

Medical Benefit		Effective Date: 04/01/09	Next Review Date: 05/15
Preauthorization	Yes	Review Dates: 11/07, 11/08, 09/09, 09/10, 07/11, 05/12, 05/13, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required for services for which we have no published Protocol which do not meet the guidelines contained in this Protocol.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Technology assessment should be based on criteria which addresses whether the technology improves health outcomes such as length of life, quality of life, and functional ability.

Policy (Formerly Corporate Medical Guideline)

Technology assessment criteria utilized:

- The technology must have final approval from the appropriate government regulatory bodies.
 - 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.
 - 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.
 - The indications for which the technology is approved need not be the same as those which we are evaluating.
- 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 journals. The quality 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 measure or 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 such measurement or alteration affects health outcomes.
- 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.

In reviewing the criteria above, physician specialty society recommendations, the view of prudent medical practitioners practicing in relevant clinical areas and any other relevant factors will be considered.

If a technology does not meet every one of the above, then it is considered investigational.

*For drug guidelines refer to Drug Therapy Guidelines.

Medicare Advantage

When deciding if a new technology is investigational, Medicare Advantage will follow Medicare's policies. If no Medicare policy, then Medicare Advantage will follow this Protocol.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross Blue Shield Association criteria used by the Technology Assessment Center for their TEC Assessments downloaded 10/05/07, 09/27/08, 05/24/09, 06/08/10, 05/08/11, 04/05/12, 03/27/13, and 3/21/14.
2. CMS National Coverage Determinations Manual.
3. Member Contracts