(c)¹; based on the circumstances of each specific individual, including the patient’s medical history, physician recommendations, and clinical notes; and in line with all fully established Traditional Medicare coverage criteria. This includes established criteria in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When Medicare coverage criteria are not fully established, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature, as permitted in § 422.101(b)(6).

¹ MA organizations must make medical necessity determinations based on all of the following:

- (A) Coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not specified in § 422.101(b) or (c).
- (B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
- (C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
- (D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

2. Question: Do the new rules on clinical coverage criteria for basic Medicare benefits mean that MA organizations cannot use algorithms or artificial intelligence to make coverage decisions?

Answer: There are many overlapping terms used in the context of rapidly developing software tools. Algorithms can imply a decisional flow chart of a series of if-then statements (i.e., if the patient has a certain diagnosis, they should be able to receive a test), as well as predictive algorithms (predicting the likelihood of a future admission, for example). Artificial intelligence has been defined as a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments². Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action³.

An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made. For example, compliance is required with all of the rules at § 422.101(c) for making a determination of medical necessity, including that the MA organization base the decision on the individual patient's circumstances, so an algorithm that determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes would not be compliant with § 422.101(c). In an example involving a decision to terminate post-acute care services, an algorithm or software tool can be used to assist providers or MA plans in predicting a potential length of stay, but that prediction alone cannot be used as the basis to terminate post-acute care services. For those services to be terminated in accordance with § 422.101(c), the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services. Additionally, for inpatient admissions, algorithms or artificial intelligence alone cannot be used as the basis to deny admission or downgrade to an observation stay; the patient's individual circumstances must be considered against the permissible applicable coverage criteria under § 422.101(c).

MA organizations may only deny coverage for basic benefits based on coverage criteria that are specified in § 422.101(b) or (c) or for other expressly permissible bases, such as network limitations or failure to comply with prior authorization requirements. Therefore, the algorithm or software tool should only be used to ensure fidelity with the posted

² 15 U.S.C. 9401(3)

³ *Id.* See also Executive Order (E.O.) 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (88 FR 75191 (11/1/2023)), <https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence>;

internal coverage criteria which has been made public under § 422.101(b)(6)(ii). Because publicly posted coverage criteria are static and unchanging, artificial intelligence cannot be used to shift the coverage criteria over time. And, predictive algorithms or software tools cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard in § 422.101(b)(6).

Furthermore, we are concerned that algorithms and many new artificial intelligence technologies can exacerbate discrimination and bias. We remind MA organizations of the nondiscrimination requirements of Section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. MA organizations should, prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases.

3. Question: For purposes of § 422.101(b)(6)(ii), which states that MA organizations must provide internal coverage criteria in a publicly accessible way, what does “publicly accessible” mean?

Answer: In the 2024 MA and Part D [final rule](#), CMS did not specify how compliant MA plan internal coverage criteria and related information must be made publicly available. We recommended that MA organizations refer to the coverage criteria and summary of evidence presented by Medicare Administrative Contractors (MACs) as a guide and best practice for how to present this information publicly. However, in response to additional questions about what would meet the standard to be “publicly accessible,” we are further elaborating here that the internal coverage criteria used by plans must be accessible via a website and cannot be behind a paywall or require a subscription for access. The information must be available to all in the public (not just enrollees and/or contracted providers of the MA plan) and may be hosted on the MA plan’s website or a delegated vendor’s website that is accessible from the MA plan’s website. MA organizations are required to have a website under § 422.111(h)(2); therefore, use of that website is appropriate. At this time, we do not believe that requiring one or two pieces of basic information to gain access to the internal coverage criteria information required by § 422.101(b)(6)(ii) *necessarily* undermines public access. However, we have concerns that in cases where plans contract with multiple utilization management vendors and place a link to each vendor’s website on the plan website to comply with this provision, the burden of accessing and reviewing the collective internal coverage criteria used by the plan could compromise the public accessibility required by § 422.101(b)(6)(ii). We will continue to monitor access and transparency limitations and may revisit this issue if we see overly burdensome information collection in order to gain access to and analyze internal coverage criteria that should be accessible and transparent to all in the public. The final rule clearly explained that the information required by § 422.101(b)(6) must be publicly accessible, which means generally accessible to CMS, enrollees, providers, researchers, and other stakeholders and that CMS believes that this transparency provides

a measure of protection for enrollees and assurances that the coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature.

4. Question: What does the internal coverage criteria standard “based on current evidence in widely used treatment guidelines or clinical literature” mean as used in § 422.101(b)(6)?

Answer: In circumstances when Medicare Part A and B coverage criteria are not fully established and MA plan internal coverage criteria are permitted, CMS elaborated on the meaning of current, widely used treatment guidelines and clinical literature in the preamble of the [final rule](#) on pages 22189, 22196, and 22197. Current, widely used treatment guidelines are those developed by organizations representing clinical medical specialties and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question. MA organizations may not add coverage criteria that are not supported in such guidelines or literature, or change the substantive recommendations contained in such guidelines or literature to support coverage criteria. If the internal coverage criteria cannot be supported by current evidence in widely used treatment guidelines or clinical literature, publicly and in a way that meets the evidentiary standard in the final rule, plans should not develop internal coverage criteria even if the Traditional Medicare coverage criteria are not fully established. Referencing information, such as a book, website, or third-party criteria, without directly describing and referencing the requisite source citations from primary literature that are widely used treatment guidelines or clinical literature, would not comply with § 422.101(b)(6)(ii). These transparency measures will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS's expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

5. Question: What does it mean for internal coverage criteria to have clinical benefits that are highly likely to outweigh any clinical harms?

Answer: Section 422.101(b)(6)(i)(A) requires that when additional, unspecified criteria are needed to interpret or supplement general provisions, the MA organization must demonstrate in a publicly accessible way how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including (but not limited to) from delayed or decreased access to services. CMS expects that, in order to demonstrate in its public explanation of the rationale support for establishing the internal coverage criteria, the MA organization would compare the clinical benefits of the policy

to the harms that patients may experience as a result of the coverage criteria. For example, take the hypothetical example of an MA organization that establishes internal coverage criteria for Magnetic Resonance Imaging (MRIs) with contrast for patients with a history of established hypersensitivity to Gadolinium-based contrast media (a type of contrast often used in MRIs). NCD 220.2 Magnetic Resonance Imaging states that physicians elect to use a specific Magnetic Resonance Angiography or Contrast-enhanced technique *based upon clinical information from each patient*. Here, the MA organization may adopt an internal policy to not allow contrast-enhanced MRIs with Gadolinium-based contrast media when the patient has a history of hypersensitivity to Gadolinium unless the patient receives appropriate pretreatment. In its rationale, the clinical benefit of avoiding MRIs in patients with established hypersensitivity to Gadolinium-based contrast media may be avoidance of hypersensitivity reaction, which for some patients can be life threatening and cause significant morbidity and mortality. However, omitting contrast when it is indicated can lead to diagnostic and treatment errors, or repeated tests and delayed diagnoses. Additionally, the coverage criteria in and of itself could cause a dangerous delay in an important diagnosis. In order to compare the relative clinical harm and benefit, factors such as prevalence of expected clinical benefits and harms, relative morbidity and mortality, and frequency of delayed diagnoses for specific conditions that result from delayed or decreased access to MRIs, and relative outcomes, including through pretreatment, could be weighed in the public rationale.

Demonstrating that the additional coverage criterion (or criteria) meets the regulatory standard in § 422.101(b)(6)(i)(A) would involve a discussion of the relative clinical benefits and harms to the patient population. The clinical coverage criteria should be narrowly tailored to the patient population that stands to benefit in the public rationale and justification (i.e. the internal coverage criteria could be created for patients with a history of gadolinium hypersensitivity who have been ordered an MRI with Gadolinium contrast in this example—not all patients who have been ordered an MRI). Because the MA organization must demonstrate the comparative benefit of the additional coverage criteria, a public explanation that *assumes* that clinical coverage criteria *in general offers clinical benefits* to patients that are highly likely to outweigh clinical costs is not sufficient. The public explanation should systematically explain the harms and benefits and use appropriate clinical evidence and citation of current, widely used treatment guideline or clinical literature. (See also § 422.101(b)(6)(ii)(C).)

Further, if the standards in § 422.101(b)(6) and 422.101(b)(6)(i)(A) cannot be met because there are no widely used treatment guidelines or high-quality clinical literature to suggest that the clinical benefit of the internal coverage criteria is highly likely to outweigh the clinical harm, the MA organization is not permitted to adopt that internal coverage criteria even if the Traditional Medicare coverage criteria are not fully established. Stated succinctly, we believe that all internal coverage criteria should clearly and explicitly support patient safety before the criteria are used by an MA plan, even

where other minimum requirements in the regulation (that is, where Traditional Medicare coverage policies are not fully established) are met.

We will continue to monitor the rationales made public under § 422.101(b)(6) to ensure compliance. We may issue additional guidance as needed to ensure that internal coverage criteria are being developed only in those situations where clinical benefit is highly likely to outweigh clinical harm, including from delayed or decreased access to items or services.

6. Question: Can MA organizations apply coverage criteria from a Traditional Medicare Local Coverage Determination (LCD) that is not applicable to the service area where the MA plan is available?

Answer: If the LCD is not from the applicable service area, use of the LCD is use of internal coverage criteria and all associated requirements would still apply; an MA organization is not exempted from the requirements of § 422.101(b)(6) by using an LCD adopted in a geographic area that is not the MA plan's service area. MA organizations must follow all Traditional Medicare NCDs, LCDs applicable to the MA plan's service area, and general coverage and benefit conditions included in Traditional Medicare per 42 CFR § 422.101. In situations where Traditional Medicare coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs (applicable to the applicable service area), MA organizations may create internal coverage criteria as long as they comply with rules at § 422.101(b)(6). An MA plan's internal coverage criteria may be similar or the same as criteria found in LCDs that are applicable outside of the MA plan's service area, but the MA organization must still ensure that the criteria are based on current evidence in widely used treatment guidelines or clinical literature and is made publicly available, as required by § 422.101(b)(6).

7. Question: Can an MA organization deny admission of a patient to a post-acute care facility from an acute care hospital if it's ordered by their physician and the patient meets the coverage criteria for admission into that facility?

Answer: No, if a patient is being discharged from an acute care hospital to a post-acute care facility that would be covered under Traditional Medicare and the patient's attending physician orders post-acute care in the specific type of facility (i.e., Skilled Nursing Facility (SNF), Long Term Care Hospital (LTCH)) and the patient meets all applicable Medicare coverage criteria for admission into that facility type, the MA organization cannot deny admission to that post-acute setting and/or redirect the care to a different setting. In the context of post-acute care services furnished in a particular setting, MA organizations may only deny a request for Medicare covered post-acute care services if the MA organization determines that the Traditional Medicare coverage criteria (e.g., for SNF care in §§ 409.30-409.36) or internal coverage criteria when applicable and

authorized by § 422.101(b) for the services cannot be satisfied in that particular setting. We explained this clearly as part of the proposal that we adopted in the final rule. 88 FR 22189. We reiterate here that MA organizations may only deny a request for Medicare covered post-acute care services in a particular setting if the MA organization determines that the Traditional Medicare coverage criteria or internal coverage criteria (when applicable and authorized by § 422.101(b)) for the services cannot be satisfied in that particular setting. However, MA plans are permitted to offer coverage of alternatives to Medicare covered post-acute care services in a particular setting and an enrollee is permitted to elect different treatment. The requirement for MA plans to cover all basic benefits consistent with Traditional Medicare coverage criteria does not prohibit discussions with the enrollee of other treatment options that are covered by the MA plan. However, the flexibility for MA plans to cover and deliver care in cost-effective approaches does not replace the obligation for MA plans to cover all basic benefits consistent with the established coverage criteria for Traditional Medicare.

MA organizations may only terminate coverage for post-acute care services based on coverage criteria that are specified in § 422.101(b) or (c), which include medical necessity. An algorithm or software tool may be used to assist MA plans in predicting a length of stay, but that prediction alone must not be used as the basis to terminate post-acute care services; the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services. An MA organization's decision to terminate post-acute care services and discharge a patient from a home health agency (HHA), skilled nursing facility (SNF), or comprehensive outpatient rehabilitation facilities (CORF) is an organization determination and is appealable in accordance with rules in §§ 422.624 and 422.626.⁴ The specific expedited appeal process applicable to such terminations of provider services provides that the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies, and that the MA organization must supply a specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered, including a description of the applicable coverage criteria and rules. 42 CFR § 422.626(c) and (e).

8. Question: Does the CY 2024 final rule mean that MA organizations must follow the Medicare “two-midnight rule”?

⁴ Discharge from an inpatient hospital is appealable in accordance with §§ 422.620 and 422.622. In these expedited reviews by the QIO, the MA organization also bears the burden of proof that the discharge “is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.” § 422.622(c).

Answer: The term ‘two-midnight rule’ is sometimes used to describe different things: either the “two-midnight presumption” or the “two-midnight benchmark” admission criteria. As explained further below, MA plans do not have to follow the “two-midnight presumption,” which relates to medical review instructions for contractors in Traditional Medicare. However, another colloquial use of the term “two-midnight rule” is to describe the inpatient admission criteria in 42 C.F.R. § 412.3, which include a “two-midnight benchmark;” MA plans are required to follow these inpatient admission criteria.

In regard to the two-midnight presumption, we explained in the preamble of the CY 2024 final rule that the “two-midnight presumption” (the presumption that all inpatient claims that cross two midnights following the inpatient admission order are “presumed” appropriate for payment under Medicare Part A and are not the focus of medical review absent other evidence) does not apply to MA plans’ decision about when and how to engage in review of a particular inpatient stay. The two-midnight presumption is a medical review instruction given to Medicare post-payment audit and compliance contractors (for example, Recovery Audit Contractors, or Quality Improvement Organizations) to help them in the selection of claims for post-payment medical necessity reviews in Traditional Medicare, which are conducted to ensure that claims have been appropriately paid under Medicare rules. Any sub-regulatory guidance issued by these contractors does not directly apply to MA plans but likely contain useful explanations and interpretations of Traditional Medicare policies. As clarified in [the CY 2024 final rule](#),⁵ MA organizations are not required to use the two midnight presumption to decide which claims to review, but may instead decide which claims are subject to review in accordance with procedures for making determinations as provided by Section 1852(g)(1)(A) of the Act. MA plans may still use prior authorization or concurrent case management review of inpatient admissions to determine whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission under 42 C.F.R. 412.3. MA medical necessity reviews may be conducted before the service is provided (i.e., prior authorization), during (i.e., concurrent case review), or after the service is provided (i.e., claim review). In all of these circumstances, MA organizations must comply with § 422.101(c).

The two-midnight benchmark is part of the inpatient admission criteria outlined in 42 C.F.R. § 412.3. MA plans must follow these criteria, in line with the requirement that they must follow general coverage and benefit conditions included in Traditional Medicare when making a decision about coverage of an inpatient stay. In the CY 2024 final rule, CMS updated and clarified requirements affecting MA plan coverage guidelines and the relation of such guidelines to Traditional Medicare coverage policies. The updated regulations explain that MA plans must follow all NCDs, LCDs applicable to the plan’s service area, and general coverage and benefit conditions included in Traditional Medicare laws. We directly cited the inpatient admission criteria at 42 CFR §

⁵ 88 FR 22191-22192.

412.3 as an example of Traditional Medicare rules that apply in MA (42 CFR § 422.101(b)(2)) to establish coverage. More specifically, under 42 CFR § 412.3, MA plans must provide coverage, by furnishing, arranging for, or paying for an inpatient admission when, based on consideration of complex medical factors documented in the medical record:

- the admitting physician expects the patient to require hospital care that crosses two-midnights (§ 412.3(d)(1) (the “two midnight benchmark”);
- when the admitting physician does not expect the patient to require care that crosses two-midnights, but determines, based on complex medical factors documented in the medical record that inpatient hospital care is nonetheless necessary (§ 412.3(d)(3), (the “case-by-case exception”); or
- when inpatient admission is for a surgical procedure specified by Medicare as inpatient only (§ 412.3(d)(2)).

We note that inpatient admission criteria at § 412.3(d)(1) and (3) are both based on the *expectation of the admitting physician* at the time of admission, as supported by the medical record. Whether the admission actually crossed two midnights is not a factor in the inpatient admission criteria at § 412.3. An MA organization may evaluate whether the admitting physician’s expectation that the patient would require hospital care that crosses two-midnights was reasonable based on complex medical factors documented in the medical record. Consistent with § 412.3, that evaluation should defer to the judgment of the physician as long as that judgment was reasonable based upon the complex medical factors documented in the medical record.

CMS will continue to monitor inpatient coverage criteria, in addition to all other clinical areas, to evaluate areas where there may need to be more well-established criteria implemented to best support beneficiary access to the timely care they need.

9. Question: Are plans able to do post-claim audits and deny payment and still be compliant with the effect of a prior authorization or pre-service approval rule at 422.138(c)?

Answer: Plans can conduct post-claim reviews, but it must be compliant with reopening rules and only revised within specific parameters. Subject to the limitation in § 422.138(c), discussed below, a plan is permitted to conduct post-payment review on a selected claim, consistent with the reopening rules in § 422.616 and other applicable rules in Part 422, Subpart M.

If an organization determination is reopened and revised, the plan must notify the parties of its revised determination. If the revised determination is adverse, the notice to the parties must state the rationale and basis for the reopening and revision and any applicable right to appeal. However, the final rule codified at § 422.138(c) states that if an

MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at 42 CFR § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. This means that if the MA organization pre-authorized the inpatient admission, it would be a violation of § 422.138(c) to later deny payment based on a determination that the level of care was not medically necessary.

We have heard frequently that MA organizations utilize post-claim review audits and examinations that routinely result in the denial of payment for the inpatient care that was provided to the enrollee. Further, we have heard that MA organizations characterize these reviews as “payment” reviews and that these reviews are “not organization determinations” or “level of care or medical necessity reviews.” We disagree with those characterizations of decisions that are denials of coverage or otherwise a refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization. We reiterate here that the refusal to provide or pay for services, in whole or in part, including the type or level of services (e.g., inpatient services versus outpatient services) is an organization determination by the MA plan under § 422.566(b)(3). Therefore, if the MA organization expects to issue a partially or fully adverse decision about whether the services are or were medically necessary, that decision – meaning that organization determination - must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. See 42 CFR § 422.566(d).

10. Question: Does the Medicare “Interrupted Stay” policy apply in MA?

Answer: Traditional Medicare pays SNFs using the SNF Prospective Payment System (PPS). The SNF PPS includes an “interrupted stay” policy that if a patient in a covered Part A SNF stay is discharged from the SNF but returns to the same SNF no more than three consecutive calendar days after having been discharged, then this would be considered a continuation of the same SNF stay (see 83 FR 39162, 39243). In such cases, no new patient assessments are required and the variable per diem adjustment is not reset. This policy of not resetting the variable per diem adjustment is not applicable in MA when MA organizations provide benefits through their contracted network of providers. The contract between MA organizations and their contracted providers governs the rates and payment policies for the delivery of services.

However, in the final rule, we strengthened policies related to prior authorization at § 422.112(b)(8)(i)(A), by requiring that approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation. This requirement applies in the context of an interrupted stay in a SNF: a new prior authorization for admission is not required when the patient returns no more than three consecutive calendar days after having been discharged. Therefore, if the MA plan uses prior authorization for a stay in a SNF, an interruption in the stay within the scope of the SNF PPS interrupted stay policy does not change or alter the scope of that prior authorization approval. Under § 422.112(b)(8)(i)(A), MA organizations that offer coordinated care plans must not require another prior authorization when a patient returns no more than three consecutive calendar days after having been discharged and the patient is still undergoing the same course of treatment that was previously approved. This policy is meant to avoid disruptions in care for the patient and does not impact or change payment or rates set between the MA organization and the provider.

When an MA plan covers out of network services (that is, services furnished by a non-contracted provider), the MA plan must pay the provider the amount that the provider would have received as payment in the Traditional Medicare program. See section 1852 of the Act and 42 CFR § 422.100(b)(2) and 422.214. Therefore, MA organizations must follow payment rates in the SNF PPS for services delivered by non-contracted SNF providers.

11. Question: Can MA plans still use prior authorization and how does the CY 2024 final rule impact the use of prior authorization?

Answer: Yes, use of prior authorization (also called pre-certification) to ensure the patient meets the applicable guidelines is still allowed *except for* emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans. In addition, MA Private Fee For Service and MA Medical Savings Account plans are not permitted to use prior authorization policies or “prior notification” policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the plan in advance that services will be furnished.

That said, the CY 2024 final rule adopted several provisions applicable beginning January 1, 2024, on the use of prior authorization:

- Prior authorization may only be used by MA coordinated care plans to confirm the presence of diagnoses or other medical criteria, to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically

appropriate (§ 422.138(b)). Therefore, prior authorization should not function to delay or discourage care.

- For MA coordinated care plans, approval of a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation. Further, MA coordinated care plans must provide a minimum 90-day transition period for new enrollees, during which the new MA plan may not require prior authorization for any active course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider (§ 422.112(b)(8)).
- To ensure prior authorization is being used appropriately, all MA plans must establish a Utilization Management Committee to annually review utilization management policies and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines (§ 422.137).

In addition, prior authorization decisions must be made as expeditiously as the enrollee's health condition requires, but no later than the deadlines established in §§ 422.568 (for non-expedited requests) and 422.572 (for expedited requests).

12. Question: Can MA organizations that share a common parent organization use personnel that serve on multiple Utilization Management (UM) committees?

Answer: CMS required that an MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)). The [final rule](#) provides that MA organizations may elect to establish UM committees at the MA organization or plan level, but does not permit the UM committee to be established at the parent organization level for all MA plans offered under that parent organization and its subsidiaries. In some cases, it may be appropriate for parent organizations that operate multiple MA organizations to establish UM committees with substantially the same membership. If all regulatory requirements, including UM committee membership, scope of work, and documentation requirements, are satisfied, then it may be appropriate for the same group of members to serve on the UM committees for multiple MA organizations. Since there are no requirements regarding how many individuals may serve on the UM committee, MA organizations and parent organizations have sufficient flexibility to establish UM committees, while also complying with all regulatory requirements. For example, a parent organization may choose to have one core group of UM committee members that serve across multiple committees under the subsidiary MA organizations, while also supplementing those committees with additional personnel based on which UM policies or procedures the UM committee must review, the geographic area served by the particular MA organization, or other factors relevant to the development, review and use of UM policies. Further, as outlined in the CY2024 final

rule, MA organizations are permitted to leverage existing committees to satisfy the new regulatory requirement. MA organizations may adapt or alter existing committees, including committees required by accrediting bodies and existing P&T committees, to conform with the regulatory requirements of § 422.137.

For additional information on this topic, please see the HPMS memo titled “[Additional Operational Instruction on the Utilization Management Committee Structure](#),” issued on November 15, 2023. Also, please see the proposed rule Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (88 FR 78476), in which CMS proposed additional changes to the UM committee:
<https://www.federalregister.gov/documents/2023/11/15/2023-24118/medicare-program-contract-year-2025-policy-and-technical-changes-to-the-medicare-advantage-program>.

13. Question: How do the new CY 2024 utilization management requirements apply to MA supplemental benefits?

Answer: As stated in the CY 2024 final rule, MA organizations may use prior authorization to ensure that the furnishing of supplemental benefits is clinically appropriate. The regulation text uses the term “clinically appropriate” as opposed to “medically necessary.” While supplemental benefits must be medically necessary based on long standing guidance, certain supplemental benefits (that is, SSBCI) may be non-primarily health related and must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Thus, a standard based on medical necessity may not always be appropriate and using the term “clinically appropriate” is more inclusive of SSBCI. In line with these standards, prior authorization for supplemental benefits may only be used to ensure the furnishing of a service or benefit is clinically appropriate. As it relates to coverage criteria, Medicare does not have coverage criteria for supplemental benefits because, by their nature, they are not Medicare Part A or Part B benefits.

14. Question: How will CMS enforce the CY 2024 changes in coverage criteria and utilization management requirements?

Answer: As we first announced on October 24, 2023, in the HPMS memo titled, “[2024 Oversight Activities](#)” and subsequently on December 19, 2023, in the HPMS memo titled, “2024 Program Audit Updates” CMS will conduct both routine and focused program audits of organizations in 2024 to assess compliance with the coverage and UM requirements finalized in the CY 2024 final rule. For MA organizations that have routine program audits scheduled for 2024, these audits will follow our standard process similar to prior years, covering all applicable program areas, but will target the new UM

requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review, as well as the Compliance Program Effectiveness (CPE) review. In addition, CMS is also adding new focused audits for plans that don't have routine scheduled audits, which are limited to ODAG and CPE, and are designed specifically to target compliance with the coverage and UM policies in the CY 2024 final rule. Through this combination of routine and focused audits in 2024, CMS expects to evaluate the UM-related performance of plans serving approximately 88% of people with MA. This expansion of our audit activity will help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled. During both the routine and focused program audits, CMS will utilize physician reviewers to review denied requests to assess whether MAOs are meeting new clinical coverage requirements, such as following coverage and benefit conditions included in Medicare laws, NCDs, or LCDs, , and when permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, National Coverage Decisions, and Local Coverage Decisions. CMS program audits will also ensure that internal coverage criteria are publicly available and otherwise meet regulatory requirements, MAOs are only using physicians (or other appropriate health care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

CMS has increased its scheduled program audit activities to help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled.

We will be monitoring closely whether MA plans are utilizing and applying internal coverage criteria that are not found in Medicare laws, NCDs, or LCDs, and whether the internal coverage criteria are publicly accessible and coverage policies meet the regulatory requirements.

CMS has a number of tools it can use to address non-compliance with the new requirements, including issuing compliance and enforcement actions.

- Compliance actions include Notices of Non-Compliance, Warning Letters, and Requiring Corrective Action Plans.
- Enforcement actions include civil money penalties and enrollment and/or marketing sanctions.

If you have any questions, please submit an inquiry to the Part C Policy portal at: dpap.lmi.org

Appendix A

Final List of Outpatient Department Services That Require Prior Authorization

The following is the list of codes associated with the list of hospital outpatient department services contained in 42 CFR 419.83(a)(1) and (2).	
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after <i>July 1, 2020</i> :	
(i) Blepharoplasty (ii) Botulinum toxin injections (iii) Panniculectomy (iv) Rhinoplasty (v) Vein ablation	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair ¹
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, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services

¹ CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

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 ²
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

² CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

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
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:	
(i) Cervical Fusion with Disc Removal	
(ii) Implanted Spinal Neurostimulators	
Code	Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators ³
63650	Percutaneous implantation of neurostimulator electrode array, epidural
The following service category comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2023: Facet Joint Interventions.	
Code	Facet Joint Interventions ⁴
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
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;

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	second level
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

³CPT 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 CMS-1736-FC.

⁴CPT codes 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)) and 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)) will be removed on August 16, 2024.

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