CLINICAL MEDICAL POLICY	
Policy Name:	Serum Biomarker Panel Testing for Systemic Lupus Erythematosus
Policy Number:	MP-124-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	09/01/2024; 08/01/2023
Effective Date:	10/01/2024; 09/01/2023
Next Annual Review:	06/2025
Implementation Date:	06/19/2024; 06/21/2023
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Policy History

Date	Action
10/01/2024	Provider Effective date
08/14/2024	PARP Approval
06/19/2024	QI/UM Committee review
06/19/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' section.
09/01/2023	Provider Effective date
07/11/2023	PARP Approval
06/21/2023	QI/UM Committee review
06/21/2023	Policy initially developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary serum biomarker panel testing for systemic lupus erythematosus.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Systemic lupus erythematosus (SLE) - an autoimmune connective tissue disease (CTD) that can be difficult to diagnose because patients often present with diverse, nonspecific symptoms that overlap with other CTDs. Commonly used laboratory tests are also not highly accurate. Currently, the diagnosis of SLE depends on a combination of clinical signs and symptoms and individual laboratory tests. More accurate laboratory tests for SLE could facilitate the diagnosis of the disease and are commercially available.

Procedures

1. Serum biomarker panel testing (i.e, Avise® SLE) for SLE and Avise® CTD may be considered medically necessary when AT LEAST three (3) of the following criteria are met:
    A. Discoid lupus erythematosus (i.e., malar rash); OR
    B. Photosensitivity; OR
    C. Oral ulcers; OR
    D. Nonerosive arthritis; OR
    E. Pleuritis or Pericarditis; OR
    F. Renal disorder with either persistent proteinuria or cellular casts; OR
    G. Neurological disorder, specifically seizures or psychosis; OR
    H. Hematologic disorder, lymphopenia, leukopenia, hemolytic anemia or thrombocytopenia; OR
    I. Immunologic disorder- positive Anti-DNA or Anti-Sm or any individual antiphospolipid antibody (either anticardiolipin or lupus anticoagulant); OR
    J. Positive antinuclear antibody; OR
    K. Positive antinuclear antibody.

2. When serum biomarker panel testing for systemic lupus erythematosus services are not considered medically necessary
    - Serum biomarker panel testing not meeting the criteria as indicated in this policy is considered not medically necessary.
    - Avise® MTX, Avise APS, and Avise Vasculitis-AAV, are considered not medically necessary.

3. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

4. Place of Service
   Serum Biomarker Panel Testing for SLE is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

5. Genetic Counseling
   Pre- and post-test genetic counseling is required to be performed by an independent (not employed by a genetic testing lab) genetic specialist/counselor prior to genetic testing for mutations. This service is necessary in order to inform persons being tested about the benefits and limitations of a specific genetic test for the specific patient. Genetic testing for mutation requires documentation of medical necessity from one of the following providers who has evaluated the patient and intends to see the patient after testing has been performed for counseling:
   - Board Eligible or Board Certified Genetic Counselor
   - Advanced Genetics Nurse
   - Genetic Clinical Nurse
   - Advanced Practice Nurse in Genetics
   - Board Eligible or Board Certified Clinical Geneticist
   - A physician with experience in cancer genetics
   - A physician specializing in the care for the indication(s) for genetic testing

Governing Bodies Approval

CLIA

Serum biomarker panel testing for SLE tests are offered as laboratory-developed tests under Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories. Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratories offering such tests as a clinical service must meet general regulatory standards of CLIA and must be licensed by CLIA for high complexity testing.

Coding Requirements

Procedure Codes

CPT Code	Description
81599	Unlisted multianalyte assay with algorithmic analysis
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment

Diagnosis Codes

ICD-10 Code	Description
D68.312	Antiphospholipid antibody with hemorrhagic disorder
D68.62	Lupus anticoagulant syndrome
D72.819	Decreased white blood cell count, unspecified
F29	Unspecified psychosis not due to a substance or known physiological condition
I30.0	Acute nonspecific idiopathic pericarditis
I30.8	Other forms of acute pericarditis
I20.9	Acute pericarditis, unspecified
K12.30	Oral mucositis (ulcerative), unspecified
K12.39	Other oral mucositis (ulcerative)
L56.8	Other specified acute skin changes due to ultraviolet radiation
H53.71	Glare sensitivity
M06.4	Inflammatory polyarthropathy
R09.1	Pleurisy
R80.1	Persistent proteinuria, unspecified
R82.998	Other abnormal findings in urine
R56.9	Unspecified convulsions
R76.0	Raised antibody titer

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.