

## Serum Biomarker Panel Testing for Systemic Lupus Erythematosus and Other Connective Tissue Disease

<b>Policy ID:</b>	HHO-DE-MP-1040
<b>Approved By:</b>	Highmark Health Options – Market Leadership
<b>Provider Notice Date:</b>	
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<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
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### Disclaimer

Highmark Health Options 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 Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary Serum biomarker panel testing for systemic lupus erythematosus and other connective tissue disease.

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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**Systemic Lupus Erythematosus (SLE)** – The most common type of lupus. SLE is an autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels. There is no cure for lupus, but medical interventions and lifestyle changes can help control it.

## PROCEDURES

1. Serum biomarker panel testing (i.e., Avise® CTD) may be considered medically necessary when the following criteria is met:
  - Clinical suspicion of CTD; and
  - Serum biomarker panel testing is ordered by treating rheumatologist.

Serum biomarker panel testing not meeting the above criteria will be considered experimental/investigational, and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Avise® MTX is considered experimental/investigational, and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

2. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

3. Place of Service

Experimental/investigational (E/I) services are not covered regardless of place of service.

Serum Biomarker Panel Testing for SLE and Other CTD 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 comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

## CODING REQUIREMENTS

CPT code	Description
84999	Unlisted chemistry procedure.

## REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

## References

Centers for Disease Control and Prevention. (2018). Systemic Lupus Erythematosus (SLE). Retrieved from <https://www.cdc.gov/lupus/facts/detailed.html>.

Wallace DJ, Silverman SL, Conklin J, et al. Systemic lupus erythematosus and primary fibromyalgia can be distinguished by testing for cell-bound complement activation products. *Lupus Sci Med*. 2016; 3(1): e000127.

Liang E, Taylor M, McMahon M. Utility of the AVISE connective tissue disease test in predicting lupus diagnosis and progression. *Lupus Sci Med*. 2020;7(1):e000345.

Ramsey-Goldman R, Alexander RV, Massarotti EM, et al. Complement activation in patients with probable systemic lupus erythematosus and ability to predict progression to American College of Rheumatology-classified systemic lupus erythematosus. 2020;72(1):78-88.

Wallace DJ, Alexander RV, O'Malley T, et al. Randomised prospective trial to assess the clinical utility of multianalyte assay panel with complement activation products for the diagnosis of SLE. Lupus Sci Med. 2019;6(1):e000349.

Mossell J, Goldman JA, Barken D, et al. The AVISE lupus test and cell-bound complement activation products aid the diagnosis of systemic lupus erythematosus. Open Rheumatol J. 2016;10: 71-80.

Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. Arthritis Rheumatol. 2019;71(9):1400-1412.

**POLICY UPDATE HISTORY**

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