Subject: Clinical Trials*

Updated: October 28, 2008

Department(s): Utilization Management

Policy: Routine patient care costs incurred during clinical trials are reimbursable under Plans administered by QualCare, Inc.

Objective: To assure proper and consistent reimbursement, to provide coverage of members in clinical trials, and to establish reasonable definitions of routine patient care in the context of clinical trials.

Procedure:

1. Routine patient care costs in clinical trials (including, but not limited to: per diem hospital charges, routine hematology and chemistry laboratory tests, imaging studies not directly related to the investigational intervention) will be covered, if the trial has been approved by all relevant Institutional Review Boards (IRBs).

2. For the member enrolled in a clinical trial, there must be no reasonable alternative intervention for a serious or life-threatening condition.

3. Determination of the availability and applicability of such reasonable alternative interventions shall rest with the Medical Director.
4. The written protocol describing the scientific basis for the clinical trial must be made available to the Medical Director for review when requested.

5. Members must meet all applicable Plan requirements for precertification and referrals for participation in a clinical trial to be considered for coverage.

6. Utilization management rules and coverage policies shall apply to routine care for members in clinical trials as they apply to members not in clinical trials.

7. Routine costs of treating conditions that result as unexpected consequences of clinical trials are reimbursable.

8. The following clinical trial costs are NOT reimbursable:

   a. The experimental device or intervention itself unless the device is a Category B device (newer generation of proven technology) and is covered by an FDA-approved Investigational Device Exemption
   b. Costs of data collection and record keeping that are required only because of participation in the clinical trial
   c. Other protocol-induced costs (including but not limited to costs incurred to enable data to be collected and stored)
   d. Items and services provided by the trial sponsor without charge.
   e. Costs of investigational drugs or devices not yet FDA approved, and costs of laboratory or imaging procedures required by the FDA for monitoring of the drug or device prior to its approval

References


Todd MB. New Jersey’s Approach to Paying for Clinical Trials. (Presentation at Cancer Institute of New Jersey March 3, 2005)

Goodin S. Importance of Cancer Clinical Trials as a Treatment Option. (Presentation at Cancer Institute of New Jersey March 3, 2005)


Benditt PL. The Medical Director’s Role in Oncologic Treatment Coverage. *Managed Care* (suppl) 2005;14(2):15-21 (Feb)


ECRI. Should I Enter a Clinical Trial? A Patient Reference Guide for Adults with a Serious or Life-Threatening Illness. February 2002


NJ Legislature. S1845 and A 2768 “Requires clinical trial sponsor to provide certain information to New Jersey Residents concerning continued payment for medication after clinical trial.” Bills 2002-2003. (November 25, 2002)

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.