If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Texas may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSTX has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Biomarker Testing for Autoimmune Rheumatic Disease

Policy Number: CPCPLAB011

Version 1.0

Approval Date: April 28, 2025

Plan Effective Date: August 8, 2025

Description

The plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. For individuals with signs or symptoms of an autoimmune disease, screening for disease using antinuclear antibodies/ANA **may be reimbursable:**
    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 **may be reimbursable.**

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 **may be reimbursable:**
    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 times per year **may be reimbursable.**

5. For individuals with a negative or low positive ANA test, the following condition specific antibody testing **may be reimbursable**:
    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 **is not reimbursable.**

7. For individuals without symptoms suggestive of an autoimmune disorder, ANA and/or ENA testing, **is not reimbursable**.

8. For all other situations not described above, testing of specific antibodies in the absence of a positive ANA test **is not reimbursable**.

9. For asymptomatic individuals, testing of ANA and/or ENA during a wellness visit or a general exam without abnormal findings **is not reimbursable.**

10. For the diagnosis of RA, testing for serum biomarkers not discussed above, alone or in a panel (e.g., Seronegative Rheumatoid Arthritis Profile) **is not reimbursable.**

11. For the management of RA serum biomarker panel testing (e.g., Vectra DA score, PrismRA) **is not reimbursable.**

12. For the diagnosis of systemic lupus erythematosus/SLE the use of cell-bound complement activation products (e.g., AVISE Lupus) **is not reimbursable.**

13. For the diagnosis, prognosis, or monitoring of SLE or connective tissue diseases, serum biomarker panel testing with proprietary algorithms and/or index scores (e.g., AVISE CTD, AVISE SLE Monitor, AVISE SLE prognostic, aisle® DX Disease Activity Index, Early Sjögren's Syndrome Profile) **is not reimbursable.**

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
81490, 81599, 86038, 86039, 86200, 86225, 86235, 86430, 86431, 0039U, 0062U, 0312U, 0446U, 0447U, 0521U

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Policy Update History:

Approval Date	Effective Date: Summary of Changes
04/28/2025	08/08/2025; Document updated with literature review. The following changes were made to Reimbursement Information: #1, #2, #3 edited for clarity on the allowed frequency of biomarker testing. Addition of new #10: "For the diagnosis of RA, testing for serum biomarkers not discussed above, alone or in a panel (e.g., Seronegative Rheumatoid Arthritis Profile) is not reimbursable. Added the following to #13 as not reimbursable: aisle® DX Disease Activity Index, Early Sjögren's Syndrome Profile. Added codes 0446U, 0447U, 0521U; deleted code 0456U. References revised.
02/05/2025	05/15/2025; Added code 0521U. No other changes.
09/13/2024	01/01/2025: New policy.