Subject: **Clinical Trials***

Effective Date: **May 23, 2005**

Department(s): **Utilization Management**

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

Objective: To assure proper and consistent reimbursement for coverage of medically necessary routine patient care costs in approved clinical trials.

Procedure:

1. An approved clinical trial is a phase I, II, II or IV clinical Trial that investigates the prevention, detection, or treatment of cancer or other life- threatening disease or condition and that is either funded or approved under a federal agency, a clinical trial conducted under an FDA investigational new drug application, or is a drug trial that is exempt from the requirement of an investigational new drug application. The approved clinical trial must have relevant institutional review board approval. The approved clinical trial must be determined to be appropriate to treat the individual's disease or condition.

2. Routine patient care costs include items and services consistent with the coverage provided under the plan for an individual who is not enrolled in a clinical trial including, but not limited to: per diem hospital charges, routine hematology and chemistry laboratory tests,

and imaging studies not directly related to the investigational intervention.

3. Routine patient care costs for treatment for unexpected consequences of clinical trials are also reimbursable.

4. The level of benefit for medically necessary routine care received will correspond to the network participation status of the clinical trial's provider(s) and facility. If out of network benefits for routine care are not available under the member's plan, benefits for routine care within a clinical trial from out of network providers are also not available

5. The written protocol describing the scientific basis for The clinical trial must be made available to the Medical Director for review when requested.

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

7. 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.

8. Clinical trial costs that are NOT reimbursable include, but are not limited to, the following:

   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
f. An item or service that is not used for direct clinical management of the individual
g. An item or service that is inconsistent with widely accepted and established standards of care for the particular diagnosis or condition

References

Byrne M, Danielson N, Harris A, Savani BN. Making inroads to the cure: Barriers to clinical trial enrollment in hematopoietic cell transplantation. Clin Transplant. 2017;31(5)(May)

Weber JS, Levit LA, Adamson PC, Bruinooge S, et al. American Society of Clinical Oncology Policy Statement Update: The Critical role of Phase 1 Trials in Cancer Research and Treatment. J Clin Oncol 2015;33(3):278-284(Jan)

Palackdharry CS, Evans DL, McDonough RS, et al. Payer coverage for patients enrolled onto clinical trials: Making the process easy and transparent for everyone. Am J Manag Care. 2012;18(2 Spec No.):SP91-SP97.

-----. Coverage for Individuals Participating in Approved Clinical Trials under the Patient Protection and Affordable Care Act of 2010 (PPACA). Available at: http://www.accc-cancer.org/advocacy/pdf/PPACA-Coverage-for-Approved-Clinical-Trials.pdf accessed 07/12/2010

University of Pennsylvania Abramson Cancer Center. Oncolink. Insurance Coverage for Clinical Trial Costs: Beyond the Recent New Jersey Agreement. Available at: http://www.oncolink.org/resources/article.cfm?c=6&s=26&ss=26&id=111 accessed 07/12/2010

American Society of Hematology. Clinical Trials Coverage Provision Among Health Reform Benefits Deemed Not Applicable to "Grandfathered" Heath Plans. Available at: http://www.hematology.org/News/2010/5364.aspx accessed 07/12/2010

American Cancer Society. Clinical Trials: State Laws Regarding Insurance Coverage. Avalable at:

http://www.cancer.org/acs/groups/cid/documents/webcontent/002552-pdf.pdf accessed 07/12/2010

US National Institutes of Health. National Cancer Institute. Clinical Trials. Available at: http://www.cancer.gov/clinicaltrials accessed 07/12/2010

US National Institutes of Health. Understanding Clinical Trials Available at: http://clinicaltrials.gov/ct2/info/understand accessed 07/12/2010

Centers for Medicare and Medicaid Services. Decision Memo for Clinical Trial Policy (CAG-00071R). 07/09/07 Available at: https://www.cms.gov/scripts/ctredirector.dll/.pdf?@_CPR0a0a043a07d1.TW_LKXt_h2qE accessed 07/12/2010

Centers for Medicare and Medicaid Services. Investigational Device Exemption. Provider Education Medicare Part B. available at http://www.medicarenhic.com/providers/pubs/investdevicegd.pdf accessed 10/02/08

Devine S, Dagher RN, Weiss KD, et al. Good Clinical Practice and the Conduct of Clinical Studies in Pediatric Oncology. Ped Clin N Amer 2008;55(1):187-290 (Feb)

Rahbari NN, Diener MK, Wente MN, *et al*. Development and perspectives of randomized controlled trials in surgery. Am J Surg 2007;194(4 Suppl):S148-S152 (Oct)

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)

Kurzrock R, Benjamin RS. Risks and Benefits of Phase 1 Oncology Trials, Revisited. New Eng J Med 2005;352(9):930-932 (March 3)

Horstmann BA, McCAbe MS, Grochow L, et al. Risks and Benefits of Phase 1 Oncology Trials, 1991 through 2002. New Eng J Med 2005;352(9):895-904 (March 3)

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

Piantadosi S. Biotatistics for Clinical Trials. Ch. 19 in Abeloff MD, Armitage JO, Niederhuber JE, et al. Clinical Oncology 3rd ed. Philadelphia. Elsevier Churchill Livingstone. 2004.

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

Newcomer LN. Managing Coverage for Clinical Trials. Policy Matters. Effective Clin Prac. 1999;2:244-246 (Sep-Oct)

CMS. NCD for Routine Costs in Clinical Trials (310.1). Medicare Coverage Database. http://www.cms. hhs.gov/mcd/viewncs.asp?ncd_id=310.1&ncd_version=1&basket=ncd%3... (accessed 4/20/05)

NIH. ClinicalTrials.gov. An Introduction to Clinical Trials. http://www.clinicaltrials.gov/ct/gui/ nfo/whatis;jsessionid=89E9A9863C22F2B622275F13... (accessed 4/20/05)

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)

Drafted By: B.Fisher, MD 04/20/05
Approved By/Date: QMCommittee 4/23/05
Revised By/Date: BFisher, MD 03/09/08
Approved By/Date: QM Committee 04/29/08
Revised By/Date: MBueno, PhD, RN, BFisher, MD 10/02/08
Approved By/Date: QM Committee 10/28/08
Revised By/Date: BFisher, MD 07/12/2010
Approved By/Date: QM Committee 07/27/10
Reviewed without Revision By/Date: MMcNeil, MD 05/21/12
Approved By/Date: QM Committee 06/12/12
Revised By/Date: MMcNeil, MD 06/26/14
Approved By/Date: QM Committee: 07/22/14
Reviewed w/o Revision By/Date: M McNeil, MD 11/16/16
Approved By/Date: QM Committee 12/13/16
Reviewed w/o Revision By/Date: M McNeil, MD 06/05/18
Approved By/Date: QM Committee 06/19/18

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