BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Analysis of Proteomic Patterns in Serum to Identify Cancer

Policy #: 176
Latest Review Date: May 2022
Category: Medicine

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 **analysis of proteomic patterns in serum to identify cancer** as a **non-covered** benefit and as **investigational.**

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.

DESCRIPTION OF PROCEDURE OR SERVICE:

The analysis of proteomic patterns in serum for early detection of cancer has been proposed. Several of these proteomic tests are being studied, particularly in ovarian and prostate cancer. Proteomics involves the use of mass spectrometry to study differences in patterns of protein expression. Proteomic patterns are patterns of proteins present within a clinical sample used as a diagnostic "fingerprint" that is proposed to provide an early diagnosis for some types of cancer.

KEY POINTS:

The most recent literature update was performed through May 11, 2022.

Summary of Evidence

While patterns of protein expression have been proposed to yield more biologically relevant and clinically useful information than assays of single proteins, many limitations in the use of proteomics exist. In contrast to genomics, in which amplification techniques like polymerase chain reaction (PCR) allow for the investigation of single cells, no technology is available at the protein level. Other issues between studies have been lack of uniform patient inclusion and exclusion criteria, small patient numbers, absence of standardized sample preparations, and limited analytical reproducibility. Data in the peer-reviewed literature are inadequate to permit scientific conclusions regarding ovarian, prostate, or other malignancies. The utility of this technology is unproven and is considered investigational.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN) Guidelines

NCCN guidelines for the common cancers addressed in this policy do not comment on the use of proteomics.

KEY WORDS:
Proteomics, ovarian cancer, OvaCheck™, Correlogic Systems, ProstaCheck, MammoCheck, NovellusDX, Vermillion

APPROVED BY GOVERNING BODIES:
Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug administration has chosen not to require any regulatory review of this test.

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

CURRENT CODING:
There is no specific code for this type of testing. One of the following codes might be used to report the test:

83789	Mass spectroscopy and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified, quantitative, each specimen
84999	Unlisted chemistry procedure

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POLICY HISTORY:

Adopted for Blue Advantage, November 2006
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Medical Policy Group, November 2007
Medical Policy Group, March 2009
Medical Policy Group, March 2010
Medical Policy Group, July 2011
Medical Policy Group, July 2012
Medical Policy Group, August 2013
Medical Policy Group, December 2015
Medical Policy Group, August 2016
Medical Policy Group, June 2017
Medical Policy Group, June 2019
Medical Policy Group, May 2021
Medical Policy Group, October 2021: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, May 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
