

Current Effective Date: 5/1/25

Status: Approved

Reviewed by Medical Policy Subcommittee: 5/1/25

Reviewed Dates: 3/20/25

INSTRUCTIONS FOR USE DISCLAIMER:

SummaCare posts policies relating to coverage and medical necessity issues to assist members and providers in administering member benefits. These policies do not constitute a contract or agreement between SummaCare and any member or provider. The policies are guidelines only and are intended to assist members and providers with coverage issues. SummaCare is not a health care provider, does not provide or assist with health care services or treatment, and does not make guarantees as to the effectiveness of treatment administered by providers. The treatment of members is the sole responsibility of the treating provider, who is not an employee of SummaCare, but is an independent contractor in private practice. The policies posted to this site may be updated and are subject to change without prior notice to members or providers.

Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Salimetrics® Salivary Melatonin Profile Policy

Indication/Usage:

Sjögren's syndrome is a systemic autoimmune disease characterized primarily by the immune system's attack on the body's moisture-producing glands, most notably the lacrimal and salivary glands, leading to dry eyes and dry mouth. Sjögren's syndrome can also affect other parts of the body, causing a range of systemic manifestations, including joint pain, fatigue, and organ involvement. Diagnosing **Sjögren's syndrome** is done through blood tests, eye tests, laboratory testing imaging and biopsy. The Early Sjögren's Syndrome Test Panel is a immunological tool for clinicians to identify patients earlier and to identify progression. Proprietary Laboratory Analyses (PLA) codes describe proprietary analyses licensed by 1 or multiple labs that may provide the analysis. They are meant to represent specific laboratory tests developed by a proprietary lab. When PLA codes are released there is inadequate

information clearly demonstrating that clinical validity or a definitive positive impact on clinical outcomes have been established.

Medical Indications for Authorization Commercial and Medicare Members

SummaCare considers the following laboratory test experimental, investigational, or unproven because the effectiveness of these approaches has not been established.

CPT Code

0472U: Carbonic anhydrase VI (CA VI), parotid specific/secretory protein (PSP) and salivary protein (SP1) IgG, IgM, and IgA antibodies, enzyme-linked immunosorbent assay (ELISA), semi qualitative, blood, reported as predictive evidence of early Sjögren's syndrome (Salimetrics® Salivary Melatonin Profile)

There are currently no NCD or LCD for per CMS

Limitations

There is limited information for the CPT codes listed in this policy and are considered experimental, investigational, or unproven.

Coverage Decisions

Coverage decisions made per CMS, Hayes and industry standards research

Plans Covered By This Policy

Commercial and Medicare

Considered experimental and investigational for all lines of business

Sources Reviewed

[Trinity-Biotech-Announces-Application-for-Early-Sjogrens-Syndrome-Test-Panel-PLA-Code.pdf](#)

[CPT® PLA Codes | American Medical Association](#)

[How To Use CPT Code 0462U - Updated 2025 - Coding Ahead](#)

[Sjogren's syndrome - Diagnosis and treatment - Mayo Clinic](#)

[CMS MCD Search](#)

[Hayes Knowledge Center | symplr](#)