Humana. Claims Payment Policy

Subject: Laboratory – Biomarker Testing for Autoimmune Rheumatic Disease

Application: Medicare Advantage Products
Policy number: LAB2023024
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Medicare Advantage Payment Policy

As a Medicare Advantage plan, we have developed payment policies to explain coverage more fully for services. The criteria outlined will apply to Medicare Advantage plans except when the procedure(s) has established criteria through the Original Medicare Local Coverage Determinations (LCDs) as outlined below.

In addition to this policy, claims payments are subject to other plan requirements for the processing and payment of claims, including, but not limited to, requirements of medical necessity and reasonableness and applicable referral or authorization requirements.

1. For individuals at a wellness visit or a general encounter without abnormal findings, Antinuclear antibodies (ANA) (CPT code 86038, CPT code 86039) and extractable nuclear antigen (ENA) (CPT code 86235) testing **IS NOT REIMBURSABLE**.
2. The use of cell-bound complement activation products (e.g., Avise Lupus) (CPT code 0312U) **IS NOT REIMBURSABLE**.
3. Any other serum biomarker panel testing with proprietary algorithms and index scores for the diagnosis of systemic lupus erythematosus or connective tissue diseases (CPT code 0062U) **IS NOT REIMBURSABLE**.

Applicable procedures for Medicare Advantage plans

Procedure Code	Code Description
86038	Antinuclear antibodies (ANA)
86039	Antinuclear antibodies (ANA); titer
86235	Extractable nuclear antigen, antibody to, any method (e.g., nRNP, SS-A, SS-B, Sm, RNP, Sc170, J01), each antibody
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

*The payment criteria for 0312U applies to all Medicare jurisdictions, except those states awarded to CGS Administrators, LLC; Noridian Healthcare Solutions, LLC; Palmetto GBA; and WPS Insurance Corporation

Original Medicare LCDs

Contractor Name	Policy Title	Policy Number	Procedure Code
CGS Administrators, LLC	MolDX: Molecular Diagnostic Tests (MDT)	L36021	0312U
Noridian Healthcare Solutions, LLC	MolDX: Molecular Diagnostic Tests (MDT)	L35160	0312U
Noridian Healthcare Solutions, LLC	MolDX: Molecular Diagnostic Tests (MDT)	L36256	0312U
Palmetto GBA	MolDX: Molecular Diagnostic Tests (MDT)	L35025	0312U
Wisconsin Physician Services Insurance Corp.	MolDX: Molecular Diagnostic Tests (MDT)	L36807	0312U

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