Wellmark®

An Independent Licensee of the Blue Cross and Blue Shield Association

Technology Assessment Evaluation Criteria

1. The technology must have final approval from the appropriate government regulatory bodies.

A. A device, drug, or biological product must have Food and Drug Administration approval to market for those specific indications and methods of use that Wellmark Blue Cross Blue Shield is assessing.

B. Approval to market refers to permission for commercial distribution. Any other approval that is granted as an interim step in the FDA regulatory process, e.g. as Investigational Device Exemption, is not sufficient.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

A. The evidence must consist of an adequate number of well-designed studies with sufficient numbers of patients in relation to the incidence of the disease. The evidence must also be published in major peer reviewed journals that publish original manuscripts only after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity, and reliability.

B. The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should also be evidence or a convincing argument based on established medical facts that such measurement or alteration affects the health outcomes.

C. Opinions and evaluations by national medical associations, consensus panels, or other technology assessment evaluation bodies are evaluated according to the scientific quality of supporting evidence and rationale.

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.

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 #3 and #4.

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Technology Assessment Evaluation Criteria Form

Provider Name: _____

Provider Number: _____

Address: _____

Phone: _____

Date of Request: _____/_____/_____

1. What is the name and the description of technology:

2. What criteria must patients meet before they can become candidates for use of this technology?

3. What are the specific indications and methods of use for which this technology has received FDA approval?

4. How does this technology benefit patients' health outcomes?

5. Indicate relevant peer-reviewed journal references, which demonstrate the efficacy and safety of this technology.

6. What medical associations, consensus panels, and/or other technology assessment bodies have evaluated the safety and efficacy of this technology?

7. How do the health outcomes using this technology compare to the available alternatives?

8. What are the fixed and variable costs of this technology?

9. How does the cost of this technology compare to the alternatives?

10. What is this technology's estimated yearly volume of use?

11. Do you have any financial interest in this technology? If yes, please explain.

Mail this completed assessment to:
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Or Fax to:
515-376-9015