

(Formerly Technology Assessment)

| | | | |
|-------------------------|-----|--|--------------------------------|
| Medical Benefit | | Effective Date: 03/01/20 | Next Review Date: 05/21 |
| Preauthorization | Yes | Review Dates: 11/07, 11/08, 09/09, 09/10, 07/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 11/19, 05/20 | |

Preauthorization is required for services for which we have no published protocol which do not meet the guidelines contained in this protocol.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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

“Medically Necessary Services” are technologies, procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms. The medical necessity of such services should be based on criteria which addresses whether the service improves health outcomes such as length of life, quality of life, and functional ability.

POLICY

Medically necessary services assessment criteria utilized:

1. The service 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 service.
 - 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 service is approved need not be the same as those which we are evaluating.
2. The scientific evidence must permit conclusions concerning the effect of the service 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 service 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.
3. The service must improve the net health outcome.
 - The service's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
 4. The service must be as beneficial as any established alternatives.
 - The service 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 service should be reasonably expected to satisfy criteria #3 and #4.
 6. The service is not primarily for the convenience of the patient, physician or other health care provider. This includes Durable Medical Equipment (DME) with features added for aesthetic reasons or added convenience when standard equipment is available.

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 service meets all of the above criteria numbered 1-6, then it is considered **medically necessary**.

If a service does not meet any of the above criteria numbered 1-5, then it is considered **investigational**.

If a service does not meet all of the above criteria numbered 1-6, then it is considered **not medically necessary**.

*For drug guidelines refer to Drug Therapy Guidelines.

MEDICARE ADVANTAGE

When deciding if a new technology or service 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 and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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 05/04/2012 accessed 10/05/07, 09/27/08, 05/24/09, 06/08/10, 05/08/11, 04/05/12, 03/27/13, 03/21/14, 03/19/15, 03/17/16, 03/16/17, 03/07/18, 03/11/19.
2. Blue Cross Blue Shield Association criteria used by the Center for Clinical Effectiveness (CCE) Assessment Criteria. Accessed 03/16/2020.
3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) Manual. Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS): 90 - Payment for Additional Expenses for Deluxe Features.; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>. Accessed October 30, 2019.
4. Blue Cross Blue Shield of WNY and NENY. Certificate of Coverage. Medical Necessity. January 2018.
5. Blue Cross Blue Shield of WNY and NENY. Plan Document and Summary Plan Description. Medical Benefits – Medical Necessity. March 2017.