BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Investigational Criteria

Policy #: 495
Latest Review Date: January 2022
Category: Administrative

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat investigational procedures, treatments, supplies, devices, and/or drugs as a **non-covered benefit** and as **not medically necessary**.

Investigational is defined as any treatment, procedure, facility, equipment, drug, drug usage or supplier that either the plan has not recognized as having scientifically established medical value, or does not meet generally accepted standards of medical practice. Information is reviewed from the published peer-reviewed literature, recognized standards of practice and technology assessments to determine if the service in question meets specific criteria to determine coverage.

The following criteria are used to determine if a service or supply will be considered non-investigational:

- The technology must have final approval from the appropriate government regulatory bodies.
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
- The technology must improve the net health outcome;
- The technology must be as beneficial as any established alternatives; AND,
- The improvement must be attainable outside the investigational setting.

All five criteria referenced above must be met before a service or device is determined not to be investigational. The FDA status is only one of the criteria which must be met.

The following descriptions may assist in determining if a service should be questioned as possibly investigational or experimental.

- Very few providers perform this procedure.
- The patient may have to travel to another area of the Country to receive this treatment and the condition is not extremely rare.
- The treatment is not performed in the United States.
- There is not a Current Procedural Terminology (CPT) code for the service, or the only code assigned is a category III tracking code.
- There is not a specific HCPCS code to report the service or supply.
- The only clinical studies published are not peer-reviewed or are sponsored by the manufacturer or developer.
- The device has to be approved by an Institutional Review Board or is part of a clinical trial.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians

should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

KEY WORDS:
Investigational, Experimental

APPROVED BY GOVERNING BODIES:
This includes product approvals issued by the Food and Drug Administration, an agency of the United States Department of Health & Human Services.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CODING:
CPT Codes: Not applicable

REFERENCES:

1. FDA.gov website.
2. Blue Cross and Blue Shield Association, the Technology Evaluation Center (TEC): Evidence-based Practice Center. October 2007. Agency for Healthcare Research and Quality, Rockville, MD. archive.ahrq.gov/research/findings/evidence-based-reports/centers/bcbsatec.html

POLICY HISTORY:
Adopted for Blue Advantage, May 10, 2012
Available for comment May 14 – June 26, 2012
Medical Policy Group, March 2015
Medical Policy Group, August 2017
Medical Policy Group, October 2019
Medical Policy Group, March 2021
Medical Policy Group, January 2022: No new literature or information to reference; reviewed by consensus; no change in policy statement.

services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.