Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD, and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

**POLICY:**


For Priority Partners MCO see COMAR 10.09.67.26-1: Clinical Trial Items and Services – Coverage for Routine Costs.

For Advantage MD, see Medicare Coverage Database: National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

I. **ALL** requests for coverage must be reviewed by a Medical Director for determination.

II. JHHC considers the following member costs not medically necessary:
   A. The cost of an investigational drug or device*;
   B. The cost of non-health care services that a patient may be required to receive as a result of the treatment being provided for purposes of the clinical trial (including travel, lodging and meals);
   C. Costs associated with managing the research associated with the clinical trial (protocol-induced costs), **OR**;
   D. Costs that would not be covered under the member’s benefits for non-investigational treatments.

III. When benefits are provided under the members contract, JHHC considers member costs* medically necessary when **ALL** of the following requirements and criteria are met:
A. To the extent that other non-investigational treatments require pre-notification or pre-authorization, the member or treating physician must provide pre-notification of participation in clinical trials, AND;

B. Treatment is being provided for:
   1. A life threatening condition, OR;
   2. Prevention, early detection, and treatment studies on cancer, AND;

C. One of the following:
   1. The treatment is being provided or the studies are being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer, OR;
   2. The treatment is being provided in a phase II, phase III, or phase IV clinical trial for any other life-threatening condition, AND;

D. The treatment must be provided in a clinical trial approved by:
   1. One of the National Institutes of Health (NIH);
   2. An NIH cooperative group or NIH center (including the National Cancer Institute Clinical Cooperative Group, The National Cancer Institute Community Oncology Program, The AIDS Clinical Trials Group, and the Community Programs for Clinical Research in AIDS),
   3. The FDA in the form of an investigational new drug application;
   4. An Institutional Review Board (IRB) of an institution in the state which has a multiple project assurance contract approved by the office of protection from research risks of the National Institutes of Health.
   5. The Centers for Disease Control and Prevention
   8. The Department of Defense (DOD) or Department of Veterans Affairs (VA), OR;
   9. As a clinical trial with deemed status through an exemption from having an IND under 21 CFR §312.2(b)(1), AND;

E. The faculty and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise, AND;

F. There is no clearly superior, non-investigational treatment alternative, AND;

G. The available pre-clinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative.

IV. Costs incurred for drugs and devices that have been approved for sale by the Food and Drug Administration (FDA) whether or not the FDA has approved the drug or device for use in treating the member’s particular condition, may be covered, to the extent that the drugs or devices are not paid for by the manufacturer, distributor, or provider of that drug or device.
APPENDIX:

Definition of Life-Threatening is taken from the document, Guidance for Industry, Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) March 2002: The term life-threatening is defined as

1. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted, AND;
2. Diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival (21 CFR 312.81(a)).

*This Clinical Trials policy provides guidance for determining coverage for member costs incurred as a result of treatment being provided or studies being conducted under experimental protocols. Member costs for the purposes of this policy are defined as the costs of medically necessary health services that are incurred as a result of the treatment being provided to the member for purposes of a clinical trial, such as:

1. The cost of all medically necessary items and services that are otherwise available to the member such as hospital services, physician services, or diagnostic tests, AND;
2. The cost of medically necessary items or services required solely for the provision of the following: (a) Administration of trial chemotherapeutic or other agents; (b) The clinically appropriate monitoring of the effects of the item, treatment or service; or (c) The prevention, diagnosis, and treatment of complications.

For USFHP ONLY:

According to the TRICARE Operations Manual 6010.51-M, AUGUST 1, 2002; Chapter 20, Section 2: Department of Defense Cancer Prevention and Treatment Clinical Trials Demonstration, Clinical Trials can be considered for coverage as long as “protocols receive formal notification of approval from The Clinical Protocol Review and Monitoring Committee (National Institutes of Health) and, therefore, are considered National Cancer Institute (NCI) sponsored, but may not appear in the Physician Data Query (PDQ). A provider who is seeking to enter a patient into a Cancer Center Study must provide evidence of NCI sponsorship by forwarding the formal notification of approval from this specific committee.”

BACKGROUND:

A Clinical Trial is a type of research study carefully designed to determine the effectiveness and safety of a drug or device in humans. Clinical trials, particularly treatment and prevention trials often have several components or phases.
The following Phases (I-IV) relate to the scope of the trial:\textsuperscript{13}

1. Phase I trial evaluates the new drug or treatment in a small group of people. The trial’s purpose is to provide early indications of a drug or treatment’s safety, safe dosage range, and side effects.
2. Phase II trial follows phase I trial. The objective of Phase II is to better determine effectiveness and to monitor a promising drug or treatment more critically.
3. Phase III trial evaluates a drug or treatment that has been proven effective in the phase I and II trials; the drug or device is tested on a large population to confirm its effectiveness, reveal any rarer side effects, and gather information that will allow the drug or treatment to be safely marketed.
4. Phase IV trial occurs after a product has been released in the marketplace and provides further information on benefits and risks.

CODING INFORMATION:

\textit{CPT Copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.}

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage and referral requirements. All inpatient admissions require pre-authorization.

\textbf{PRE-AUTHORIZATION REQUIRED}

\textit{Compliance with the provision in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits}

<table>
<thead>
<tr>
<th>CPT ® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>S9988</td>
<td>Services provided as part of a Phase I clinical trial</td>
</tr>
<tr>
<td>S9990</td>
<td>Services provided as part of a Phase II clinical trial</td>
</tr>
<tr>
<td>S9991</td>
<td>Services provided as part of a Phase III clinical trial</td>
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CPT/HCPCS NOT COVERED

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<tr>
<th>CPT ® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>S9992</td>
<td>Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion</td>
</tr>
<tr>
<td>S9994</td>
<td>Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion</td>
</tr>
<tr>
<td>S9996</td>
<td>Meals for clinical trial participant and one caregiver/companion</td>
</tr>
</tbody>
</table>

REFERENCE STATEMENT:

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

REFERENCES:


COMAR. Clinical Trial Items and Services – Coverage for Routine Costs. Title 10: 10.09.67.26-1 and 10.09.67.27. Retrieved: http://www.dsd.state.md.us


