WAC 284-46-507 Experimental and investigational prescriptions, treatments, procedures, or services—Definition required—Standard for definition—Written notice of denial required—Appeal process required. (1) Every health maintenance agreement 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 agreement 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 maintenance organization 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 agreement and any certificate of coverage issued thereunder. As an example, and not by way of limitation, the requirement to set forth criteria in the agreement or any certificate of coverage 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 maintenance organization 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 agreement 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 maintenance organization 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 maintenance organization 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 maintenance organization 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 maintenance organization in each agreement and any certificate of coverage issued thereunder which contains an experimental or investigational exclusion or limitations.

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

[Statutory Authority: RCW 48.02.060. WSR 16-14-106 (Matter No. R 2016-11), § 284-46-507, filed 7/6/16, effective 8/6/16. Statutory Authority: RCW 48.02.060, 48.18.120, 48.20.450, 48.20.460, 48.30.010, 48.43.055, 48.44.050, 48.46.100 and 48.46.200. WSR 99-24-075 (Matter No. R 98-17), § 284-46-507, filed 11/29/99, effective 12/30/99. Statutory Authority: RCW 48.02.060 (3)(a) and 48.46.200. WSR 92-21-098 (Order 92-14), § 284-46-507, filed 10/21/92, effective 11/21/92.]