

Clinical Trials

Policy

Mass General Brigham Health Plan reimburses routine costs for services rendered during qualified clinical trials for cancer and other life-threatening conditions, in accordance with state and federal mandates for coverage, as described below.

Reimbursement

Providers are reimbursed according to the plan's network provider reimbursement or contracted rates. Claims are subject to payment edits that are updated at regular intervals.

Mass General Brigham Health Plan's reimbursement is based on the line of business, unless otherwise specified within the medical policies; please follow the guidelines based on membership type. Covered services are defined by the member's benefit plan. The manner in which covered services are reimbursed is determined by the Mass General Brigham Health Plan payment policy and by the provider's agreement with Mass General Brigham Health Plan. Member liability amounts may include but are not limited to: copayments; deductible(s); and/or co-insurance; and will be applied dependent upon the member's benefit plan.

Various services and procedures require referral and/or prior authorization. Referral and prior authorization requirements can be located [here](#).

Please reference procedure codes from the current CPT, HCPCS Level II, and ICD-10-CM manuals, as recommended by the American Medical Association (AMA), the Centers for Medicare & Medicaid Services (CMS), and the American Hospital Association (AHA). CMS and the AMA revise HIPAA medical codes on a pre-determined basis, including changes to CPT, HCPCS, Revenue and ICD-10 codes and definitions.

Please refer to the CMS or CPT guidelines for requisite modifier usage when reporting services. The absence or presence of a modifier may result in differential claim payment or denial.

Mass General Brigham Health Plan reviews claims to determine eligibility for payment. Services considered incidental, mutually exclusive, integral to the primary service rendered, or part of a global

Provider Payment Guidelines

allowance, are not eligible for separate reimbursement. Please refer to [General Coding and Billing Provider Payment Guidelines](#) for more information.

All claims are subject to audit services and medical records may be requested from the provider.

Mass General Brigham Health Plan's reimbursement is based on line of business. Unless otherwise specified within the medical policies, please follow the guidelines based on membership type:

MassHealth or MGB ACO: Please refer to the MassHealth Physician Manual for a list of payable services.

- *Commercial: Entire policy applies.*
- *Medicare Advantage: Entire policy applies.*

Background

A clinical trial is a prospective biomedical or health-related research study of human subjects designed to test new methods of screening, prevention, diagnosis, or treatment of a disease. These studies are conducted by physicians and other health professionals in a controlled environment to help determine the safety and efficacy of biological products, devices, drugs, medical treatments, procedures, or therapies to improve health.

Clinical trials are conducted in phases that help answer different scientific questions.

- **Phase I trials** test a new drug or treatment for the first time to evaluate safety in a very small group of people.
- **Phase II trials** study an experimental drug or treatment to determine its effectiveness and further evaluate safety in a large group of people.
- **Phase III trials** confirm the drug or treatment effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely in larger groups of people.
- **Phase IV trials** are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Effective January 1, 2014, in accordance with Section 2709 of the Patient Protection and Affordable Care Act (ACA), the plan will provide coverage for 'routine costs' when a member is a 'qualified individual' enrolled in an 'approved clinical trial':

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- In general, routine patient costs for a qualified individual participating in a qualified clinical trial include all items and services consistent with coverage that a member would be eligible for if not enrolled in a clinical trial.
- A 'qualified individual' is someone who is eligible to participate in an 'approved clinical trial' according to the trial protocol and either the individual's doctor has concluded that participation is appropriate, or the participant provides medical and scientific information establishing that their participation is appropriate.
- An 'approved clinical trial' is a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition. A life-threatening disease or condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

There are several types of clinical trials that are eligible for coverage of routine costs:

1. Trials approved or funded by the:
 - National Institutes of Health (NIH)
 - Centers for Disease Control and Prevention (CDC)
 - Agency for Health Care Research & Quality (AHRQ)
 - Centers for Medicare & Medicaid Services (CMS)
2. Trials approved or funded by the below entities when the trial has been reviewed and approved through a system or peer review that the Secretary of Health and Human Services determines is comparable to the peer review system used by the NIH and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:
 - Department of Defense (DoD)
 - Department of Veteran Affairs (VA)
 - Department of Energy (DOE)
3. Trials approved or funded by centers or cooperative groups of the NIH, CDC, AHRQ, CMS, DOD, and/or VA.
4. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration.
5. Phase II, III, or IV clinical trials only, a trial is approved by a qualified institutional review board (IRB).

Policy and Coverage Criteria

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Mass General Brigham Health Plan will reimburse routine patient costs when medically necessary and consistent with the member's benefit if the member was not participating in a clinical trial.

Routine costs include:

- Items or services typically provided absent a clinical trial (e.g., conventional care)
- Items or services solely for the provision of the investigational item or service that are not statutorily excluded from coverage (e.g., cosmetic surgery)
- Clinical monitoring for the effects of the investigational item or service
- Prevention and management of complications
- Items or services for reasonable and necessary care that may occur from the provision of an investigational service or item
- In addition to the above, pursuant to [MGL 175 Section 110L\(a\)\(1\)](#), the actual costs of the device or drug when it is not paid for by the manufacturer, distributor, or provider of the drug/device

Note: Mass General Brigham Health Plan supports inclusive enrollment of diverse populations in clinical trials.

Exclusions

Routine costs do not include ANY of the following:

- The investigational item, device, or service itself when paid for by the manufacturer, distributor, or provider of the drug/device [{MGL 175 Section 110L\(a\)\(1\)}](#)
- Items and services that are provided solely to satisfy data collection, analysis needs and that are not used in the direct clinical management of the member
- Any item, service, or cost that is reimbursed or provided by the sponsors of the clinical trial
- Non-health care services that a member may receive as a result of being enrolled in the qualified clinical trial
- Services or costs that are not covered under the member's plan

Coding

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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Table 1 contains modifiers which are item/service specific and constitute medically necessary routine patient care or treatment of complications arising from a member's participation in a qualified clinical trial.

Note: Use for professional and facility outpatient claims.

Table 1: Modifiers

Modifiers	Description
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Table 2 contains the diagnosis code that must be reported with the primary ICD-10-CM diagnosis code consistent with the clinical trial indication.

Table 2: ICD-10-CM Code(s)

ICD-10-CM Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Billing Guidelines

Member's medical records must document that services are medically necessary for the care provided. Mass General Brigham Health Plan maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to Mass General Brigham Health Plan upon request. Failure to produce the requested information may result in denial or retraction of payment.

Related Policies

[General Coding and Billing](#)

References

Provider Payment Guidelines

[CMS Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, Section 68 & 69](#)

[CMS Medicare Clinical Trial Policies](#)

[CMS Local Coverage Article, Clinical Trials – Medical Policy Article \(A52840\)](#)

[CMS National Coverage Determination \(NCD\) - Routine Costs in Clinical Trials \(310.1\)](#)

[Massachusetts General Law \(M.G.L.\), Chapter 175, Section 100L Clinical Trials; definitions; coverage](#)

[The Patient Protection and Affordable Care Act \(PPACA\), Sec. 2709. March 23, 2010. Affordable Care Act, Health Care Law](#)

[U.S. National Library of Medicine, National Institutes of Health, Clinical trial phases, Phases of Clinical Trials](#)

Publication History

Topic: Inpatient Rehabilitation/Long-Term Acute Care	Owner: Network Management
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January 1, 2023

Original documentation

This document is designed for informational purposes only. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization/notification and utilization management guidelines when applicable, adherence to plan policies and procedures, claims editing logic, and provider contractual agreement. In the event of a conflict between this payment guideline and the provider's agreement, the terms and conditions of the provider's agreement shall prevail. Payment policies are intended to assist providers in obtaining Mass General Brigham Health Plan 's payment information. Payment policy determines the rationale by which a submitted claim for service is processed and paid. Payment policy formulation takes into consideration a variety of factors including: the terms of the participating providers 'contract(s); scope of benefits included in a given member's benefit plan; clinical rationale, industry-standard procedure code edits, and industry-standard coding conventions.

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc., and Mass General Brigham Health Plan Insurance Company.