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Objective:

I. To ensure that Tuality Health Alliance (THA) members have equitable access to safe and effective care as new technologies may be applied to that 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.

Definition:

Healthcare technologies may include medical, surgical, diagnostic, substance abuse or other supplies, treatments, procedures, drug therapies or devices.

Policy:

I. This policy applies to THA/Oregon Health Plan (OHP) members only.

II. Healthcare technologies/services are considered experimental, investigational, or unproven, if any of the criteria below are not met upon THA Medical Management review:

- The technology must have final approval from the appropriate government regulatory bodies.
  - A device must have final approval from the Food and Drug Administration (FDA) for the specific indications and methods of use for which THA is reviewing/evaluating as part of a Utilization Management determination.
  - Any approval that is granted as an interim step in the FDA regulatory process is not sufficient.
- Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
  - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals and appropriate government regulatory bodies.
  - The evidence must demonstrate that the technology affects health outcomes or can measure or alter physiological changes related to a disease, injury, illness, or condition.
  - McKesson InterQual Guidelines literature pertaining to supporting evidence and rationale is reviewed and evaluated for scientific quality.
  - The THA Medical Director may seek input from specialists and professionals who have expertise in this technology.
  - The provider requesting new technology would be encouraged to supply two refereed clinical journal articles to support the request.
- The technology must improve the net health outcome; its beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- There has been an attempt to utilize currently available treatment modalities.

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- The technology must be as beneficial as, or more beneficial than, established alternatives.
  - The benefits must be attainable outside of the investigational setting(s).

III. Investigational services are not considered a covered benefit.

IV. The THA Medical Director must review any request for new technology services, drugs, or devices.

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