

Corporate Medical Policy

Antiprothrombin Antibody Testing

File Name: antiprothrombin_antibody_testing
Origination: 5/2011
Last CAP Review: 10/2011
Next CAP Review: 10/2012
Last Review: 10/2011

Description of Procedure or Service

Anti-phospholipid antibodies (aPL) are a distinct group of autoantibodies that appear in a variety of autoimmune diseases, particularly systemic lupus erythematosus (SLE). They are associated with clinical events such as arterial and/or venous thrombosis, and obstetric complications

The term anti-phospholipid syndrome (APS) has been used to describe a condition in which these clinical manifestations are linked to the persistence of aPL. The syndrome occurs in isolation (primary antiphospholipid syndrome) or in association with connective tissue diseases (secondary antiphospholipid syndrome), particularly systemic lupus erythematosus. Detection of anti-cardiolipin antibodies (aCL) by enzyme-linked immunosorbent assay (ELISA) and detection of lupus anticoagulant (LA) activity by phospholipid-dependent coagulation assays have been standardized for the diagnosis of APS.

Other autoantibodies have been associated with anti-phospholipid syndrome, including those reactive with prothrombin. However, testing for antiprothrombin antibodies is problematic due to reproducibility and interpretation of the results.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Antiprothrombin Antibody Testing is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Antiprothrombin Antibody Testing is covered

Not Applicable

Antiprothrombin Antibody Testing

When Antiprothrombin Antibody Testing is not covered

Antiprothrombin antibody testing for diagnosis of anti-phospholipid syndrome (APS) is considered investigational. The clinical value of this procedure has not been established.

Policy Guidelines

Testing for antiprothrombin antibodies has been studied as an indicator for APS, however, the clinical significance of antiprothrombin antibodies has not been established and additional studies are required to assess the predictive value of these antibodies.

The American College of Obstetricians and Gynecologists (ACOG) Guideline for Antiphospholipid Syndrome recommends testing for anticardiolipin antibodies or lupus anticoagulant, but does not include testing for antiprothrombin antibodies.

The British Committee for Standards in Hematology guideline titled, "The Investigation and Management of Antiphospholipid Syndrome" states "Antiprothrombin antibodies generally exhibit poor specificity for venous thrombosis and recurrent fetal loss and may be found in patients with infection. Their precise clinical significance is not yet clear."

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0030T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Donohoe S. Detection and clinical associations of antiprothrombin antibodies. *Am J Med.* 2001;110:229-230.

The American College of Obstetricians and Gynecologists (ACOG) Guideline for Antiphospholipid Syndrome. Nov. 2005. Retrieved on April 19, 2011 from <http://www.guideline.gov/content.aspx?id=10928>

British Committee for Standards in Haematology, Haemostasis and Thrombosis Task Force. Guidelines on the investigation and management of the antiphospholipid syndrome. *Br J Haematol.* 2000;109:704-715. Retrieved on April 19, 2011 from http://www.bcsghguidelines.com/documents/antiphospholipids_bjh2000.pdf

Specialty Matched Consultant Advisory Panel review 10/2011

Antiprothrombin Antibody Testing

Policy Implementation/Update Information

5/24/11 New policy implemented. Antiprothrombin antibody testing for diagnosis of anti-phospholipid syndrome (APS) is considered investigational. The clinical value of this procedure has not been established. Medical Director review 4/2011. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Policy Statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.