



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. 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)>
- B. 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>
- C. 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)>
- D. If an MA plan approves an item or service through prior authorization, or pre-service determination of coverage, or payment, 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 Fed. Reg. § 422.138>
- E. 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)>
- F. 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 - General

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

5. Emergency department claims with modifier ET or revenue code 45X
<Operational Guide, Section 9.2>;
 6. Part A and Part B Demonstration claims <Operational Guide, Section 9.2>; and
 7. Veterans Affairs and Indian Health Services <Operational Guide, Section 9.5>.
- D. The list of CPT/HCPCS codes which will require prior authorization can be found in Appendix A of the Operational Guide and Table 103 of the CY2023 OPPS Final Rule, included in the materials behind the outline. <See Operational Guide, Appendix A; 87 *Fed. Reg.* 72230-233>
1. CMS finalized five categories of services requiring prior authorization, effective July 1, 2020:
 - a. Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair;
 - i. Effective January 7, 2022, CMS removed 67911 (Correction of lid retraction) from the list of applicable blepharoplasty codes.
 - b. Rhinoplasty;
 - c. Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy);
 - d. Botulinum toxin injections;
 - i. Prior authorization is only required when one of the listed Botulinum Toxin codes is billed with one of the listed injection codes. Botulinum Toxin billed with other procedure codes will not require prior authorization. <Operational Guide, Section 6.2.2>
 - e. Vein ablation. <84 *Fed. Reg.* 61448, 42 *C.F.R.* 419.83(a)(1)>
 2. CMS finalized two additional categories of services requiring prior authorization, effective July 1, 2021:
 - a. Cervical Fusion with Disc Removal; and
 - b. Implanted Spinal Neurostimulators. <85 *Fed. Reg.* 86246-248, 42 *C.F.R.* 419.83(a)(2)>
 - i. In May 2021, CMS announced that two codes (63688 and 63685), which were finalized as requiring prior authorization July 1, 2021, were temporarily removed from the list, presumably because they can be used to code revision, removal, or replacement procedures. <See Operational Guide, Appendix A>

- ii. If a trial and permanent implantation are performed, a PAR should be request for the trial and the Unique Tracking Number (UTN) for the trial should be reported for both the trial and permanent implantation.
<Operational Guide, Section 6.3.2.2>
- 3. CMS finalized one additional category of services requiring prior authorization, effective July 1, 2023:
 - a. Facet Joint Interventions <87 *Fed. Reg.* 72230, 42 *C.F.R.* 419.83(a)(3)>

E. 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-fluorodeoxyglucose positron emission tomography (FDG PET) for oncologic conditions (NCD Manual §220.6.17). In both NCDs, data were submitted to CMS-approved registries. While the intent of these CED NCDs was to monitor the appropriateness of use of these items and services, we recognized that the data could also be used to generate useful clinical evidence. More recent NCDs have tended to rely on section 1862(a)(1)(E) of the Act, in which CED is used to support clinical research.

Section 1142 of the Act

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

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

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

IV. Principles governing the application of CED:

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

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

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

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

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

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

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

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

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

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

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

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

VIII. Ending CED

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

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

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

IX. Transparency of CED

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

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

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

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

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

XI. Additional Information

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Veterans Health Administration Hospitals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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