Technology Assessment Evaluation Criteria

1. The technology must have final approval from the appropriate government regulatory bodies.
   a. This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the technology.
   b. Any approval that is granted as an interim step in the U.S. Food and Drug Administration's or any other federal governmental body's regulatory process is not sufficient.
   c. The indications for which the technology is approved need not be the same as those which Blue Cross Blue Shield of North Dakota is evaluating.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   a. The 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.
   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.

Technology Assessment Evaluation

Submit completed form with additional documentation.

Return completed forms to:

- Mail: Blue Cross Blue Shield of North Dakota
  Attn: Medical Policy
  4510 13th Avenue S.
  Fargo, ND 58121

Provider Information		
Name	NPI	
Street Address		
City	State	Zip
Phone Number	Date of Request	

Evaluation Questions
1. 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 market approval?
4. How would this technology benefit patients' health outcomes?

29381152 • 11-19

Evaluation Questions *(Continued)*
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 would the health outcomes using this technology compare to the available alternatives?
8. What would be the fixed and variable costs of this technology?
9. How would the cost of this technology compare to the alternatives?
10. What would be this technology's estimated yearly volume of use?
11. Do you have any financial interest in this technology?

29381152 • 11-19