Genetic Testing

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

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, pharmacogenomic testing, liquid-based panel testing (liquid biopsy), whole exome and genome sequencing, and polygenic risk score.

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

The codes considered out of scope by Carelon Medical Benefits Management will be reviewed by PacificSource using Carelon criteria. 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

I. Genetic Testing

Prior authorization is required.

PacificSource considers genetic testing medically necessary when the following conditions are met:

A. The testing request is submitted by the ordering/requesting provider. Requests from servicing providers (e.g., third party or rendering) will not be accepted

AND at least **ONE** of the following:

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

C. 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 the codes within the requested 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

D. 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

II. Genetic Testing Limitations

PacificSource limits coverage of the following three genetic tests, which will not require prior authorization after 11/1/2024:

- Once per member lifetime:
  - Spinal Muscular Atrophy, CPT 81329
  - Cystic Fibrosis, CPT 81220
- Once per calendar year:
  - Fetal Chromosomal Aneuploidy (e.g., trisomy 21, monosomy X), CPT 81420

Note: Additional testing or coverage of these genetic tests may require Medical Director review for approval.

Medicaid

PacificSource Community Solutions follows an internal hierarchal process in the *"Clinical Criteria Used in UM Decisions"* policy, which includes reviewing each code to identify relevant guideline notes from the OHP Prioritized List of Health Services and Oregon Administrative Rules (OAR) for coverage of Genetic Testing.

In the absence of OHA guidance, PacificSource Community Solutions (PCS) follows Carelon Medical Benefits Management Genetic Testing criteria.

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Medicare

PacificSource Medicare follows CMS guidelines and criteria set forth by National Coverage Determinations (NCDs), or Local Coverage Determinations (LCDs). In the absence of CMS guidelines and criteria, PacificSource Medicare will follow Carelon external criteria guidelines or commercial criteria within a specific PacificSource (Genetic Testing or New and Emerging Technologies - Coverage Status) policy, as applicable, for coverage and medical necessity determinations.

PacificSource Medicare will begin limiting three genetic tests (per Section E, under Commercial Section), effectively after 1/1/2025 and prior authorization will no longer be required.

Experimental/Investigational/Unproven

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

Genetic Test	**CPT/HCPCS Codes**
Human epididymis protein 4 HE4 Assay*	86305
Chemoresistance and 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

Note: * indicates the item remains E/I/U but will not be reviewed annually by the NTOC Committee, unless requested.

Note: PacificSource Community Solutions (PCS) and PacificSource Medicare require items listed on this policy's E/I/U list, to be reviewed by medical necessity review guidelines. Please see related policy, "Clinical Criteria Used in UM Decisions" to review criteria hierarchy and "Medical Necessity Reviews" for determination of coverage and medical necessity guidelines.

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.

81220 CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines)

81329 SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed

81420 Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21

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

81599 Unlisted multianalyte assay with algorithmic analysis

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

84999 Unlisted chemistry procedure

86305 Human epididymis protein 4 (HE4)

88358 Morphometric analysis; tumor (e.g., DNA ploidy)

Related Policies

Clinical Criteria Used in UM Decisions

Clinical Resources Used for Medical Necessity Determinations When No Other UM Clinical Criteria or Guideline Exists

New and Emerging Technologies - Coverage Status

References

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American College of Obstetricians and Gynecologist (ACOG). (2018). Screening for Fetal Chromosomal Abnormalities.

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

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Appendix

Policy Number:

Effective: 6/1/2020 **Next review:** 11/1/2026

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): Oregon Administrative Rules (OARs) 410-141-3820, 410-141-3825, 410-120-1200, 410-151-0001, 410-151-0002

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