Routine Costs Associated with Clinical Trials

Policy Number: MM.12.002
Original Effective Date: 11/13/2001
Line(s) of Business: HMO; PPO
Current Effective Date: 05/01/2013
Section: Other/Miscellaneous

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. Clinical trials must meet the following criteria:
   1. The subject or purpose of the trial must be the evaluation of an item or service that falls within an HMSA benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not excluded from coverage by contract (e.g., cosmetic surgery); and
   2. The trial must have a therapeutic intent (e.g., is not designed exclusively to test toxicity or disease pathophysiology); and
3. A trial of therapeutic intervention must enroll patients with diagnosed disease rather than healthy volunteers. A trial of diagnostic intervention may enroll healthy patients in order to have a proper control group;

   **AND either**

4. The trial must have desirable characteristics:
   a. The purpose of trial is to test if an intervention potentially improves health outcomes;
   b. The trial is supported by the literature or is intended to clarify or establish health outcomes of interventions in clinical use;
   c. The trial does not duplicate existing studies;
   d. The trial design is suited to answer the research question being asked;
   e. The trial is sponsored by a credible organization or individual capable of executing the trial successfully;
   f. The trial is in compliance with federal regulations to protect human subjects; and
   g. All aspects of the trial are conducted in accordance with standards of scientific integrity.

   **Or**

5. The trial is conducted under an investigational new drug application (IND) or is funded by the following organizations:
   a. National Institute of Health (NIH)
   b. Centers for Disease Control and Prevention (CDC)
   c. Agency for Healthcare Research and Quality (AHRQ)
   d. Centers for Medicare and Medicaid (CMS)
   e. Department of Defense (DOD)
   f. Veterans Administration (VA)
   g. National Cancer Institute (NCI)
   h. Food and Drug Administration (FDA)

B. Routine costs associated with a clinical trial are covered (subject to Limitations/Exclusions and Administrative Guidelines) and include the following:
   1. Items or services that are typically provided absent a clinical trial (e.g., medically necessary conventional care).
   2. Items or services required for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent).
   3. Items or services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
   4. Items or services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

C. For the Fed 87 plan, please refer to the plan’s Guide to Benefits.

### III. Limitations/Exclusions

A. Items and services that are excluded and are not eligible for coverage are:
   1. The item or service being tested.
   2. Items and services:
      a. For which there is no plan benefit category.
b. Which are considered HMSA plan benefit exclusions.
c. That fall under a national Medicare noncoverage policy
d. Customarily provided by the research sponsors free of charge for enrollees in the trial.
e. Provided solely to determine trial eligibility.

3. Items and services furnished solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan).

B. No trials are covered based on self-certification.

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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<tr>
<td>ICD-9</td>
<td>Description</td>
</tr>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
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</tbody>
</table>

ICD-10 diagnosis codes are provided for your information. These will not become effective until 10/1/2014:

<table>
<thead>
<tr>
<th>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 consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity 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