Assessment of New Medical Technology

Ultimate Health Plans, (UHP) evaluates the incorporation of new technology and the new application of existing technology in its benefit plan, including medical and behavioral healthcare procedures, pharmaceuticals and devices.

UHP has a formal mechanism to evaluate and address new developments in technology and new applications of existing technology for inclusion in its benefits plan to keep pace with changes and to ensure that members have equitable access to safe and effective care.

UHP’s written process for evaluating new technology and the new application of existing technology for inclusion in its benefits plan includes an evaluation of the following:

- Medical Procedures
- Behavioral healthcare procedures
- Pharmaceuticals
- Devices

UHP’s written evaluation process includes the following;

- The process and decision variables that UHP uses to make determinations
- A review of information from appropriate government regulatory bodies
- A review of information from published scientific evidence
- A process for seeking input from relevant specialists and professionals who have expertise in the technology

Technology assessment procedures will be used to review at least one type of technology the review can result either of two types of decision:

- A policy determination to include a new technology as a covered benefit in the future or
- A case-based decision on whether or not to cover a specifically requested service. There must be evidence that case-based decisions result in the review of medical necessity guidelines and procedures for possible revision.

Our Process

- UHP receives a request for a procedure that is not identified in the approved medical review criteria and is considered new or experimental.
- The request is entered on the Pre-Determination Review Form and forwarded to the appropriate Medical Director, with attached medical records, for further research.
- The Medical Director or designated researcher will compile the following data elements (as available) for each technology evaluation requested:
  a. Potential clinical indications and uses of the technology
  b. Alternative technologies that address these same indications
  c. Critical outcomes expected given the use of the technology
  d. Medline literature search, or equivalent, and query of the Agency for Health Care Research and Quality (AHRQ) database.
  e. Legal regulatory status of the technology when such regulation exists (e.g. drug or device approval by the FDA)
f. Review NCD determinations issued by CMS
g. Review any legislature change in benefit coverage requirements.

- We also access the following web sites to obtain information:
  a. CMS- www.cms.gov
  b. Medscape
  c. Wed MD
  d. Major HMO coverage guidelines
  f. Clinical Trials National Cancer Institute- www.centerwatch.com

- All applicable information and research will be attached to the Pre-Determination Review Form by the Medical Director or designated researcher.

- The Medical Director will make a determination to approve or deny based on the following:
  a. The technology must have final approval from the appropriate government regulatory bodies, when such approval is applicable:
     1. A drug, biological product or medical device must have final approval from the Food and Drug Administration (FDA) for the specific indications and method of use requested
     2. Interim approvals are not sufficient for evaluation of the intended clinical use
  b. Scientific information must exist from at least two independent sources in the peer-reviewed medical literature demonstrating benefit from the use of the technology
     1. The committee will consider the quality of the scientific studies and the consistency of results in reaching a determination
     2. The scientific studies must be properly designed and conducted
     3. The scientific evidence must permit conclusions or convincing arguments based on established medical facts concerning the effects of the technology on medical outcomes (e.g. quality of life, functional ability)

The initial determination will apply only to the member for whom it was made. A general recommendation for the technology may be made by the Medical Advisory Committee (MAC). The Quality Management Steering Committee (QMSC) makes the final determination regarding coverage.

- The Medical Director may request a review by an independent expert review agent at any time during this process

- From the Medical Director’s determination, a Coverage Guideline may be drafted

- The draft Coverage Guideline is then presented to the MAC for review.

- The MAC will evaluate coverage of new technologies or new uses of existing technologies when:
  a. The treatment provided through the use of technology is a covered benefit; and
  b. The technology is shown to improve medical outcomes and:
     1. No existing technologies show superior outcome improvement, or
     2. If existing technologies show comparable clinical benefit over existing technologies; and
c. Published evidence or the judgment of the MAC, determines that the technology can be successfully applied outside of the research setting; and
d. The committee determines that the use of the technology is justified by the potential benefits

- The QMSC will evaluate the MAC’s recommendation. If approved, the final decision will be incorporated in the final Coverage Guideline, which is then distributed to the staff

- Experimental therapy is excluded from coverage by all UHP’s policies

- Any requests for enrollment in clinical studies will be received and handled according to Medicare Guidelines

- If the request is approved, UM 001 - Organization Determinations Policy and Procedure is followed.

- If the request is not approved, UM 002 - Adverse Organization Determinations Policy and Procedure is followed.