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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.

2025 Oncology and PLA Biomarkers Policy

Indication/Usage:

Individualized molecular tumor profiling is a laboratory method of testing a panel of tumor markers, which may include genetic as well as biochemical markers, to establish a personalized molecular profile of a cancer to recommend treatment options. 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 tests experimental, investigational, or unproven because the effectiveness of these approaches has not been established.

CPT Codes

- 0450U:** Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, and results reported as baseline presence or absence of detectable clonotypic peptides. (M-insight)
- 0458U:** Oncology (breast cancer), S100A8 and S100A9, by enzyme-linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
- 0295U:** Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score (MammaPrint)
- 0558U:** Oncology (colorectal), quantitative enzyme linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression. IGoCheck™ (Blood-Based Colorectal Cancer Test), Milagen, Inc, Milagen, Inc
- 0559U:** Oncology (breast), quantitative enzyme linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression. MammoCheck™ (Blood-Based Breast Cancer Test), Milagen, Inc, Milagen, Inc
- 0573U:** Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastrin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non mucinous. Amplified Sciences PanCystPro™, Amplified Sciences, Inc

Other experimental PLA Codes

- 0574U:** Mycobacterium tuberculosis, culture filtrate protein 10 kDa (CFP 10), serum or plasma, liquid chromatography mass spectrometry (LC MS) NanoDetect-TB™, NanoPin Technologies, Inc

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

CPT® Code 0295U - Proprietary Laboratory Analyses - Codify by AAPC

DCISionRT (Prelude Corp.)

CPT® PLA Codes | American Medical Association

CMS MCD Search

Hayes Knowledge Center | symplr