Clinical Review Criteria Related to Clinical Trials

I. Criteria for Approval

In accordance with Section 2709 of the Patient Protection and Affordable Care Act (ACA), Minuteman Health, Inc. (MHI) will provide coverage for routine costs when a Member is a qualified individual’ enrolled in an ‘approved clinical trial:

Clinical Trials are covered when the following criteria are met:

A. A qualified individual and approved clinical trial must follow definitions set forth in Massachusetts General Laws Chapter 175 Section 110L (if a Massachusetts member) or New Hampshire 415:18-l Coverage Required for Qualified Clinical Trials (if a New Hampshire member), and be consistent with Centers for Medicare & Medicaid Services (CMS.gov) and Patient Protection and Affordable Care Act (PPACA) requirements regardless of the members’ state.

1. 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 MHI member would be eligible for if not enrolled in a clinical trial. For Massachusetts members only, routine costs also include the actual costs of the device or drug when it is not paid for by the manufacturer, distributor, or provider of the drug/device.

2. 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.

3. 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

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1 MGL 175 Section 110L(a)(1),
B. There are several types of clinical trials that are eligible for coverage of routine costs:

1. Trials approved or funded by the:
   a. National Institutes of Health (NIH)
   b. Centers for Disease Control and Prevention (CDC)
   c. Agency for Health Care Research & Quality (AHRQ)
   d. 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:
   a. Department of Defense (DoD)
   b. Department of Veteran Affairs (VA)
   c. 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. For Massachusetts products under MGL Ch. 175 Section 110L(c) and (d), with respect to Phase II, III, or IV clinical trials only, a trial is approved by a qualified institutional review board (IRB) as defined in the statute.

6. For New Hampshire products, a trial is approved by an institutional review board in New Hampshire that has a multiple assurance contract approved by the Office of Protection from Research Risks of the NIH.

C. The trial must not be designed to test toxicity or disease pathophysiology. It must have therapeutic intent.

D. The referring health care professional is a participating provider and has concluded that the individual’s participation in such trial would be appropriate; or the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate.
I. Required Documentation

A. Copy of the study protocol including the documented therapeutic intent.

B. Detailed outline of what is covered and provided by the trial, and what services are requested for coverage of the health insurance plan.

C. Documentation of informed consent for participation in the clinical trial in a manner consistent with current legal and ethical standards.

D. Limitations

1. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials.

2. Routine costs do not include for Massachusetts members: the investigational item, device, or service itself when paid for by the manufacturer, distributor, or provider of the drug/device. ²

3. Routine costs do not include for New Hampshire products: The cost of an investigational new drug or device that is not approved for market for any indication by the FDA. ³

Please note:
There is coverage for costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials. There is also coverage for costs related to routine items and services furnished in connection with participation in the trial. (CMS.gov)

II. What is Not Covered

A. The health insurance plan does not cover experimental or investigational treatments, drugs, or procedures.

B. An investigational drug or device paid for by the manufacturer, distributor, or provider of the drug or device.

² MGL 175 Section 110L(a)(1)
³ NH RSA 415:18-I Section I (h) (1)
C. Trials designed to exclusively test toxicity or disease pathophysiology. It must have therapeutic intent.

D. Trials on healthy volunteers.

E. Members who are not clinically eligible or qualified for participation in the clinical trial.

F. Members who have not provided informed consent for trial participation.

G. Non-healthcare services that a Member may be required to receive as a result of being enrolled in the clinical trial.

H. Costs of services which are provided primarily to meet the needs of the trial, including, but not limited to: research, data collection, and analysis not used in the direct clinical management of the member (e.g., monthly CT scans for a condition usually requiring only a single scan), tests.

I. Services or items that are specifically excluded in member’s Explanation of Coverage.

J. Services or items that would not be covered if a member was not enrolled in a clinical trial.

III. CPT/ICD-10/HCPCS Codes

Applicable Coding: Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

**CPT Codes**

Z00.6 Encounter for examination for normal comparison and control in clinical research program

**HCPC Codes Related to Clinical Trial**

G0293 Non-covered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day

G0294 Non-covered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day
S9988 Services provided as part of Phase I trial
S9990 Services provided as part of a phase II clinical trial
S9991 Services provided as a part of Phase III clinical trial

Modifier Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study

IV. References

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

NIH Clinical Research Trials and You, July 2, 2013
https://www.nih.gov/health-information/nih-clinical-research-trials-you
(Last Accessed 7/1/16, 3/16/17)

Clinical Trials.gov - A Registry of Clinical Trials
https://clinicaltrials.gov/
(Last Accessed 7/1/16, 3/16/17)

Commonwealth of Massachusetts, House Bill 4376 (Chapt. 257)
An Act Providing for Insurance Coverage of Certain Clinical Trials
(Last Accessed 7/1/16, 3/16/17)

CMS.gov, Centers for Medicare & Medicaid Services, The Center for Consumer Information & Insurance Oversight, Coverage for Individuals Participating in Approved Clinical Trials.
https://www.cms.gov/CCIIO/Resources/FAQs/aca_implementation_faqs15.html
(Last Accessed 7/1/16, 3/16/17)

New Hampshire RSA § 415:18-I: Coverage Required for Qualified Clinical Trials.
(last accessed 10/28/2016)
The Patient Protection and Affordable Care Act (PPAC) Section 2709, March 23, 2010
(Last Accessed 7/1/16, 3/16/17)

V. Summary of Changes

06/29/2017
• Added Disclaimer, updated references and last accessed dates

VI. Review Dates

HNE Review Dates: 12/10/13, 12/9/14, 9/8/15, 9/13/16, 6/13/2017
MHI Review Dates: 11/1/2014, 10/7/2015, 10/20/2016, 06/29/2017
Medical Guideline Disclaimer
The treating physician or primary care provider must submit to Minuteman the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Minuteman will not be able to properly review the request for prior authorization. The clinical review criteria expressed herein reflects how Minuteman determines whether certain services or supplies are medically necessary. Minuteman established the clinical review criteria based upon a review of currently available clinical information (including, without limitation clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Minuteman expressly reserves the right to revise these criteria as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by Minuteman. If there is a discrepancy between this policy and a member’s benefit program, the benefit program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the federal government or the Centers for Medicare & Medicaid Services (CMS). Minuteman has adopted the herein policy in providing management, administrative and other services to its members.