Clinical Trials – Routine Costs

I. Description
A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (such as drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

Phase I Clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range, and to identify side effects).

Phase II Clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III Studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV Studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

II. Criteria/Guidelines
A. Routine costs associated with a clinical trial are covered (subject to Limitations/Exclusions and Administrative Guidelines) and include items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care).

B. Routine costs associated with a clinical trial are covered for individuals who meet the following conditions:
   1. The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.
   2. Either, the referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph above; or the participant or
beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described above.

C. Routine costs associated with a clinical trial are covered for approved clinical trials which are defined as follows:
   1. An approved clinical trial means 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; life-threatening condition means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted; and
   2. The study or investigation is:
      a. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
         i. The National Institutes of Health (NIH)
         ii. The Centers for Disease Control and Prevention (CDC)
         iii. The Agency for Healthcare Research and Quality (AHRQ)
         iv. The Centers for Medicare and Medicaid (CMS)
         v. A cooperative group or center of any of the entities described above (1-4)
         vi. A cooperative group or center of the Department of Defense (DOD) or the Department of Veterans Affairs (DVA) or the Department of Energy (DOE)
         vii. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
         viii. The DOD, DVA, or Department of Energy but only if that study/investigation has been reviewed and approved through a system of peer review approved by the Department of Health and Human Services (HHS); or
      b. Conducted under an investigational new drug (IND) application reviewed by the Food and Drug Administration; or
      c. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

III. Limitations/Exclusions
   A. Items and services that are excluded and are not eligible for coverage are:
      1. The item, device or service being tested.
      2. Items and services:
         a. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
         b. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis

IV. Administrative Guidelines
   A. Precertification is required and will extend for the length of the trial. To precertify, please complete HMSA’s Precertification Request and mail or fax the form as indicated. When submitting a precert request, attach applicable trial protocol and patient trial consent form.
B. When submitting claims, all items/services including the item/service under investigation must be identified with the appropriate “Q0” or “Q1” procedure code modifier. The modifiers are line item specific and must be used to identify items/services that constitute medically necessary routine patient care or treatment of complications arising from a beneficiary's participation in a covered clinical trial.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>Q0</td>
<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study</td>
</tr>
<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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<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
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**ICD-10 diagnosis codes are provided for your information.**
This code will not become effective until 10/1/2015.

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
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V. **Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through generally accepted standards of medical practice and review of medical literature and government approval status. If a treating physician disagrees with HMSA’s determination in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
VI. References