

EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES, COVERAGE OF

Policy

VCHCP's Contracts usually contain an exclusion of coverage for "Experimental or Investigational" procedures. The definition of "Experimental or Investigational" includes, among other things, any drug, device, procedure or treatment that requires FDA approval, but for which such approval has not yet been granted. However consistent with §1370.4 of the Knox Keene Act, experimental or investigational procedures may be approved if:

A. All the following criteria are satisfied:

- the patient has a life threatening or seriously debilitating disease which is expected to cause death within one year in the absence of effective treatment
- the usual modalities of conventional, standard treatment have been unsuccessful
- the member's physician certifies that standard therapies have been ineffective or are not medically appropriate for the member, or that the proposed treatment is more likely to be effective than standard treatments.
- the proposed treatment is promising and likely to be effective for the patient. A promising treatment is one that has shown effectiveness as supported in credible peer reviewed literature or by the credible medical opinion of independent medical experts in the relevant specialty, designated by VCHCP.

-OR-

B. The member is to be treated as part of a clinical trial satisfying all the following criteria:

- the investigational drug, device, therapy or procedure is under current review by the FDA and has been determined to be safe for human use
- the clinical trial has been approved by an Institutional Review Board (IRB) that will oversee the investigation
- there is credible evidence in the peer-reviewed medical literature showing benefit from the proposed treatment
- the clinical trial is sponsored by the National Cancer Institute (NCI) or similar national cooperative body and conforms to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials and must be pre-approved by the Plan.
- All pre-approved services are subject to co-payments.

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Procedure

Requests for experimental/investigational treatments must be submitted to UR as a Treatment Authorization Request (TAR). The TAR must be approved by the member's Plan PCP or specialist and must be accompanied by at least 2 supporting peer reviewed documents for medical and scientific evidence.

Medical and scientific evidence may be from 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:
 - The American Hospital Formulary Service-Drug Information
 - The American Medical Association Drug Evaluations
 - The American Dental Association Accepted Dental Therapeutics
 - The United States Pharmacopoeia Drug Information
- E. Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - Federal Agency for Healthcare Research and Quality
 - National Institutes of Health
 - National Cancer Institute
 - National Academy of Sciences
 - Centers for Medicare and Medicaid Services (CMS)

- Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
- F. Peer-reviewed abstracts accepted for presentation at major medical association meetings.

Appeals Process

If the criteria listed above are not judged by the Plan Medical Director to be satisfied, the member will in all cases be informed of the right to request an independent medical review and will be assisted in this process. Notification will be accomplished within 5 days of the denial. Such an appeal will be expedited when required by the member's medical condition. The following information will be supplied to the enrollee:

- A. a statement setting forth the specific medical and scientific reasons for denying coverage
- B. a description of alternative treatment, services, or supplies covered by the Plan, if any
- C. copies of the Plan's grievance procedures or complaint form and
- D. an opportunity for the enrollee to request a conference within 30 calendar days or within 5 business days if the treating participating physician determines, after consultation with the Plan Medical Director or designee, based on standard medical practice, that the effectiveness of either the proposed treatment, services, or supplies or any alternative treatment, services, or supplies covered by the Plan would be materially reduced if not provided at the earliest possible date. The enrollee will have the opportunity to attend this conference conducted by a Plan representative having authority to determine the disposition of the complaint to review the information provided to the enrollee regarding the denial. The Plan allows attendance, in person or via teleconference, at the meeting, by an enrollee, a designee of the enrollee, or both, or, if the enrollee is a minor or incompetent, the parent, guardian, or conservator of the enrollee, as appropriate.

Attachments: None

History:

Reviewers/Authors: Richard O. Ashby MD, John Prichard MD,
Committee Review: QAC: November 8, 2001
Reviewers/Revised: David Chernof, MD; Date: 07/01/04
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Reviewed/Revised: Cynthia Wilhelmy, MD; Date: 07/31/06
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2/20/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Grammar changes. Added "or via teleconference, at the meeting" to what the Plan allows in attendance

A. References:

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 15. *Investigational new drug application; exception from informed consent; technical amendment-- FDA. Final rule. Fed Regist 1997 Jun 16;62(115):32479*
 16. *Beebe DB, Rosenfeld AB, Collins N. An approach to decisions about coverage of investigational treatments. HMO Pract 1997 Jun;11(2):65-7*