

TECHNOLOGY ASSESSMENT CRITERIA

The first step in determining whether a medical procedure is eligible for coverage is evaluating its health effects, a process known as technology assessment or technology evaluation. The Blue Cross Blue Shield Association (BCBSA) uses the 5 criteria listed below to determine if a technology improves health outcomes, is safe, effective and has established long-term results. Blue Shield of California has adopted BCBSA criteria but substituted the grading of evidence listed in Criterion 2.

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.
- A device must have final approval from the FDA for those specific indications and methods of use that are being evaluated.
- Any approval that is granted as an interim step in the FDA regulatory process is not sufficient.

2. **The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

- Evidence should consist of well designed and well conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- Evidence about the effectiveness will be graded as follows, according to the criteria proposed by Cook, et al¹.
 - Level 1: Randomized trials that had enough power to demonstrate a statistically significant health outcome.
 - Level 2: Randomized trials with results that were not statistically significant but where a larger trial might have shown a clinically important difference.
 - Level 3: Nonrandomized concurrent cohort comparisons between contemporaneous patients.
 - Level 4: Nonrandomized historical cohort comparisons between current patients and former patients (from the same institution or from the literature).
 - Level 5: Case series without control subjects.

TECHNOLOGY ASSESSMENT CRITERIA (CONTINUED)

- Evidence from Level 1 studies are the preferred basis for deciding whether this criterion is met.
- In the absence of Level 1 studies technologies may be eligible for coverage if, overall, Level 2-4 studies indicate that:
 - a. The technology provides substantial benefits to important health outcomes and
 - b. The new technology has been shown to be safer or more beneficial than existing technologies or alternative treatments in comparative studies.
- In general, technologies will not be approved based on evidence from Level 5 studies (case series without controls).
- 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.

Cook DJ, et al. Rules of evidence and clinical recommendations on the use of antithrombotic agents. *Chest*, 1992; 4 (suppl): 305S-311S.

3. **The technology must improve the net health outcomes.**

- The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- For diagnostic tests, there is evidence that use of the test would result in improved medical management in a way that will benefit the patient.

4. **The technology must be as beneficial as any established alternatives.**

- The technology should improve the net health outcomes as much as or more than established alternatives.

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 satisfy Criteria No. 3 and No. 4.

Effective: 6/7/00