Medical Technology Assessment
Clinical Coverage Criteria

Description

Services covered by Fallon Health must meet medical necessity requirements as set forth in plan documents and applicable program regulations.

Fallon Health applies the following Technology Assessment Criteria when assessing whether a service is considered medically necessary. In order for a service to be considered medically necessary all five criteria must be met. If any one or more of the following criteria are not met, the technology will be considered experimental/investigational (noncovered):

1. The technology must have final approval from the appropriate government regulatory body. This applies to drugs, devices, biologics, and treatments or procedures that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology. The technology must have approval for the specific indication under evaluation by Fallon.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the study as well as the results are considered in evaluating the evidence. Opinions by national medical associations, consensus panels, or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence.
3. The evidence must show that the technology improves health outcomes. Specifically, the technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
4. The technology must be at least as effective as the established technology. In addition, the technology must be as cost-effective as any established alternatives that achieve a similar health outcome.
5. The outcome must be attainable outside investigational settings.

Definitions

Experimental/investigational

In cases where a drug, device, treatment or procedure does not meet one or more of Technology Assessment Criteria, the drug, device, treatment or procedure will be considered experimental/investigational. No coverage is provided for drugs, devices, treatments or procedures that Fallon Health considers experimental/investigational. If the Fallon Health determines that a technology is experimental/investigational, Fallon Health will not pay for any services, including but not limited to, drugs, devices, treatments, procedures, or facility and professional charges related to that technology.

If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. The presence of a payment amount on the Medicare Physician Fee Schedule does not imply that CMS has determined that the service may be covered by Medicare (Medicare Claims Processing Manual, Chapter 23, Section 30 A.).

Medically necessary/reasonable and necessary

Community Care

Medically necessary (service): A service or supply that is consistent with generally accepted principles of professional medical practice, as determined by whether or not:

(1) the service is the most appropriate available supply or level of service for the member in question, considering potential benefits and harms to the individual;
(2) is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or
(3) for services and interventions not in widespread use, is based on scientific evidence (211 CMR 52.00 Managed Care Consumer Protections and Accreditation of Carriers).

For these purposes, generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment (Kaminski, 2007).

Medicare Advantage and NaviCare

In general, Medicare coverage and payment is contingent upon a determination that:

- A service is in a covered benefit category;
- A service is not specifically excluded from Medicare coverage by the Social Security Act; and
- The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service (Medicare Managed Care Manual, Chapter 4, Section 10.2).

Section 1862(a) (1) (A) of the 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."

An item or service is "reasonable and necessary" under § 1862(a)(1)(A) of the Social Security Act when the service is:

- Safe and effective;
- Not experimental or investigational and
- Appropriate for the patient, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative

(Medicare Program Integrity Manual, Chapter 13, Section 13.5.4).

Fallon Health's Medicare Advantage and NaviCare Evidence of Coverage defines medically necessary as the services, supplies or drugs that are needed for the prevention, diagnosis or treatment of the member's medical condition and meet generally accepted standards of medical practice.

For these purposes, generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment (Kaminski, 2007).

MassHealth

Medically necessary or medical necessity – in accordance with MassHealth Administrative and Billing Regulations, medically necessary services are those services:

(1) which are reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member 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; and

(2) 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. Medically Necessary services must be 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 (130 CMR 450.204).

Policy

This Policy applies to the following Fallon Health products:

☒ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

☒ MassHealth ACO

☒ NaviCare HMO SNP, NaviCare SCO

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed

care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

For services requiring prior authorization for which there are no clinical coverage criteria, a Fallon Health Medical Director will conduct a medical necessity review on an individual case-by-case basis. When assessing whether a service is considered medically necessary, the Medical Director will apply Fallon Health's Technology Assessment Criteria. These Technology Assessment Criteria are included in the Description section above.

The requesting provider should submit medical records relevant to the service being request. If the medical records do not provide sufficiently detailed information to understand the member's current clinical status, then medical necessity for the request cannot be established and the request cannot be approved. Specific elements of a member's medical records commonly required to establish medical necessity include, but are not limited to:

- Recent clinical evaluation which includes a detailed history and physical examination;
- Laboratory studies;
- Imaging studies;
- Pathology reports;
- Procedure reports; and
- Reports from other providers participating in treatment of the relevant condition.

The requesting provider should also submit peer-reviewed published literature that permits conclusions about the effect of the technology on the health outcome of interest.

References

1. Kaminski, JL. Defining Medical Necessity. February 23, 2007. Available at: https://www.cga.ct.gov/hs/tfs/20090701_Medical%20Inefficiency%20Committee/20100107/Defining%20Medical%20Necessity.pdf. Accessed 10/26/2021.

Policy history

Origination date:	06/01/2022
Approval(s):	Technology Assessment Committee 10/26/2021 (policy origination); 12/12/2023 (updated definition of experimental or investigational to include Medicare Claims Processing Manual reference; updated Policy section to include regulatory requirements/business rules for Medicare and MassHealth products).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.