



## 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.