Clinical Policy Bulletin: Clinical Trials, Coverage of Routine Patient Care Costs

Number: 0466

Policy

Notes:

I. Consistent with Centers for Medicare & Medicaid Services (CMS) policy and Patient Protection and Affordable Care Act (PPACA) requirements, Aetna covers medically necessary routine patient care costs in clinical trials (in the same way that it reimburses routine care for members not in clinical trials) according to the limitations outlined below. All of the following limitations apply to such coverage:

   A. All applicable plan limitations for coverage of out-of-network care will apply to routine patient care costs in clinical trials; and
   B. All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials; and
   C. Members must meet all applicable plan requirements for precertification, registration, and referrals; and
   D. To qualify, a clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled. Providers will not routinely be required to submit documentation about the trial to Aetna, but Aetna can, at any time, request such documentation to confirm that the clinical trial meets current standards for scientific merit and has the relevant IRB approval(s).

II. Aetna covers costs of medically necessary treatments for conditions that result as unexpected consequences (complications) of clinical trials.

III. Aetna does not cover the following clinical trial costs:

   A. Costs of data collection and record keeping that would not be required but for the clinical trial; and
   B. Items and services provided by the trial sponsor without charge; and
   C. The experimental intervention itself (except medically necessary Category B investigational devices and promising experimental and investigational interventions for terminal illnesses in certain clinical trials according to Aetna's terminal illness policy (see
benefit plan descriptions for details)); and
D. Travel, lodging and meals; and
E. Other services to clinical trial participants necessary solely to satisfy data collection
needs of the clinical trial (i.e., "protocol-induced costs").

**Background**

This policy was adapted from Centers for Medicare & Medicaid Services (CMS) policy on coverage of
routine care costs in clinical trials.

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**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes
requiring a 7th character are represented by "+":*

**ICD-10 codes will become effective as of October 1, 2015:**

**HCPCS codes not covered for indications listed in the CPB: (not all inclusive):**

- **S9992** 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

- **S9994** Lodging costs (e.g., hotel charges) for clinical trial participant and one
caregiver/companion

- **S9996** Meals for clinical trial participant and one caregiver/companion

**Other HCPCS codes related to the CPB:**

- **S9988** Services provided as a part of a phase I clinical trial

- **S9990** Services provided as a part of a phase II clinical trial

- **S9991** Services provided as a part of a phase III clinical trial

- **Modifier Q0** Investigational clinical service provided in a clinical research study that is in an
approved clinical research study

- **Modifier Q1** Routine clinical service provided in a clinical research study that is in an
approved clinical research study

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**The above policy is based on the following references:**

1. The White House, Office of the Press Secretary. President Clinton takes new action to
encourage participation in clinical trials. Medicare will reimburse for all routine patient care costs
Secretary, The White House; June 7, 2000.

2. National Academy of Sciences, Institute of Medicine. Extending Medicare Reimbursement in
Clinical Trials. Committee on Routine Patient Care Costs in Clinical Trials for Medicare

Medicare coverage of clinical trials. Proposed National Coverage Decision. Baltimore, MD:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0466 Clinical Trials, Coverage of Routine Patient Care Costs

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

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