Coverage of Experimental and Investigational Procedures

Policy
Aetna covers experimental or investigational technologies (i.e., drugs, procedures and devices) when ALL of the following criteria are met.

1. The member has a current diagnosis that will most likely cause death within one year or less despite therapy with currently accepted treatment; and
2. Standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and
3. The proposed treatment is likely to be beneficial to the member based on at least two documents of medical and scientific evidence (as defined below); and
4. The member is to be treated as part of a clinical trial satisfying ALL of the following criteria:
   a. The investigational drug, device, therapy or procedure is under current review by the FDA and has an Investigational New Drug (IND) number; and
   b. The clinical trial has passed independent scientific scrutiny and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation; and
   c. The clinical trial is sponsored by the National Cancer Institute (NCI) or similar national cooperative body (e.g., Department of Defense, VA Affairs) and conforms to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials; and
   d. The clinical trial is not a single institution or investigator study (NCI-designated Comprehensive Cancer Center trials are exempt from this requirement); and
   e. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
      c. National Cancer Institute.
      e. Centers for Medicare and Medicaid Services (CMS).
      f. Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
5. The member must:
   a. Not be treated “off protocol.”
   b. Actually be enrolled in the trial.

Note: Some investigational studies are not conducted under FDA scrutiny, but meet all the other criteria. For example, new uses of old technologies, new uses of drugs already approved by the FDA (as these would not have an IND number).

Medical and scientific evidence means the following sources:

a. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

b. Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health’s National Library of Medicine for indexing in index Medicus, Excerpta Medicus (EMBASE), Medline, or MEDLARS database Health Services Technology Assessment Research (STAR).

c. Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act (42 U.S.C. 1395x).

d. The following standard reference compendia:
   a. The American Hospital Formulary Service-Drug Information,
   b. The American Medical Association Drug Evaluations,
   c. The American Dental Association Accepted Dental Therapeutics, and
   d. The United States Pharmacopoeia Drug Information.

If the criteria listed above are not satisfied, and the member desires reconsideration, the member may submit an appeal in accordance with the relevant appeal process. Any such appeal may be expedited when required by the member’s medical condition.

Note: For coverage of Category B investigational devices, please see CPB #164 — Coverage of Category B Investigational Devices. See also CPB #466 — Clinical Trials, Coverage of Routine Patient Care Costs.
Application to products

Unless indicated otherwise above, this policy applies to all fully insured Aetna HMO, POS and PPO plans and to all other plans, unless a specific limitation or exception exists. For self-funded plans, consult individual plan sponsor benefit descriptions. If there is a discrepancy between this policy and a self-funded customer’s plan of benefits, the provisions of the benefits plan will govern. With respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans, applicable state mandates will take precedence over either. Texas specific coverage issues can be found on the following Aetna website: www.aetna.com/cpb/data/texas_lang.htm. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to individuals covered under a Medicare+Choice and state Medicaid benefit plan issued, serviced or administered by Aetna, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Coverage Policy Bulletin. CMS’s Coverage Issues Manual can be found on the following website: www.hcfa.gov/pubforms/06_cim/ci00.htm.

The above policy is based on the following references:


©2002 Aetna Inc. Coverage Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Coverage Policy Bulletin contains only a partial, general description of plan or program benefits and does not constitute a contract. Aetna does not provide health care services and, therefore, cannot guarantee any results or outcomes. Participating providers are independent contractors in private practice and are neither employees nor agents of Aetna or its affiliates. Treating providers are solely responsible for medical advice and treatment of members. This Coverage Policy Bulletin may be updated and therefore is subject to change.

June 21, 2002

Aetna is the brand name used for products and services provided by one or more of the Aetna group of subsidiary companies.