Coverage with Evidence Development (CED) Studies and Registries

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Effective January 1, 2008, all claims submitted for patient care in clinical research studies must use the –Q0 or –Q1 modifiers for routine and investigational clinical services. This includes "studies that are certified under the Medicare Clinical Research Policy, Investigational Device Exemption (IDE) trials, and studies required under a coverage with evidence development (CED) national coverage determination (NCD)."[1]

- Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

- Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.

In addition to the above modifiers, claims also need to include the ICD-10 code Z00.6 (or ICD-9 code V70.7 if the services were rendered prior to October 1, 2015).

Some of these services are covered by Original Medicare (or the local Medicare Administrative Contractors, also known as "MACs") as the primary carrier, while services would be processed by the Medicare Advantage Organization (MAO). Therefore, claims reported with these modifiers and diagnoses codes require some review to ensure accurate adjudication.

For national coverage determinations (NCDs) that may provide some allowance under the Coverage With Evidence Development (CED) provision, MAOs are responsible for payment of items and services unless CMS determines that the significant cost threshold is exceeded for that item or service.[5] However, Medicare only covers these items and services when they are provided within the context of CMS-approved CED studies. Approved studies are posted on the CMS Coverage with Evidence Development web page. In addition, CMS may also publish billing instructions for each NCD.

This policy is intended to aid decision-making regarding:

(1) The appropriate primary payor for the service(s) in question; and
(2) When further medical necessity review may be necessary.

Definitions and Acronyms

CED:	Coverage with Evidence Development
MAC: *(also seen as "A/B MACs")*	Medicare Administrative Contractor, also known as a local contractor. Part A and Part B MACs process Medicare Part A and Medicare Part B claims for a defined geographic area or "jurisdiction," servicing institutional providers, physicians, practitioners, and suppliers.
MAO:	Medicare Advantage Organization. Also referred to as Medicare Advantage (MA) Plans, Medicare+Choice Organizations, or Medicare Part C.[2]

MEDICARE ADVANTAGE POLICY CRITERIA

Notes:

- This policy is **not** intended to provide coverage for devices or procedures excluded by Medicare (i.e., devices or procedures statutorily excluded from coverage based on CMS manuals or other regulation).
- Procedures and devices deemed experimental or investigational (and therefore not medically necessary) ***by the Medicare Advantage Organization (MAO)*** following an evidence-based review process are not addressed by this policy. These are addressed in separate Medicare Advantage medical policies specific to the service in question.
- This policy does not address Humanitarian Use Devices (HUDs) and Exemptions (HDEs).

Type of Clinical Trial, Registry, or Study	***Financial Responsibility/Where to submit claims***	***Covered / Non-Covered Items and Services***	***Party Responsible for Study Approval and/or Criteria Development***
Clinical trials/registries not otherwise specified Category A and Category B Investigational Device Exception (IDE) Study	See Cross References for Separate Medicare Advantage Medical Policy, Medicine, Policy No. M-150		
Coverage with Evidence Development (CED) Studies and Registries (See Appendix I)	MAO plan *unless* Medicare has determined the significant threshold is exceeded and has accepted financial responsibility.	Routine services and item/device under investigation if both are used within a CMS-approved CED study *(If the item in question is not FDA-approved for **any** indication, further research may be required. The item would not be expected to be covered under Medicare.)*	Medicare. Approved CED studies and registries are found on the CMS CED web site. For applicable Medicare criteria, see Appendix 1 (below).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- The name of the trial, registry, or study;
- The clinical trial number;
- The name of the device or drug (if applicable).

BACKGROUND

Coverage with Evidence Development (CED) Studies and Registries

What is Coverage with Evidence Development (CED)?

CED is a Medicare provision to cover items and services only when furnished in the context of approved clinical studies or with the collection of additional clinical data. Medicare has implemented an evidence-based medicine coverage process for coverage determinations, and therefore, does not generally cover experimental or investigational items and services as reasonable and necessary under section 1862(a)(1)(A) of the Act. However, Medicare frequently receives requests for coverage of certain items and services when the expectations of interested parties are not supported by the existing evidence.

Medicare believes they 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. Examples include new technologies, or existing technologies for which the evidence is incomplete. By implementing this CED provision, beneficiaries may gain access and coverage to innovative technology sooner, while ensuring systematic patient safeguards are in place to reduce the risks of new technologies, or to new applications of existing technologies.[3]

NCDs that include CED criteria can be found on the CMS web page for Coverage with Evidence Development[4] and "…MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service..."[5]

Some procedures and items subject to CED criteria are addressed in separate Medicare Advantage medical policies, while others are not. See Table 1 for review processes for

various CED topics, and Appendix I for separate Medicare Advantage medical policies with CED coverage requirements.

Table 1. Medicare Advantage Review Process for Coverage with Evidence Development (CED)

Topics that have a separate Medicare Advantage medical policy	Topics that do NOT have a separate Medicare Advantage medical policy
• Services are likely included on the health plan's prior authorization list and are always reviewed for medical necessity. • ***Reviews are performed using the clinical criteria found in the applicable NCD, as well as confirming the study or registry is Medicare-approved***. Examples include, but are not limited to: vagus nerve stimulation, transcatheter aortic valve replacement (TAVR), transcatheter mitral valve replacement (TMVR), and leadless pacemakers.	• Medical necessity review is not routinely performed unless an advance organization determination is requested, the services are reported with an unlisted CPT® code, or the health plan decides to add the procedure to their review list in the future. • ***MAO reviews are limited to confirming the registry or research study is Medicare-approved to prevent MAO payment for non-Medicare-approved studies.*** Examples include, but are not limited to: CPAPs, home oxygen, TENS, and PILD (i.e., MILD®).
NOTE: While medical necessity reviews may not be routinely performed for all services, providers are expected to submit claims only for services that are medically reasonable and necessary per Title XVIII of the Social Security Act §1862(a)(1)(A).	

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

REFERENCES

1. CMS Manual System Change Request (CR) 5805, dated January 18, 2008
2. *Medicare National Coverage Determination (NCD) for* Routine Costs in Clinical Trials (310.1)
3. Medicare webpage "*Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development*"
4. Medicare webpage "*Coverage with Evidence Development*"

5. *Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections,* §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
6. *Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services*, §70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries
7. NCT number searches: http://www.clinicaltrials.gov/
8. Product Classification searches (Class I, Class II, or Class III): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
9. Medicare "*Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Qs & As*" Document

CODING

NOTE: Services for registries and trials are recognized by the use of the applicable clinical trial number, the modifiers –Q0 and –Q1, and the use of ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)

Codes	Number	Description
CPT	N/A	
HCPCS	J0174	Injection, lecanemab-irmb , 1 mg
	J0175	Injection, donanemab-azbt, 2 mg
	J3490	Unlisted drugs
	J3590	Unclassified biologics

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*

Appendix I. Coverage With Evidence Development (CED) and Medicare Advantage Medical Policies

*Note: Some services may be reviewed by a contracted vendor (radiology services, pain management, spinal procedures, etc).

CED/Clinical Trial/Study/ Registry	Active Medicare Advantage medical policy? *If a Medicare Advantage medical policy with link **IS** provided, and the services are on the health plan's pre-authorization list, then a full "medical necessity review" should be performed using the policy specific to the services in question. If there is no Medicare Advantage medical policy developed for a service, medical necessity reviews are not routinely performed for that service; however, providers are still expected to submit claims only for services that are medically reasonable and necessary per Title XVIII of the Social Security Act §1862(a)(1)(A). Reviews will focus on confirming the registry or research study is Medicare-approved.
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease	Coverage criteria outlined in CAG-00460N
Allogeneic Hematopoietic Stem Cell Transplant for MDS, Multiple Myeloma, Myelofibrosis, or Sickle Cell Disease (NCD 110.23)	Policy No. M-TRA45, Stem Cell and Bone Marrow Transplants
Amyloid PET (NCD 220.6.20)	AIM Specialty Health administers our Radiology Quality Initiative (RQI) program.
Autologous Platelet-rich Plasma (NCD 270.3)	Policy No. M-MED77, Autologous Blood-Derived Growth Factors as a Treatment for Wound Healing and Other Miscellaneous Conditions
Cochlear Implantation (NCD 50.3)	No Medicare Advantage medical policy or vendor review
CPAP for Obstructive Sleep Apnea (NCD 240.4)	AIM Specialty Health administers our sleep medicine management program.

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Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant (NCD 110.4)	No Medicare Advantage medical policy or vendor review
FDG PET and Other Neuroimaging Devices for Dementia (NCD 220.6.13)	AIM Specialty Health administers our Radiology Quality Initiative (RQI) program. (PET for Dementia Trials)
Home Use of Oxygen in Approved Clinical Trials (NCD 240.2.1)	No Medicare Advantage medical policy or vendor review
Leadless Pacemaker (NCD 20.8.4)	Policy No. M-SUR217, Leadless Pacemakers
NaF-18 PET for Bone Metastasis (NCD 220.6.19)	AIM Specialty Health administers our Radiology Quality Initiative (RQI) program.
Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (NCD 150.13)	No Medicare Advantage medical policy or vendor review (image-guided minimally invasive *cervical* or *thoracic* decompression is addressed in Policy No. M-SUR176)

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Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)	No Medicare Advantage medical policy or vendor review
Pharmacogenomic Testing for Warfarin Response (NCD 90.1)	Policy No. M-GT64, Genetic and Molecular Diagnostics – Next Generation Sequencing and Genetic Panel Testing
TENS for Chronic Low Back Pain (NCD 160.27)	No Medicare Advantage medical policy or vendor review
Transcatheter Aortic Valve Replacement (NCD 20.32)	Policy No. M-SUR221, Transcatheter Heart Valve Procedures
Transcatheter Mitral Valve Repair (NCD 20.33)	Policy No. M-SUR221, Transcatheter Heart Valve Procedures
Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (Decision Memo CAG-00313R2 and NCD 160.18)	Policy No. M-SUR74, Vagus Nerve Stimulation (VNS)