

# MEDICAL POLICY

<b>SUBJECT: ANTICOAGULATION TESTING</b>	<b>EFFECTIVE DATE: 06/16/11</b>
<b>POLICY NUMBER: 2.02.40</b>	<b>REVISED DATE: 06/21/12, 06/20/13, 07/17/14, 06/18/15,</b>
<b>CATEGORY: Technology Assessment</b>	<b>07/21/16, 07/20/17, 08/16/18</b>
<b>PAGE: 1 OF: 4</b>	

- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

## **POLICY STATEMENT:**

Based upon our criteria and assessment of the peer-reviewed literature, anticoagulation testing is considered **investigational** in the evaluation for Antiphospholipid Syndrome.

## **POLICY GUIDELINES:**

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## **DESCRIPTION:**

Antiprothrombin antibodies are members of the ill-defined, heterogeneous family of antiphospholipid antibodies, whose persistent presence in association with thromboembolic complications, recurrent miscarriage, or immune thrombocytopenia defines the antiphospholipid syndrome (APS). According to the Sapporo definition, established by an international panel of experts (Sapporo, Japan, 1999), the diagnosis of APS requires the combination of at least one clinical criterion and at least one positive test for antiphospholipid-protein antibody (aPL) confirmed at least 6-12 weeks apart. Clinical criteria include peripheral deep venous thrombosis (DVT), pulmonary embolism (PE), and/or arterial thrombotic events, which may be accompanied by thrombocytopenia and livedo reticularis. Antiphospholipid-protein antibodies include the lupus anticoagulant antibody (LA), anticardiolipin (aCL) antibodies, or anti-beta-2 glycoprotein 1 ( $\beta$ 2GPI) antibodies. Antiprothrombin antibody is another aPL that has been explored as a possible autoantibody associated with APS. Antiprothrombin antibodies are commonly detected by ELISA, using irradiated plates (aPT) or in complex with phosphatidylserine (aPS-PT). However the precise clinical significance of antiprothrombin antibodies has not been determined.

## **RATIONALE:**

The American College of Obstetricians and Gynecologists (ACOG 2011) state that only three antiphospholipid antibodies - lupus anticoagulant, anticardiolipin, and anti- $\beta$ 2-glycoprotein I- can be used to establish the diagnosis of APS. Results from other antiphospholipid antibodies assays do little to improve the accuracy of the diagnosis of APS and testing for such antibodies is not recommended. Miyaki et al. (2006), reported recommendations from the Eleventh International Congress on antiphospholipid antibodies for revisions to the international classification criteria for APS (Sapporo criteria). The authors found data on the clinical associations of antiprothrombin antibody are contradictory, and they imply low specificity of these antibodies for APS diagnosis (Evidence Level II). A systematic review on antiprothrombin antibodies and risk of thrombosis in APS failed to reveal an association, irrespective of isotype, site and type of event, or presence of SLE. The committee considers that the inclusion of antiprothrombin antibodies in the classification criteria for APS is premature. A systematic review by Galli et al. (2003) found no clear association with thrombosis for antiprothrombin antibodies, irrespective of isotype, site and type of event, and systemic lupus erythematosus. Therefore any increase of risk of thrombosis beyond what is predicted by lupus anticoagulants and anticardiolipin antibodies has still to be defined and their utility in clinical practice remains to be established.

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	<b>PAGE: 2 OF: 4</b>

**CODES:**     Number                     Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**             86849                     Unlisted immunology procedure

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**HCPCS:**     No specific code(s)

**ICD10:**     D59.0                     Drug-induced autoimmune hemolytic anemia  
D59.1                     Other autoimmune hemolytic anemias  
D68.311                 Acquired hemophilia  
D68.312                 Antiphospholipid antibody with hemorrhagic disorder  
D68.318                 Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors  
D69.6                     Thrombocytopenia, unspecified  
I74.01-I74.09            Embolism and thrombosis of abdominal aorta (code range)  
I74.10-I74.19            Embolism and thrombosis of unspecified parts of aorta (code range)  
I77.6                     Arteritis, unspecified  
I82.0                     Budd-Chiari syndrome  
I82.1                     Thrombophlebitis migrans  
I82.210-I82.499         Embolism and thrombosis of vena cava and other thoracic veins, renal vein, and of deep veins of lower extremity (code range)  
I82.4Y1-I82.4Y9         Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity (code range)  
I82.4Z1-I82.4Z9         Acute embolism and thrombosis of unspecified deep veins of distal lower extremity (code range)  
I82.501-I82.599         Chronic embolism and thrombosis of deep veins of lower extremity (code range)  
I82.5Y1-I82.5Y9         Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity (code range)  
I82.5Z1-I82.5Z9         Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity (code range)  
I82.601-I82.629         Acute embolism and thrombosis of deep veins of upper extremity (code range)  
I82.701-I82.729         Chronic embolism and thrombosis of veins of upper extremity (code range)  
I82.811-I82.91            Embolism and thrombosis of other specified veins or unspecified veins (code range)  
I82.A11-I82.A29         Embolism and thrombosis of axillary vein (code range)  
I82.B11-I82.B29         Embolism and thrombosis of subclavian vein (code range)  
I82.C11-I82.C29         Embolism and thrombosis of internal jugular vein (code range)

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	<b>PAGE: 3 OF: 4</b>

O09.291-O09.299	Supervision of pregnancy with other poor reproductive or obstetric history (code range)
O10.011-O10.93	Pre-existing hypertension complicating pregnancy, childbirth and the puerperium (code range)
O11.1-O11.9	Pre-existing hypertension with pre-eclampsia (code range)
O26.20-O26.23	Pregnancy care for patient with recurrent pregnancy loss (code range)
P55.0-P55.9	Hemolytic disease of newborn (code range)
P56.0-P56.99	Hydrops fetalis due to hemolytic disease (code range)
P57.0	Kernicterus due to isoimmunization
Z86.718	Personal history of other venous thrombosis and embolism

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	<b>PAGE: 4 OF: 4</b>

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\*key article

**KEY WORDS:**

Hughes syndrome, lupus anticoagulant (LA) syndrome, “sticky blood syndrome”, Antiphospholipid Syndrome, Antiprothrombin antibodies

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## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Antiprothrombin Antibody testing.