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 I (β2GP1) 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 phospatidylserine (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-β2-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.
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

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)
SUBJECT: ANTICOAGULATION TESTING
POLICY NUMBER: 2.02.40
CATEGORY: Technology Assessment
EFFECTIVE DATE: 06/16/11
REVISED DATE: 06/21/12, 06/20/13, 07/17/14, 06/18/15, 07/21/16, 07/20/17, 08/16/18
PAGE: 3 OF: 4

Embolism and thrombosis of internal jugular vein (code range)
Supervision of pregnancy with other poor reproductive or obstetric history (code range)
Pre-existing hypertension complicating pregnancy, childbirth and the puerperium (code range)
Pre-existing hypertension with pre-eclampsia (code range)
Pregnancy care for patient with recurrent pregnancy loss (code range)
Hemolytic disease of newborn (code range)
Hydrops fetalis due to hemolytic disease (code range)
Kernicterus due to isoimmunization
Personal history of other venous thrombosis and embolism

REFERENCES:
Bertolaccini ML and Sanna G. Recent advances in understanding antiphospholipid syndrome. F1000Res. 2016; 5: 2908.


*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**

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