



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](#)).