

**Objective:**

- I. To ensure that members have equitable access to safe and effective care.
- II. To appropriately identify and review requests for drugs, devices, or services that may be considered investigational and may not be proven to be efficacious.

**Policy:**

- I. Health care services may include medical, surgical, diagnostic, substance abuse or other health care technologies, supplies, treatments, procedures, drug therapies or devices.
- II. Health care services are considered experimental, investigational or unproven, if any of the criteria below are not met as determined by THA Medical Management review:
  - A. The technology must have final approval from the appropriate government regulatory bodies.
    1. A device must have final approval from the Food and Drug Administration (FDA) for those specific indications and methods of use that THA is evaluating.
    2. Any approval that is granted as an interim step in the FDA regulatory process is not sufficient.
  - B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
    1. The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals and appropriate government regulatory bodies.
    2. The evidence demonstrates the technology can measure or alter the physiological changes related to a disease, injury, illness or condition, or affects the health outcomes.
    3. McKesson InterQual Guidelines literature is reviewed and evaluated according to the scientific quality of the supporting evidence and rationale.
    4. The THA Medical Director may seek input from specialists and professionals who have expertise in this technology.
    5. The requesting provider would be encouraged to supply 2 refereed clinical journal articles to support the request.

- C. The technology must improve the net health outcome. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
  - D. There has been an attempt to utilize currently available treatment modalities.
  - E. The technology must be as beneficial or more than as any established alternatives.
  - F. The improvement must be attainable outside the investigational setting.
- III. The Tuality Health Alliance (THA) Medical Director must review any request for new technology services, drugs, or devices. Investigational services are not considered a covered benefit. This policy is for THA-Oregon Health Plan (OHP) members only.
- IV. For Providence Health Plan (PHP) members, refer to policy for their coverage of new technology.

Formulated: July 1998  
Reviewed: February 2002  
Revised: August 1999  
September 2000  
February 2003  
April 2004  
May 2005  
September 2006  
July 2007