Subject: Clinical Trials: Routine Costs

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’:

- 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:**
The Plan will cover 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
- For Massachusetts products only, 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:** Point32Health supports inclusive enrollment of diverse populations in clinical trials.

**Exclusions:**
Routine costs do not include ANY of the following:
- For Massachusetts products: 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)}
- For Rhode Island products: the investigational item, device, or service is not covered regardless of manufacturer, distributor, or provider of the drug/device payment or nonpayment
- 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 Evidence of Coverage (EOC)

**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.

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>
<thead>
<tr>
<th>Modifier Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q1</td>
<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study</td>
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<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study</td>
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Table 2 contains the diagnosis code that must be reported with the primary ICD-10-CM diagnosis code consistent with the clinical trial indication.
Note: Use for professional, facility outpatient, and/or facility inpatient claims.

Table 2: ICD-10 Code(s)

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
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Billing Guidelines:
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care 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 HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:
3. Massachusetts General Law (M.G.L), Chapter 175: Section 100L Clinical Trials; definitions; coverage. Accessed at: mass.gov

Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>4/22</td>
<td>New policy for integration purposes with Tufts Health Plan (THP)</td>
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Approved by Medical Policy Committee: 4/20/22
Approved by Clinical Policy Operational Committee: 5/22
Policy Effective Date: 6/1/22
Initiated: 4/22