Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Payment Policy:

Laboratory: Biomarker Testing for Autoimmune Rheumatic Disease

Effective date: Nov. 1, 2025

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products
☐ Tufts Health Plan Commercial products

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan
☐ Tufts Health One Care – A dual-eligible product

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO) (a dual-eligible product)
☐ Tufts Medicare Preferred HMO/PPO (Medicare Advantage products)

Policy

Systemic autoimmune rheumatic diseases (SARDs) are a diverse group of conditions that primarily affect the joints, bones, muscle, and connective tissue. SARDs are characterized by dysregulated immunity and inflammatory responses, resulting in damage and destruction to joints, connective tissues, skin, blood elements, and other target organs; however, considerable diversity in clinical presentation, disease course, and treatment response exists.

The diagnostic workup for SARDs may involve the antinuclear antibody (ANA) assay, which is used to detect autoantibodies (AAB) against intracellular antigens, originally known as antinuclear antibodies. Commonly used as part of the initial diagnostic workup to screen for evidence of systemic autoimmunity, detection and identification of AABs are important in the diagnosis of SARDs, such as systemic lupus erythematosus (SLE), Sjögren's syndrome (SjS), mixed connective tissue disease (MCTD), systemic sclerosis (SSc), and idiopathic inflammatory myopathies (IIMs). Extractable nuclear antigens or ENAs (a historical term from when the antigens were extracted from the cell into saline solution prior to testing) include Sm, U1 ribonucleoprotein (RNP), Ro, and La antigens, and are also useful for evaluating individuals with suspected connective tissue disease.

Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

1. For individuals with signs or symptoms of an autoimmune disease, screening for disease using antinuclear antibodies (ANA) **MEETS COVERAGE CRITERIA**:
   a. Once during initial workup.
   b. Up to two additional tests per lifetime if new or more severe signs or symptoms of an autoimmune disease develop.
2. For individuals with an abnormal, raised ANA titer and a clinical correlation with the appropriate autoimmune disorder, extractable nuclear antigens (ENA) panel testing of specific autoantibodies **MEETS COVERAGE CRITERIA**.
3. For individuals with painful and swollen joints suggestive of rheumatoid arthritis (RA), testing for rheumatoid factor (RF) and/or anti-cyclic citrullinated peptide (anti-CCP) antibodies **MEETS COVERAGE CRITERIA**:
   a. Once during initial workup.
   b. If initial testing did not result in a diagnosis of RA, up to two additional tests per lifetime if symptoms persist or additional symptoms of RA develop.
4. For individuals with an initial positive ANA test and a diagnosis of systemic autoimmune rheumatic disease, testing of dsDNA up to four (4) times per year **MEETS COVERAGE CRITERIA**.
5. For individuals with a negative or low positive ANA test, the following condition specific antibody testing **MEETS COVERAGE CRITERIA**:
   a. Testing for anti-Jo-1 in a unique clinical subset of myositis.
   b. Testing for anti-SSA in the setting of lupus or Sjögren's syndrome.

6. Monitoring of disease with ANA testing or ANA titers **DOES NOT MEET COVERAGE CRITERIA**.
7. For individuals without symptoms suggestive of an autoimmune disorder, ANA and/or ENA testing **DOES NOT MEET COVERAGE CRITERIA**.
8. For all other situations not described above, testing of specific antibodies in the absence of a positive ANA test **DOES NOT MEET COVERAGE CRITERIA**.
9. For asymptomatic individuals, testing of ANA and/or ENA during a wellness visit or a general exam without abnormal findings **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

10. For the diagnosis of RA, testing for serum biomarkers not discussed above, alone or in a panel (e.g., Seronegative Rheumatoid Arthritis Profile), **DOES NOT MEET COVERAGE CRITERIA**.
11. Serum biomarker panel testing designed to manage RA (e.g., Vectra , PrismRA) **DOES NOT MEET COVERAGE CRITERIA**.
12. Cell-bound complement activation products (e.g., AVISE Lupus) designed to diagnose, prognose, or monitor systemic lupus erythematosus (SLE) **DO NOT MEET COVERAGE CRITERIA**.
13. Serum biomarker panel testing (with or without proprietary algorithms and/or index scores) that is designed to diagnose, prognose, or monitor SLE or connective tissue diseases (e.g., Tissue Specific Markers for Early Diagnosis of Sjögren's Disease)) **DOES NOT MEET COVERAGE CRITERIA**.

Applicable CPT/HCPCS Procedure Codes

Procedure codes appearing in policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

Coding

Code	Description
81490	Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score Proprietary test: Vectra® Lab/Manufacturer: Labcorp
81599	Unlisted multianalyte assay with algorithmic analysis
86038	Antinuclear antibodies (ANA)
86039	Antinuclear antibodies (ANA); titer
86200	Cyclic citrullinated peptide (CCP), antibody
86225	Deoxyribonucleic acid (DNA) antibody; native or double stranded
86235	Extractable nuclear antigen, antibody to, any method (eg, nRNP, SS-A, SS-B, Sm, RNP, Sc170, J01), each antibody
86430	Rheumatoid factor; qualitative
86431	Rheumatoid factor; quantitative
0062U	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score Proprietary test: SLE-key® Rule Out Lab/Manufacturer: Veracis Inc.
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 Proprietary test: Avise® Lupus Lab/Manufacturer: Exagen Inc.
0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity Proprietary test: aisle® DX Disease Activity Index Lab/Manufacturer: Progenotes Diagnostics, Inc.
0447U	Autoimmune diseases (systemic lupus erythematosus [sle]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a

Code	Description
	clinical flare Proprietary test: aisle® DX Disease Activity Index Lab/Manufacturer: Progenotes Diagnostics, Inc.
0521U	Rheumatoid factor IgA and IgM, cyclic citrullinated peptide (CCP) antibodies, and scavenger receptor A (SR-A) by immunoassay, blood Proprietary test: Seronegative Rheumatoid Arthritis Panel Lab Manufacturer: KSL Diagnostics-Beutner Laboratories, Inc, KSL Biomedical, Inc.
0522U	Carbonic anhydrase VI, parotid specific/secretory protein and salivary protein 1 (SP1), IgG, IgM, and IgA antibodies, chemiluminescence, semiqualitative, blood Proprietary test: Tissue Specific Markers for Early Diagnosis of Sjögren's Disease Lab Manufacturer: KSL Diagnostics, Inc, KSL Diagnostics, Inc. (Effective for DOS beginning 9/1/2026)

Evidence-based Scientific References

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Publication History

09/01/2026: Annual policy review; administrative edits; added code 0522U effective for DOS beginning Sept. 1, 2026
09/01/2025: Policy created to support coverage guidelines, effective for dates of service beginning Nov. 1, 2025

Background and Disclaimer Information

This policy applies to the products of Harvard Pilgrim Health Care and Tufts Health Plan and their affiliates, as identified in the check boxes on the first page for services performed by contracted providers.

Payment is based on member benefits and eligibility on the date of service, medical necessity review, where applicable, and the provider's network participation agreement with the Plan. As every claim is unique, this policy is neither a guarantee of payment, nor a final indication of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization, and utilization management requirements (when applicable), adherence to Plan policies and procedures, and claims editing logic. An authorization is not a guarantee of payment.

Point32Health reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated as applicable; please adhere to the most recent CPT and HCPCS coding guidelines.

We reserve the right to conduct audits on any provider and/or facility to ensure accuracy and compliance with the guidelines stated in this payment policy. If such an audit determines that a provider/facility did not comply with this payment policy, Harvard Pilgrim Health Care and Tufts Health Plan will expect the provider/facility to refund all payments related to noncompliance.