Genetic Testing

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon* ☐ *Washington*

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Genetic testing, for purposes of this policy, are defined as tests performed to detect gene sequences or mutations which contribute to or cause certain diseases or conditions. This includes prenatal carrier screening and testing, chromosomal mircroarrray analysis, pharmoacogenomic testing, liquid-based panel testing (liquid biopsy), whole exome and genome sequencing, and polygenic risk score.

Carelon Medical Benefits Management, formerly AIM Specialty Health, reviews genetic testing codes (in scope) for PacificSource.

The codes considered out of scope by Carelon Medical Benefits Management will be reviewed by PacificSource. If Carelon Medical Benefits Management criteria is not available, PacificSource will use MCG, member specific benefit books or this policy to review genetic testing requests.

Note: In scope codes may require PacificSource review, rather than Carelon Medical Benefits Management due to a member's location, timeframes, or appeal process requirements.

Criteria

Commercial

Prior authorization is required.

PacificSource considers genetic testing medically necessary when at least **ONE** of the following conditions are met:

A. A requested genetic test meets the specific Carelon Medical Benefits Management criteria

B. A requested genetic test does not have specific Carelon Medical Benefits Management criteria available, but meets **ALL** of the following conditions:

- Original requisition form is submitted and clearly identifies requested test
- Confirming diagnosis by genetic testing would significantly influence medical or drug therapy, provide prognostic information, or provide prenatal/carrier information
- All codes within a panel are considered medically necessary. If any of the codes within a requested panel are considered to be experimental, investigational, or unproven; the entire panel will be considered to be experimental, investigational, or unproven

C. Veristrat proteomic testing (tumor marker) for advanced non-small cell lung cancer (NSCLC) when **ALL** of the following criteria is met:

- Tumor(s) are without tumor-cell epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) mutations
- Tumor(s) progression after at least one (1) chemotherapy regimen

Note: Results from Veristrat proteomic testing may be used to decide whether to proceed with erlotinib (Tarceva®) therapy

Medicaid

PacificSource Community Solutions follows the Oregon Health Plan (OHP) Prioritized List of Health Services and all Guideline Notes within, the OHP Diagnostic Procedure Codes/Procedure Group 1119.

PacificSource Community Solutions considers CPT codes 81535, 81536, 81538, 81417, 81479, 81599, 84999, S3854, 81541, , and 83722 to be experimental, investigational, or unproven per the New and Emerging Technologies - Coverage Status policy.

Medicare

PacificSource Medicare will use coverage determination set forth by Noridian MoIDx Covered-tests for clarification or tests out of the scope of AIM, in addition to diagnosis specific genetic testing outlined in LCDs and NCDs, respectively.

Experimental/Investigational/Unproven

PacificSource considers the following genetic tests to be Experimental/Investigational/ Unproven:

Genetic Test	**CPT/HCPCS Codes**
4K Score testing for prostate cancer	81539
Human epididymis protein 4 HE4 Assay	86305
Chemoresistance /chemosensitivity testing	81535, 81536, 88358
ST2 Assay	83006
Vectra™ DA (multi-biomarker blood test)	81490
VeriStrat Test (for all other indications not listed above)	81538

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

81417 Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g., updated knowledge or unrelated condition/syndrome)

81479 Unlisted molecular pathology procedure

81490 Autoimmune (rheumatoid arthritis), analysis of 12 biomarkers using immunoassays, utilizing serum, prognostic algorithm reported as a disease activity score

81535 Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination

81536 Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)

81538 Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival

81539 Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score

81541 Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score

81599 Unlisted multianalyte assay with algorithmic analysis

83006 Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)

86305 Human epididymis protein 4 (HE4)

83722 Lipoprotein, direct measurement; small dense LDL cholesterol

84999 Unlisted chemistry procedure

S3854 Gene expression profiling panel for use in the management of breast cancer treatment

Related Policies

New and Emerging Technologies - Coverage Status

References

Carelon Medical Benefits Management. Genetic Testing Guidelines. https://guidelines.carelonmedicalbenefitsmanagement.com/current-genetic-testing-guidelines/

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Oregon Health Authority. Oregon Health Plans Prioritized List Guideline Notes D1 and D17. https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx

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Washington State Health Care Authority. (July 13, 2018). Health Technology Clinical Committee (HTCC): Pharmacogenetic testing for patients being treated with oral anticoagulants. https://www.hca.wa.gov/assets/program/pharmaogenetic-testing-anticoagulants-final-findings-decision-20180713.pdf

Washington State Health Care Authority. (March 17, 2017). Health Technology Clinical Committee (HTCC): Pharmacogenetic testing for selected conditions. https://www.hca.wa.gov/assets/program/PDX-final-findings-decision-20170317.pdf

Appendix

Policy Number:

Effective: 6/1/2020 **Next review:** 3/1/2025

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s):

Commercial OPs: 5/2024

Government OPs: 5/2024