MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Technology Assessment Guidelines
Policy Number: 350

Blue Cross and Blue Shield of Massachusetts uses the five criteria below to assess whether a technology improves health outcomes such as length of life, ability to function or quality of life.

Note: All five (5) guidelines must be met.

1. **The technology must have final approval from the appropriate government regulatory bodies.**
   - This criterion applies to drugs, biological products, devices and diagnostics.
   - A drug or biological product must have final approval from the Food and Drug Administration (FDA), any approval granted as an interim step in the FDA regulatory process is not sufficient.
   - A device must have final approval from the Food and Drug Administration.

2. **The 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 English-language journals. The qualities of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measurably alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that the measured alterations affect health outcomes.
   - Opinions and evaluations by national medical associations, consensus panels or other technology evaluation bodies are evaluated according to the scientific quality of the supporting evidence upon which they are based.

3. **The technology must improve the net health outcome.**
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. **The technology must be as beneficial as any established alternatives.**
   - The technology should improve the net health outcome as much as or more than established alternatives.
   - The technology must be cost-effective as any established alternatives that achieve a similar health outcome.

5. **The improvement must be attainable outside the investigational settings.**
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to improve health outcomes to a degree comparable to that published in the medical literature.

Note: A technology (medical and behavioral healthcare procedures, drugs, and devices) **is considered investigational (non-covered)** if they do not meet the above Blue Cross Blue Shield Medical Technology Assessment Guidelines (Medical Policy #350).