EXPERIMENTAL AND INVESTIGATIONAL SERVICES

Policy Number: BIP060.G
Effective Date: September 1, 2019

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Covered benefits are listed in three (3) Sections - A, B and C. 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.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit document to determine benefit coverage.

A. FEDERAL/STATE MANDATED REGULATIONS

WASHINGTON:
WAC 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).

B. STATE MARKET PLAN ENHANCEMENTS

None
C. COVERED BENEFITS

IMPORTANT NOTE: Covered benefits are listed in Sections A, B and C. Always refer to Sections A and B for additional covered 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:
1. When mandated by the state or federal law (Refer to Section A and/or B); or
2. As determined by a UnitedHealthcare Medical Director, or his/her designee (Refer to Section E for the definition of “Experimental and/or Investigational”).

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

D. NOT COVERED

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

E. 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:
1. It is being provided pursuant 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.
2. It is being delivered or should be delivered subject to approval and supervision of an institutional review board (IRB) as required and defined by federal regulations or other official actions (especially those of the FDA and DHHS).
3. 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.
4. The predominant opinion among experts as expressed in published, authoritative medical literature is that usage should be confined to research settings.
5. It is not Experimental or Investigational itself pursuant 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).
6. 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.
7. It is a subject of a current investigation of new drug or new device application on file with the FDA.
8. 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 publications 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:
1. The member’s medical records;
2. The protocol(s) according to which the drug, device, treatment or procedure is to be delivered;
3. 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;
4. The published authoritative medical and scientific literature regarding the drug, device, treatment, or procedure;
5. Expert medical opinion;
6. Opinions of other agencies or review organizations, e.g., ECRI Health Technology Assessment Information Services, HAYES New Technology Summaries or MCMC Medical Ombudsman;
7. Regulations and other official actions and publications issued by agencies such as the FDA, DHHS and Agency for Health Care Policy and Research (AHCPR).

F. POLICY HISTORY/REVISION INFORMATION

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<tr>
<td>09/01/2019</td>
<td>All</td>
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<td>- Added language to clarify experimental and/or investigational procedures, items, treatments, studies, tests, drugs, and equipment may be covered when [the listed criteria] are met</td>
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<tr>
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<td><strong>Not Covered</strong></td>
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<td>- Added language to clarify experimental and/or investigational procedures, items, treatments, studies, tests, drugs, and equipment are not covered when the coverage criteria [listed in the Covered Benefits section of the policy] are not met</td>
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<td><strong>Definitions</strong></td>
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<td>- Updated definition of “Experimental and/or Investigational”</td>
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