BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Anti-CCP Testing for Rheumatoid Arthritis

Policy #: 353
Latest Review Date: September 2023
Category: Laboratory

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 **measurement of anti-CCP** as a **covered** benefit when used as part of the diagnostic workup for rheumatoid arthritis.

Blue Advantage will treat **measurement of anti-CCP** as a **non-covered** benefit when used to monitor disease activity and/or treatment response 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 measurement of antibodies to cyclic citrullinated peptide (anti-CCP) is highly specific testing used for the diagnosis of rheumatoid arthritis (RA). The detection of anti-CCP has been shown to be of prognostic significance in the diagnosis of RA.

Autoantibodies can cause disease by attacking the body's healthy cells by mistake. Anti-CCP target healthy tissues in the joints.

Anti-CCP targets healthy tissues in the joints. Anti-CCP is found in the blood of approximately 60-70% of people who have rheumatoid arthritis. They are almost never found in people who don't have the disease.

This testing may also be known as: Cyclic citrullinated peptide antibody, anticitrullinated peptide antibody, citrulline antibody, anti-cyclic citrullinated peptide, anti-CCP antibody, ACPA.

KEY POINTS:

This policy has been updated with literature review performed through September 21, 2023.

Summary of Evidence

Studies have shown a high specificity for anti-CCP testing. If testing is positive, it is likely to indicate accurately a diagnosis of rheumatoid arthritis. The evidence is sufficient to prove that this technology improves net health outcomes when used for the diagnosis of RA.

After a diagnosis of rheumatoid arthritis is made, there is a paucity of evidence to prove that anti-CCP levels demonstrate disease activity. A decreased anti-CCP level might be seen to indicate the patient has low disease activity or be in remission, but this response varies from patient to patient. Anti-CCP levels do not necessarily go down or go away, even if the disease is under control. This technology has not been proven useful for monitoring of this disease activity or

treatment response. The evidence is insufficient to that this technology improves net health outcomes for the monitoring of disease activity and/or treatment response in RA.

Physician Guidelines and Position Statements
American College of Rheumatology
Anti-CCP antibody test is predictive for having rheumatoid arthritis. According to the American College of Rheumatology, anti-CCP antibodies are found in 60% to 70% of people with rheumatoid arthritis. These antibodies are directed against cyclic citrulinated peptides (CCP) and can be present before rheumatoid arthritis symptoms ever develop.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
CCP, antibody testing, Cyclic citrullinated peptide antibody testing, Diastat, anti-CCP, anticitrullinated peptide antibody, citrulline antibody, anti-cyclic citrullinated peptide, ACPA.

APPROVED BY GOVERNING BODIES:
Siemens Healthcare Diagnostics, Tarrytown, NY, obtained FDA clearance in 2013 to offer U.S. laboratories an anticyclic citrullinated peptide (anti-CCP) IgG assay to aid diagnosis of rheumatoid arthritis (RA), a chronic, progressive autoimmune disease. Available on the company's IMMULITE® 2000/2000 XPi immunoassay systems, the anti-CCP IgG assay affords laboratories the ability to integrate RA testing onto an automated, random-access analyzer.

Axis-Shield Diagnostics obtained 501k FDA clearance for device: Antibodies, Anti-Cyclic Citrullinated Peptide (CCP). The device is used for the detection of anti-cyclic citrullinated peptide (CCP) antibodies in human serum or plasma as an aid in the diagnosis of rheumatoid arthritis.

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

CURRENT CODING:
CPT Codes:

86200	Cyclic citrullinated peptide (CCP), antibody

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POLICY HISTORY:

Adopted for Blue Advantage, April 2009
Available for comment April 23-June 6, 2009
Medical Policy Group, April 2011
Medical Policy Group, August 2011
Medical Policy Group, September 2019
Medical Policy Group, August 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, August 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, September 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
