

CONTRA COSTA HEALTH PLAN

Utilization Management.

Title: Experimental or Investigational Services and Independent Medical Review Option

Policy #: UM15.033

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Applies to:

- | | | | |
|--|---|--|------------------------------|
| <input checked="" type="checkbox"/> Medi-Cal | <input checked="" type="checkbox"/> Medicare | <input checked="" type="checkbox"/> Commercial | |
| <input type="checkbox"/> LIHP | <input checked="" type="checkbox"/> State Sponsored | <input type="checkbox"/> All | <input type="checkbox"/> N/A |

Regulatory/Accreditation:

- | | | |
|--|--|--|
| <input type="checkbox"/> CCR | <input checked="" type="checkbox"/> CMS: | <input checked="" type="checkbox"/> DHCS: CCR, Title 22, Section 51056.1(b), 51056.1(c), 51303(g)(h) |
| <input checked="" type="checkbox"/> DMHC | <input type="checkbox"/> NCQA: | <input type="checkbox"/> Other Reg. References: |

Units:

- | | | |
|--|---|---|
| <input type="checkbox"/> Administration | <input type="checkbox"/> Advice Nurses | <input type="checkbox"/> All Staff |
| <input type="checkbox"/> Business Services | <input type="checkbox"/> Case Management | <input type="checkbox"/> Health Ed/Cultural Ling. |
| <input type="checkbox"/> Marketing | <input type="checkbox"/> Member Services | <input type="checkbox"/> Planning, Survey, Reg Affairs |
| <input type="checkbox"/> Provider Affairs | <input type="checkbox"/> Quality Management | <input checked="" type="checkbox"/> Auth/Utilization Management |

POLICY

Contra Costa Health Plan (CCHP) shall process requests for experimental or investigational treatment/therapy in the same timely manner as indicated in policy *UM 15.015a- Timeliness of the Utilization Review Decision and Communication*, used for other medical authorization requests. In the event the Health Plan denies an experimental or investigational service request for a member considered to have a life-threatening or chronic and seriously debilitating condition, the member is eligible for an Independent Medical Review (IMR) (see *UM 15.035*). The IMR process is written in the member and provider denial or modification notice. Experimental services are not covered. Investigational services are not covered except when documented evidence, as noted in section titled, **PROCEDURE**, are met.

Please note that limited coverage related to either experimental or investigational therapies may be covered as outlined in policy *UM15.037-Cancer Clinical Trial*.

DEFINITIONS (as defined by CCR, Title 22, Section 51056.1)

Experimental services means those drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans.

Investigational services means those drugs, equipment, procedures or services for which laboratory and animal studies have been completed and for which human studies are in progress but:

1. Testing is not complete; and
2. The efficacy and safety of such services in human subjects are not yet established; and
3. The service is not in wide usage.

The determination that a service is experimental or investigational is based on:

1. Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration);
2. Consultation with provider organizations, academic and professional specialists pertinent to the specific service;
3. Reference to current medical literature.

PURPOSE

To establish guidelines when investigational services are covered and to ensure decisions for experimental or investigational services are process in the same timely manner as the Health Plan makes other determinations. In addition, to allow a member with life-threatening or chronic and seriously debilitating conditions the opportunity to participate in an appeal process other than the Plan's appeal process.

For the purpose of this section, “life-threatening” is defined as either or both:

1. Diseases or conditions where the likelihood of death is high within one year unless the course of the disease is interrupted.
2. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

For the purpose of this section, “chronic and seriously debilitating” is defined as:

1. Diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

PROCEDURE

Request for experimental or investigational services shall be reviewed for medical necessity based on established guidelines, standard of practice and literature search, or as appropriate, through an external peer review process. A determination shall be made within the timeframe standards set forth in the above policy, which is used for all other authorization requests submitted to the Health Plan. Criteria and guidelines must be applied to determine medical necessity. Upon determination to approve, deny, modify or defer the request for service(s), the member shall be notified in the same timely manner as noted in the above policy.

Investigational services are not covered **except** when it is clearly documented that **ALL** of the following apply:

1. Conventional therapy will not adequately treat the intended patient's condition.
2. Conventional therapy will not prevent progressive disability or premature death.
3. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service.
4. The investigational service is the lowest cost item or service that meets the member's medical needs and is less costly than all conventional alternatives.
5. The service is not being performed as a part of a research study protocol.
6. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living.

All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above conditions or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such unapproved, uncovered investigational services.

Denial of a Request for Experimental/Investigational Services and the Independent Medical Review (IMR) Option

If a member is denied a service deemed to be experimental or investigational:

The member is issued a written communication within the timeframe indicated in policy *UM15.018- Timeliness of the Utilization Review Decision and Communication*. The denial notification letter (Notice of Non-Coverage **with IMR option**) will inform the member that he/she has the right to appeal the decision (grievance procedures) and the opportunity to participate in an independent medical review (IMR) process. The notification will explain the IMR process, indicate eligibility criteria, whom to contact for assistance and include the appropriate forms along with an addressed envelope for the member to complete to initial an IMR. Refer to policy *UM15.035- External Independent Medical Review* for detailed information on processing standards, procedures, external IMR criteria, eligibility requirements and accreditation of the external review group.

Additionally, the notice will include:

- (1) A statement setting forth the specific medical and scientific reasons for denying coverage.
- (2) A description of alternative treatment, services, or supplies covered by the plan, if any. Compliance with this subdivision by a plan shall not be construed to mean that the plan is engaging in the unlawful practice of medicine.

Usage of “Experimental or Investigational” Drugs

Drugs that are prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA) may be considered experimental or investigational, therefore, may also have the opportunity to participate in an IMR process. Please refer to the Pharmacy Services Department for policies and procedures.

(3) Copies of the plan's grievance procedures or complaint form, or both. The complaint form shall provide an opportunity for the enrollee to request a conference as part of the plan's grievance system provided under Section 1368.

(b) Upon receiving a complaint form requesting a conference pursuant to paragraph (3) of subdivision (a), the plan shall provide the enrollee, within 30 calendar days, an opportunity to attend a conference, to review the information provided to the enrollee pursuant to paragraphs (1) and (2) of subdivision (a), conducted by a plan representative having authority to determine the disposition of the complaint. The plan shall allow attendance, in person, at the conference, 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. However, the conference required by this subdivision shall be held within five business days if the treating participating physician determines, after consultation with the health plan medical director or his or her 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.

Experimental Health Care Services for Terminally Ill Patients

When coverage of a service to a member with a terminal illness for treatment, services, or supplies deemed experimental, as recommended by a participating Plan provider is denied, the Plan will provide to the enrollee, within five business days, all the following information:

- 1) A statement setting forth the specific medical and scientific reasons for denying coverage.
- 2) A description of alternative treatment, services, or supplies covered by the plan, if any.
Compliance with this subdivision by a plan shall not be construed to mean that the plan is engaging in the unlawful practice of medicine.
- 3) Copies of the plan's grievance procedures or complaint form, or both. The complaint form shall provide an opportunity for the member to request a conference as part of the plan's grievance system.