Experimental and Investigational Services

Policy Number: BIP060.J
Effective Date: August 1, 2023

Instructions for Use

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Related Benefit Interpretation Policies

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Related Medical Management Guideline

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Federal/State Mandated Regulations

Washington

WAC 284-44-043

https://apps.leg.wa.gov/wac/default.aspx?cite=284-44-043

Experimental and investigational prescriptions, treatments, procedures, or services—Definition required—Standard for definition—Written notice of denial required—Appeal process required.

(1) Every health care service contract which excludes or limits, or reserves the right to exclude or limit, benefits for any treatment, procedure, facility, equipment, drug, drug usage, medical device, or supply (hereinafter individually and collectively referred to as services) for one or more medical condition or illness because such services are deemed to be experimental or investigational must include within the contract and any certificate of coverage issued thereunder, a definition of experimental or investigational.

(2) The definition of experimental or investigational services must include an identification of the authority or authorities which will make a determination of which services will be considered to be experimental or investigational. If the health care service contractor specifies that it, or an affiliated entity, is the authority making the determination, the criteria it will utilize to determine whether a service is experimental or investigational must be set forth in the contract and any certificate of coverage issued thereunder. As an example, and not by way of limitation, the requirement to set forth criteria in the contract and any certificate of coverage issued thereunder may be satisfied by using one or more of the following statements, or other similar statements:

   (a) "In determining whether services are experimental or investigational, the plan will consider whether the services are in general use in the medical community in the state of Washington, whether the services are under continued scientific testing and research, whether the services show a demonstrable benefit for a particular illness or disease, and whether they are proven to be safe and efficacious."

   (b) "In determining whether services are experimental or investigational, the plan will consider whether the services result in greater benefits for a particular illness or disease than other generally available services, and do not pose a significant risk to health or safety of the patient."

   The supporting documentation upon which the criteria are established must be made available for inspection upon written request in all instances and may not be withheld as proprietary.

(3) Every health care service contractor that denies a request for benefits or that refuses to approve a request to preauthorize services, whether made in writing or through other claim presentation or preauthorization procedures set out in the contract and any certificate of coverage thereunder, because of an experimental or investigational exclusion or limitation, must do so in writing within twenty working days of receipt of a fully documented request. The health care service contractor may

extend the review period beyond twenty days only with the informed written consent of the covered individual. The denial letter must identify by name and job title the individual making the decision and fully disclose:
(a) The basis for the denial of benefits or refusal to preauthorize services;
(b) The procedure through which the decision to deny benefits or to refuse to preauthorize services may be appealed;
(c) What information the appellant is required to submit with the appeal; and
(d) The specific time period within which the company will reconsider its decision.

(4) (a) Every health care service contractor must establish a reasonable procedure under which denials of benefits or refusals to preauthorize services because of an experimental or investigational exclusion or limitation may be appealed. The appeals procedure may be considered reasonable if it provides that:
(i) A final determination must be made and provided to the appellant in writing within twenty working days of receipt of the fully documented appeal. The health care service contractor may extend the review period beyond twenty days only with the informed written consent of the covered individual;
(ii) The appeal must be reviewed by a person or persons qualified by reasons of training, experience and medical expertise to evaluate it; and
(iii) The appeal must be reviewed by a person or persons other than the person or persons making the initial decision to deny benefits or to refuse to preauthorize services.
(b) When the initial decision to deny benefits or to refuse to preauthorize services is upheld upon appeal, the written notice shall set forth:
(i) The basis for the denial of benefits or refusal to preauthorize services; and
(ii) The name and professional qualifications of the person or persons reviewing the appeal.
(c) Disclosure of the existence of an appeal procedure shall be made by the health care service contractor in each contract and any certificate of coverage issued thereunder which contains an experimental or investigational exclusion or limitation.

(5) Whenever a covered person appeals the health care service contractor's decision and delay would jeopardize the covered person's life or health, the health care service contractor must follow the appeal procedures and time frames in WAC 284-43-4040(2).

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 or 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* section); **or**
- As determined by a UnitedHealthcare Medical Director, or his/her designee.

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 publications issued by agencies such as the FDA, DHHS and Agency for Health Care Policy and Research (AHCPR).

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 or equipment that do not meet the above coverage criteria.

Policy History/Revision Information

Date	State(s) Affected	Summary of Changes
08/01/2023	All	**Covered Benefits** • Added language (relocated from *Definitions* section) to indicate 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) **Definitions** • Removed definition of “Experimental and/or Investigational” **Supporting Information** • Archived previous policy version BIP060.I

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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.