Experimental and Investigational Services

Policy Number: BIP059.I
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Instructions for Use

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CA HSC 1370.4 Experimental or Investigational Therapies

https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1370.4.

(a) Every health care service plan shall provide an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual enrollees who meet all of the following criteria:
  (1) (A) The enrollee has a life-threatening or seriously debilitating condition.
    (B) For purposes of this section, "life-threatening" means either or both of the following:
      (i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
      (ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.
    (C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.
  (2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to 1paragraph (3).
  (3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that is not otherwise covered pursuant to the plan contact.
  (4) The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3).
  (5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(b) The plan's decision to delay, deny, or modify experimental or investigational therapies shall be subject to the independent medical review process under Article 5.55 (commencing with Section 1374.30) except that, in lieu of the information

specified in subdivision (b) of Section 1374.33, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:
  (1) The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.
  (2) If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 1374.33.
  (3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.
  (4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:
  (1) 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.
  (2) 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, and MEDLARS data base Health Services Technology Assessment Research (HSTAR).
  (3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.
  (4) Either of the following reference compendia:
    (A) The American Hospital Formulary Service's Drug Information.
    (B) The American Dental Association Accepted Dental Therapeutics.
  (5) Any of the following reference compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
    (A) The Elsevier Gold Standard's Clinical Pharmacology.
    (B) The National Comprehensive Cancer Network Drug and Biologics Compendium.
    (C) The Thomson Micromedex DrugDex.
  (6) 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 Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
  (7) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

State Market Plan Enhancements

None

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

Refer to the member's Evidence of Coverage or Schedule of Benefits (SOB) to determine coverage eligibility.

Experimental and/or Investigational procedures, items, treatments, studies, tests, drugs, and equipment may be covered when:

- Mandated by the state or federal law (Refer to the *Federal/State Mandated Regulations* and/or *State Market Plan Enhancements* sections); or
- As determined by a UnitedHealthcare Medical Director, or his/her designee (Refer to the *Definitions* section for the definition of "Experimental and/or Investigational").

Also refer to Benefit Interpretation Policies titled Medical Necessity and Clinical Trials, and the Medical Management Guideline titled Clinical Trials.

Not Covered

Experimental and/or Investigational procedures, items, treatments, studies, tests, drugs and equipment that do not meet the above coverage criteria.

Definitions

Experimental and/or Investigational: For the purposes of this policy, procedures, items, treatments, studies, tests, drugs or equipment will be considered Experimental and/or Investigational if any of the following criteria/guidelines is met:

- It is being provided according to a written protocol that describes among its objectives the determination of safety, efficacy, toxicity, maximum tolerated dose or effectiveness in comparison to conventional treatments.
- Other facilities studying substantially the same drug, device, medical treatment or procedures refer to it as Experimental or as a research project, a study, an invention, a test, a trial or other words of similar effect.
- The predominant opinion among experts as expressed in published, authoritative medical literature is that usage should be confined to research settings.
- It is not Experimental or Investigational itself according to the above criteria, but would not be medically necessary except for its use in conjunction with a drug, device or treatment that is Experimental or Investigational (e.g., lab tests or imaging ordered to evaluate the effectiveness of an Experimental therapy).
- It cannot lawfully be marketed without the approval of the Food and Drug Administration (FDA) and such approval has not been granted at the time of its use or proposed use.
- It is a subject of a current investigation of new drug or new device application on file with the FDA.
- It is the subject of an ongoing clinical trial (Phase I, II or the research arm of Phase III) as defined in regulations and other official documents issued by the FDA and Department of Health and Human Services (DHHS).

The sources of information to be relied upon by UnitedHealthcare in determining whether a particular treatment is Experimental or Investigational include, but are not limited to the following:

- The member's medical records;
- The protocol(s) according to which the drug, device, treatment or procedure is to be delivered;
- Any informed consent document the member, or his or her representative, has executed or will be asked to execute, in order to receive the drug, device, treatment or procedure;
- The published authoritative medical and scientific literature regarding the drug, device, treatment, or procedure;
- Expert medical opinion;
- Opinions of other agencies or review organizations, e.g., ECRI Health Technology
- Assessment Information Services, HAYES New Technology Summaries or MCMC Medical Ombudsman;
- Regulations and other official actions and documents issued by agencies such as the FDA, DHHS and Agency for Health Care Policy and Research (AHCPR).

Policy History/Revision Information

Date	Summary of Changes
09/01/2021	Federal/State Mandated Regulations • Added reference link to *California Health and Safety Code Section 1370.4* Supporting Information • Archived previous policy version BIP059.H

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.