Clinical Review Criteria Related to Clinical Trials

I. Criteria for Approval

A. Clinical Trials are covered when the following criteria are met:

1. The trial must meet the definition of a "qualified clinical" trial as contained in Massachusetts General Laws Chapter 175: Section 110L., and be consistent with Centers for Medicare & Medicaid Services (CMS.gov) and Patient Protection and Affordable Care Act (PPACA) requirements.

2. The trial is preauthorized and reviewed by the Health Services Utilization Management Department.

3. The clinical trial must have a written protocol that has been peer reviewed and is approved by one of the United States National Institutes of Health, or a qualified nongovernmental research entity identified in guidelines issued by the National Institutes of Health.

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

5. 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. CMS.gov)

II. 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.

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)

III. 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.

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.*

ICD 10 Code - 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

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 8/03/15, 7/1/16)

Clinical Trials.gov - A Registry of Clinical Trials
https://clinicaltrials.gov/
(Last Accessed 8/03/15, 7/1/16)

Commonwealth of Massachusetts, House Bill 4376 (Chapt. 257)
An Act Providing for Insurance Coverage of Certain Clinical Trials
https://malegislature.gov/Laws/SessionLaws/Acts/2002/Chapter257
(Last Accessed 8/03/15, 7/1/16)

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/FAct-Sheets-and-FAQs/aca_implementation_faqs15.html
(Last Accessed 8/03/15, 7/1/16)

The Patient Protection and Affordable Care Act (PPAC) Section 2709, March 23, 2010
https://www.dpc.senate.gov/healthreformbill/healthbill53.pdf
(Last accessed 7/1/16)