

Current Effective Date: 8/27/25

Status New Policy: Approved

Reviewed by Medical Policy Subcommittee: 8/27/25

Reviewed Dates: 8/14/25

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#### **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.

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#### **Proprietary Laboratory Analyses Policy**

**Indication/Usage:** Proprietary Laboratory Analyses (PLA) codes are performed on humans and are requested by the clinical laboratory or the manufacturer that offers the test. Proprietary panels include gene targets that have been useful in the diagnosis of certain conditions but include gene targets of uncertain or unproven clinical significance. When PLA codes are released, there is very little clinical information available for review. Demonstrated value of the testing and to what extent the panel supports clinical decision making or definitive positive impact on clinical outcomes has not been established.

#### **Medical Indications for Authorization Commercial and Medicare Members**

The following PLA codes are considered experimental and investigational because the effectiveness has not been established.

There are currently no NCD or LCD per CMS

## CPT Codes

- 0365U:** Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
- 0503U:** Neurology (Alzheimer disease), beta amyloid (A $\beta$ 40, A $\beta$ 42, A $\beta$ 42/40 ratio) and tau-protein (ptau217, np-tau217, ptau217/np-tau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as likelihood of positive or negative for amyloid plaques
- 0577U:** Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy GlycoKnow™ Ovarian, InterVenn Biosciences
- 0579U:** Nephrology (diabetic chronic kidney disease), enzyme-linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline Promarker®D, Proteomics International USA, Proteomics International Pty Ltd
- 0580U:** *Borrelia burgdorferi*, antibody detection of 24 recombinant protein groups, by immunoassay, IgG iDart™ Lyme IgG ImmunoBlot Kit, IDFISH Technology, In
- 0581U:** Transplantation medicine, antibody to nonhuman leukocyte antigens (non-HLA), blood specimen, flow cytometry, single-antigen bead technology, 39 targets, individual positive antibodies reported Autoantibody to NonHuman Leukocyte Antigen (non-HLA), Mayo Clinic Jacksonville, Mayo Clinic
- 0584U:** Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative RT-QuIC Prion, CSF, Mayo Clinic, Mayo Clinic
- 0587U:** Therapeutic drug monitoring, 60-150 drugs and metabolites, urine, saliva, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), specimen validity, and algorithmic analyses for presence or absence of drug or metabolite, risk score predicted for adverse drug effects SafeDrugs, Astraeus Lab, LLC, Quantlio Technologies
- 0589U:** Perfluoroalkyl substances (PFAS) (e.g., perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative PFAS (Forever Chemicals) Panel 2 – 24 PFAS, Quest Diagnostics®, Quest Diagnostics®
- 0591U:** Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins and digital rectal examination,

results reported as a probability score for clinically significant prostate cancer MiCheck®  
Prostate, Minomic®, Inc, Minomic®, Inc

- 0594U:** Infectious disease (sepsis), semiquantitative measurement of pancreatic stone protein concentration, whole blood, reported as risk of sepsis IVD CAPSULE PSP – Rapid Sepsis Test, Abionic SA
- 0596U:** Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LC-MS/MS), reported as an APOE prototype Precivity-ApoETM, C2N Diagnostics, LLC
- 0598U:** Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels inFoods® IBS, Ethos Laboratories, Biomerica
- 0599U:** Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19 9, serum, diagnostic algorithm reported as positive or negative PancreaSureTM, Immunovia, Inc, Immunovia, Inc

### **Limitations**

These PLA codes are excluded from coverage due to lack of literature establishing clinical efficacy, safety, or applicability to clinical practice.

### **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® PLA Codes | American Medical Association](#)

[CPT Proprietary Laboratory Analyses Codes Short Descriptors | AMA](#)

CMS

[MCD Search](#)

Hayes

<https://evidence.hayesinc.com/>