MN.004.C New Technology

Original Implementation Date : 9/1/2016

Version [C] Date: 6/3/2024

Last Reviewed Date: May 2024

PRODUCT VARIATIONS

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

POLICY STATEMENT

Requests for services/items will be reviewed for medical necessity in accordance with each individual product's definition of medical necessity. The definition of medical necessity may vary by product due to state and federal regulatory requirements.

To assess the medical necessity of new technology or new application of existing technology, we will utilize the following resources to make the most favorable decision for the Member taking into consideration safety, efficacy, and available alternative treatments. All things being equal, the most cost-effective service/item will be preferred.

- Agency for Healthcare Research and Quality (AHRQ).
- Blue Cross Blue Shield Center for Clinical Effectiveness Assessments.
- Federal Drug Administration (FDA) documents (package labels, FDA application documents, premarket approvals).
- Hayes, Inc. Clinical Assessments.
- Nationally recognized drug compendia.
- Other local insurers coverage practices.
- Published CMS Guidance Documents (Internet Only Manuals, National Coverage Determinations, Local Coverage Determinations, and Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) documents).
- UpToDate®.

POLICY GUIDELINES

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, decisions are made as to whether 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.

- In all cases, the appropriate documentation supporting medical necessity (such as member's medical records with member's diagnosis, comorbid conditions, unique member circumstances, treatment options and recommended course of treatment) must be kept on file and presented to us upon request.

- In addition, for new technology or new application of existing technology, documentation from peer reviewed medical literature, national compendia, national guidelines, or expert consensus documents, should be supplied by the requesting provider, supporting the treatment for the member's diagnosis.

- 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.

MEDICARE'S REASONABLE AND NECESSARY GUIDELINES[1]

Medicare describes Medically Necessary Health care as those services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease or its symptoms that meet accepted standards of medicine.

In the absence of a LCD (Local Coverage Determination), NCD (National Coverage Determination), or CMS Manual Instruction, Reasonable and Necessary guidelines still apply. Section 1862(a) (1) (A) of the SSA (Social Security Act) directs the following: "No payment may be made under Part A or Part B for any expenses incurred for items or services not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Note: Malformed is defined as (of a person or part of the body) abnormally formed; misshapen.

According to Medicare a "reasonable and necessary" service is:

- Appropriate, including the duration and frequency in terms of whether the service or item 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.
  - Furnished in a setting appropriate to the beneficiary's medical needs and condition.
  - Ordered and furnished by qualified personnel; and
- Not experimental or investigational; and
- Safe and effective.
  - One that meets, but does not exceed, the beneficiary's medical need.

For any service reported to Medicare, it is expected that the medical record documentation clearly demonstrates that the service meets all the above criteria. All documentation must be maintained in the patient's medical record and be available to the contractor upon request.

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT® is a registered trademark of the American Medical Association.

CPT/HCPCS Code	Description
N/A	Specific codes do not apply to this policy. Many, but not all new technology items are reported with either non-specific (unlisted, not otherwise classified, or not otherwise specified) procedure codes or Category III codes.

ICD-10 Codes	Description
N/A	

The following quotes the American Medical Association (AMA) regarding Category III codes.

Category III codes represent temporary codes for new and emerging technologies. They have been created to allow for data collection and utilization tracking for new procedures or services. Category III codes are different from Category I CPT codes in that they identify services that may not be

performed by many health care professionals across the country, do not have FDA approval, nor does the service/procedure have proven clinical efficacy. To be eligible for a Category III code, the procedure or service must be involved in ongoing or planned research. The rationale behind these codes is to help researchers track emerging technology and services to substantiate widespread usage and clinical efficacy. In the past, researchers have been hindered by the length and requirements of the current CPT approval process.

The Category III codes are five characters long, with four digits followed by the letter 'T' in the last field (e.g. 0002T). The codes are intended to be temporary and will be retired if the procedure or service is not accepted as a Category I code within five years. In some instances, Category III codes may replace temporary local codes (HCPCS Level III) assigned by carriers and intermediaries to describe new procedures or services. If a Category III code is available, it must be used instead of the unlisted Category I code. The use of the unlisted code does not offer the opportunity for collection of specific data.

Early release of these codes is possible because payment for these services is based on the policies of payers and not on a yearly fee schedule. CMS began recognizing several of the Category III codes as of Jan. 1, 2002, and has designated certain codes as covered.

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

This policy describes considerations in determining medical necessity when a specific medical policy on the service/item does not exist. Most frequently, this is related to new technology or new application of existing technology.

CLINICAL EVIDENCE

Detailed discussion of clinical evidence is not pertinent to this document because of its broad application.

DEFINITIONS

CHIP: The Medicaid –CHIP program states the determination of whether a service is medically necessary for an individual child must be made on a case-by-case basis, taking into account the particular needs of the child. The state (or the managed care entity as delegated by the state) should consider the child's long-term needs, not just what is required to address the immediate situation. The state should also consider all aspects of a child's needs, including nutritional, social development, and mental health and substance use disorders. States are permitted (but not required) to set parameters that apply to the determination of medical necessity in individual cases, but those parameters may not contradict or be more restrictive than the federal statutory requirement, taking into account the particular needs of the child.

MEDICARE: Services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, or otherwise medically necessary under 42 U.S.C. § 1395y.

1. Services that are provided in accordance with regulations at 130 CMR 450.204;
2. Services that are reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the enrollee that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a disability, or result in illness or infirmity.
3. Services for which there is no other medical service or site of service, comparable in effect, available, and suitable for the enrollee requesting the service, that is more conservative or less costly; and that are of a quality that meets professionally recognized standards of health care and must be substantiated by records including evidence of such medical necessity and quality.

MEDICAID (HEALTHCHOICES): A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

1. The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability.
2. The service or benefit will, or is reasonably expected to, reduce, or ameliorate the physical, mental, or developmental effects of an illness, condition, injury or disability.
3. The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

NCQA: Medically Necessary: The determination that an intervention recommended by a treating practitioner is (1) the most appropriate available supply or level of service for the individual in question, considering potential benefits and harms to the individual, and (2) known to be effective in improving health outcomes. For interventions not yet in widespread use, an MCO determines effectiveness based on scientific evidence. For established interventions, an MCO determines

effectiveness based on scientific evidence, professional standards, and expert opinion.

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.	C	6/3/2024
2024 annual review. No changes to this version.	B	1/8/2021
2023 annual review. No changes to this version.	B	1/8/2021
2022 annual policy review. No changes to this version.	B	1/8/2021
2021 annual policy review. New language added for clarity.	B	1/8/2021
This policy is being reissued as part of our policy review process. Policy language remains the same. References were updated in 2019.	A	9/1/2016
This is a new policy bulletin.	A	9/1/2016

REFERENCES

1. Novitas Solutions Inc., Reasonable and Necessary Guidelines. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00099545
2. Social Security Act. Section 1812. https://www.ssa.gov/OP_Home/ssact/title18/1812.htm
3. Social Security Act 1862. https://www.ssa.gov/OP_Home/ssact/title18/1862.htm
4. Health Choices Agreement, Section II, Definitions, Medically Necessary, p 25