MN.005.D Experimental and Investigational Services, Investigational Device Exemption (IDE), and Coverage with Evidence Development (CED)

Original Implementation Date : 8/24/2016
Version [D] Date : 8/21/2024
Last Reviewed Date: August 2024

PRODUCT VARIATIONS

This policy applies to all lines of business unless noted below.

POLICY STATEMENT

General Criteria for Experimental/Investigational

A service or supply, including but not limited to, a drug, vaccine, treatment, device, or procedure is considered **experimental or investigational** if any of the following criteria are met:

- It cannot be lawfully marketed without the approval of the Food and Drug Administration (FDA) and final approval is not granted at the time of its use or proposed use. This may include drugs or devices that:
  - Have a current new drug or new device application on file with the FDA and approval is not yet granted.
  - Drugs granted orphan drug status that have not yet received approval by the FDA.
- The consensus opinion in the medical literature among experts indicates:
  - Usage is appropriate only within the context of a clinical trial.
  - Further research is needed to define safety, toxicity, effectiveness, and comparative effectiveness to standard of care treatments.
- Use of the requested service/item is dependent on a drug, device, treatment, or procedure that is investigational or experimental.

Determination of experimental and investigational status will consider:

- Guidelines from nationally recognized health care organizations.
- Peer-reviewed medical literature within published medical journals.
- Evidence based consensus statements.
- Local coverage practices.
- The member's unique medical circumstances as documented in the medical record.

POLICY GUIDELINES

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits, which may vary by product line. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the member's applicable benefit contract on the date the service was rendered. Services determined by us to be investigational or experimental, cosmetic, or not medically necessary are excluded from coverage for all lines of business.

- In all cases, the appropriate documentation supporting medical necessity must be kept on file and, upon request, presented to us.
- The definition of medical necessity may vary by product due to state and federal regulatory requirements.
- For PA Medicaid, routine care and services are covered even when included in a clinical trial.

Medicaid Guidelines

As per the State Contract, MCOs must follow the Department's Technology Assessment (TAG) process and determinations when new and existing services or items are reviewed and added to the MA Program.

The Pennsylvania Department of Human Services includes the Technology Assessment Group (TAG)

The TAG workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decision are made as to whether or not certain technologies will be covered and how they will be covered.

This includes:

- Devices
- Medical Procedures
- Pharmaceuticals

*Behavioral Health is carved out for Medicaid Plans

TAG receives requests for new and emerging technology from manufacturers, Managed Care Organizations, providers and through normal surveillance.

REQUEST PROCESS

Once the request is received; the request goes through the following processes:

1. **Policy/Regulation Review**: At this step, the TAG-BPBP lead looks at the technology from a regulatory point of view.
2. **Standard of Care Review**: At this step, the TAG-OMD lead performs literature searches, collateral surveys, and polling of the Managed Care Organizations. A summary of the findings are presented to the Medical Director in the Office of the Medical Director (TAG Member) for a clinical review of the findings to determine if the technology in question is the accepted standard of care within the community.
3. **Pricing Review:** Once a technology has passed the Policy/Regulation review and Standard of Care Review, the TAG-FFS/Pricing lead person evaluates the technology and assigns the proper payment mechanism.
4. **Preliminary Budget Review:** If the technology passes the Policy/Regulation Review, the Standard of Care Review, and the pricing review, the technology is referred to the BPBP budget area.

   Once a TAG recommendation has received final approval from the OMAP executive group, the action memo is placed on the web site under the area of Operations Memorandums. This information is available for view by all OMAP employees and the department's contracted Managed Care Organizations.

Clarification of the Medicare Variation for IDE and CED

1. Investigational Device Exemption (IDE)

Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met.[3]

Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines, prior to the submission of the first related claim, that the Medicare coverage IDE study criteria are met.[3]

Providers participating in and seeking Medicare reimbursement for items and services in Category A or B IDE study, prior to submitting claims, are responsible for checking the CMS coverage website to identify whether CMS (or its designated entity) has approved the study for purposes of Medicare coverage.

Effective January 1, 2015, the Medicare Advantage Organization (MAO) is responsible for payment of routine care items and services in CMS-approved Category A IDE studies.

We are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the Medicare administrative contractor (MAC) with jurisdiction over the Medicare Advantage (MA) plan's service area. We are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. We are also responsible for CMS-approved Category B devices. We do not approve Category A devices because they are statutorily excluded from coverage.[1]

A listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage site located at http://www.cms.hhs.gov/center/coverage.asp and published in the Federal Register.[1]

For billing requirements for items and services in FDA-approved Category A and B IDE studies, see Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 68.

2. Coverage in Evidence Development (CED)

In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. We are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold for that item or service has exceeded (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development web page at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. Billing instructions are issued for each NCD.[2]

We use InterQual as reliable, evidence-based clinical reference that promotes consistent clinical decisions for appropriate, medically necessary care, services, or items.

Upon request, Physicians can obtain a copy of the applicable InterQual criteria and/or policies associated with our determination.

CODING

Specific codes do not apply to this policy.

BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the Member's applicable benefit contract on the date the service was rendered. Services determined by the Plan to be investigational or experimental, cosmetic, or not medically necessary are excluded from coverage for all lines of business.

DESCRIPTION OF SERVICES

Experimental and investigational services (e.g., devices, drugs, procedures, supplies, technologies, treatments) are services whose safety or efficacy is not known or are services that are used in a way that departs from generally accepted standards of practice in the medical community.

DEFINITIONS

Nationally Recognized Drug Compendia: Refers to the drug compendia recognized by CMS.

Experimental Procedures and Items: Experimental procedures and items may include any procedure, study, test, drug, equipment, or facility still undergoing study and which is generally not accepted as standard therapy in the medical community where alternative therapy exists. Any interpretations for specific cases must rely on and be consistent with Medicare Rules, Statutes, Federal Regulations, CMS Program Manuals, and other publications by CMS that are in place (including all CMS National Coverage Decisions) at the time the services are provided and that apply to the specific procedure and item requested.

Category A (Experimental) Devices: Refers to a device for which "absolute risk" of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective; Category A devices are statutorily excluded from Medicare coverage. [3]

Category B- (Non-experimental/investigational) Device: Refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved) or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type. [3]

Routine Care Items and Services: Refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded and there is not a national non-coverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

Pennsylvania Department of Human Services Definition of Experimental Procedure: A procedure that deviates from customary standards of medical practice, is not routinely used in the medical or surgical treatment of a specific illness or condition or is not of proven medical value.[4]

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making.

Policy Bulletins are developed by us to assist in administering plan benefits and constitute neither offers of coverage nor medical advice.

This Policy Bulletin may be updated and therefore is subject to change.

Per DHS Medicaid and CHIP products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2024 Ad-hoc review: This policy has been updated with NCQA compliance guidelines	D	8/21/2024
2024 Annual review. No changes to this version.	C	11/1/2023
2023 Annual Review. The following statement was added to the "Guidelines" section: *For PA Medicaid, routine care and services are covered even when included in a clinical trial.*	C	11/1/2023
2022 Annual Review. No changes to this version	B	6/1/2018
2021 Annual Review. No changes to this version.	B	6/1/2018
2020 Annual Review. No changes to this version.	B	6/1/2018
2019 Annual Review. No changes to this version.	B	6/1/2018
2018 Annual Review. Language was added to the "Description of Services" section to define experimental and investigational services.	B	6/1/2018
This is a new policy.	A	8/24/2016

REFERENCES

1. Medicare Managed Care Manual, Chapter 4, Section 10.7.2 – Payment for Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.

2. Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved under Coverage with Evidence at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.

3. Medicare Benefit Policy Manual, Chapter 14, Section 20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf.

4. Definition of Experimental in the Pennsylvania Code 55 PA Code 1141.2