

Medical Policy Medically Necessary Services

Policy Number: 086

Overview

This document describes how Mass General Brigham Health Plan determines medical necessity.

Coverage Guidelines

Mass General Brigham Health Plan covers services listed in each plan's Covered Services List. Most services are covered only when medically necessary, or when required by regulation, including emergency services, medical services, transportation services, vision services, pharmacy services, home health services, behavioral health services, and some other services. Selected benefits, including wellness services and certain coaching services, are covered without regard to medical necessity as per the member's covered service list.

Except for services that must be covered by regulation or that are covered without regard to medical necessity, Mass General Brigham Health Plan covers services, procedures, devices, biologic products, and drugs (collectively "treatment") when there is sufficient scientific evidence to support their use. The policy "Experimental and Investigational" describes how Mass General Brigham Health Plan considers the hierarchy of evidence that is sufficient to support treatment. No benefits or reimbursement are provided for health care charges that are received for, or related to, care that Mass General Brigham Health Plan considers experimental and investigational services or procedures.

Determination of medical necessity: Medicare Advantage

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. The medical necessity requirements outlined in 130 CMR 450.204 establish that services must be reasonably calculated to prevent, diagnose, or alleviate conditions while adhering to accepted medical standards in appropriate settings. National Coverage Determinations (NCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for these determinations. Mass General Brigham Health Plan does not cover services listed in section 1862 of the Social Security Act (42 U.S.C. 1395y), "Exclusions from coverage and Medicare as a secondary payer". When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan medical policies are used for medical necessity determinations, including InterQual criteria (Change Healthcare) and other vendor policies for services such as sleep apnea supplies and genetic testing.

If a service is requested that requires medical necessity determination but no medical necessity criteria are available from CMS, InterQual or Mass General Brigham Health Plan medical policies, a medical director will review the request. The Medical director may also utilize external specialists to review requests.

In these circumstances, the medical director and/or external specialist will determine whether scientific evidence (using the hierarchy of reliable evidence described in the policy "Experimental and Investigational") proves that the treatment is both safe and effective for the particular clinical situation, as defined in the Medicare Program Integrity Manual at 13.5.4, including all of the following:

 Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and



- 2) Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is
 - a) 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;
 - b) Furnished in a setting appropriate to the patient's medical needs and condition;
 - c) Ordered and furnished by qualified personnel;
 - d) One that meets, but does not exceed, the patient's medical need; and
 - e) At least as beneficial as an existing and available medically appropriate alternative.

If the available high-quality evidence is insufficient to draw any of these conclusions, the treatment is not covered for that particular clinical situation.

Determination of medical necessity: Mass General Brigham ACO, Commercial Plans, and Qualified Health Plans

For services on the medical benefit, Mass General Brigham Health Plan utilizes InterQual criteria (Change Healthcare), customized criteria included within InterQual, and Mass General Brigham Health Plan medical policies to determine medical necessity. For drugs on the medical benefit of commercial plans and qualified health plans, Mass General Brigham Health Plan utilizes Mass General Brigham Health Plan medical policies and Mass General Brigham Health Plan medical specialty drug policies to determine medical necessity. For drugs on the medical benefit provided to ACO members, including all services on the MassHealth Drug List, Mass General Brigham Health Plan utilizes Mass General Brigham Health Plan medical specialty drug policies and MassHealth criteria to determine medical necessity.

When developing customized criteria and medical policies, Mass General Brigham Health Plan considers evidence as described in the policy "Experimental and Investigational." Criteria and medical policies are reviewed and updated at least annually.

If a service is requested that requires medical necessity determination but no medical necessity criteria are available in InterQual or in Mass General Brigham Health Plan medical policies, a medical director will review the request. The Medical director may also utilize external specialists to review requests.

In these circumstances, the medical director and/or external specialist will determine whether scientific evidence (using the hierarchy of reliable evidence described in the policy "Experimental and Investigational") proves that the treatment is both safe and effective for the particular clinical situation, including all of the following:

- 1) Beneficial effects on health outcomes must outweigh any harmful effects
- 2) Health outcomes are superior or comparable to established alternatives
- 3) Improvement in health outcomes have the potential to be realized outside the investigational setting
- 4) It is cost effective compared with an alternative treatment or series of treatments that is likely to produce similar outcomes
- 5) It is clinically appropriate in terms of type, frequency, extent, site, and duration, for the member's illness, injury, or disease
- 6) It is provided in accordance with generally accepted standards of medical practice
- 7) It is not primarily for the convenience of the member, the member's family, or the provider



If the available high-quality evidence is insufficient to draw any of these conclusions, the treatment is not covered for that particular clinical situation.

Determination of medical necessity: OneCare and Senior Care Options (SCO)

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. The medical necessity requirements outlined in 130 CMR 450.204 establish that services must be reasonably calculated to prevent, diagnose, or alleviate conditions while adhering to accepted medical standards in appropriate settings. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for these determinations. Mass General Brigham Health Plan does not cover services listed in section 1862 of the Social Security Act (42 U.S.C. 1395y), "Exclusions from coverage and Medicare as a secondary payer". When there is no guidance from CMS, or the guidance is very restrictive, for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or MassHealth, or the guidance is very restrictive, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations, including InterQual criteria (Change Healthcare) and other vendor policies for services such as sleep apnea supplies and genetic testing.

If a service is requested that requires medical necessity determination but no medical necessity criteria are available from CMS, MassHealth, InterQual, or Mass General Brigham Health Plan medical policies, a medical director will review the request. The Medical director may also utilize external specialists to review requests. In these circumstances, the medical director and/or external specialist will follow the guidelines described in the Medicare Variation above.

Hierarchy of criteria

Medical necessity is determined by criteria at the top of the table. If there are no such criteria for the requested service, or if the criteria are insufficiently specific to determine medical necessity for the requested service, then medical necessity is determined by criteria on the next line in the table.

Commercial	Medicare Advantage	Mass General Brigham	OneCare and Senior Care
		ACO	Options (SCO)
	NCDs, LCDs (when		NCDs, LCDs (when
	applicable to the service		applicable to the service
	provider), Medicare		provider), Medicare
	Benefit Policy Manual,		Benefit Policy Manual,
	and CMS regulations		and CMS regulations
		MassHealth Drug List	MassHealth Drug List
Mass General Brigham	Mass General Brigham	Mass General Brigham	Mass General Brigham
Health Plan medical	Health Plan medical	Health Plan medical	Health Plan medical
policies or medical	policies or medical	policies or medical	policies or medical
policies from contracted	policies from contracted	policies from contracted	policies from contracted
external vendors	external vendors	external vendors	external vendors
InterQual®	InterQual®	InterQual®	InterQual®
Literature review for	Literature review for	Literature review for	Literature review for
safety and efficacy	safety and efficacy	safety and efficacy	safety and efficacy

Clinical Trials

Consistent with state and federal laws, Mass General Brigham Health Plan coverage and medical necessity determinations are made without regard to whether a member is enrolled in a clinical trial, and Mass General Brigham Health Plan medical necessity criteria apply regardless of whether or not the treatment requested is part of a trial protocol. Mass General Brigham Health Plan does not limit participation in trials or deny care on account of trial participation.



Effective Dates

January 2026: Ad hoc review. Added determination of medical necessity section and updated hierarchy of criteria for OneCare and SCO members.

June 2025: Ad hoc review. Updated Determination of medical necessity: Medicare Advantage section. Added Hierarchy of criteria section.

May 2025: Annual review. Removed acronym for Mass General Brigham Health Plan. Added branding. January 2025: Effective Date.

References

130 CMR 450.204: Medical Necessity

42 CFR 422.101: Requirements relating to basic benefits

<u>Medicare Program Integrity Manual: Chapter 13 – Local Coverage Determinations</u>

