



Genetic Testing

State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:	LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
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Enterprise Policy

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 determination 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 procedure, is defined as those molecular genetic tests that are performed to detect gene sequences or mutations which contribute to or cause certain diseases or conditions.

PacificSource follows AIM Specialty Health genetic testing guidelines. Genetic testing requests not subject to AIM guidelines will be reviewed per this PacificSource Genetic Testing policy and appropriate contract language.

Criteria

Preauthorization is required

1. AIM Specialty Health (AIM)

- PacificSource covers genetic testing that meets AIM Specialty Health guidelines
- Genetic testing may be subject to regulatory guidelines in addition to AIM guidelines and follow:
 - **Medicaid:** must also meet the genetic testing criteria governed by the Oregon Health Plan (OHP) Prioritized List of Health Services and the OHP Diagnostic Procedure Codes / Procedure Group 1119.
<https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx>
 - <https://data.oregon.gov/Health-Human-Services/Diagnostic-Procedure-Codes-Procedure-Group-1119-/gmb4-77ea/data>
 - **Medicare:** will use coverage determination set forth by Noridian MoIDx Covered-tests for clarification or tests out of the scope of AIM
<https://med.noridianmedicare.com/web/jfb/policies/moldx/covered-tests>
 - **MCG**™ Care Guidelines
 - **Hayes** Inc. Technology and Hayes Genetic Testing Evaluation

- Hierarchy of criteria and resources identified in the PacificSource Clinical Criteria Used in UM Decisions policy

2. Criteria for genetic testing not subject to AIM Specialty Health guidelines

All of the following criteria must be met for coverage:

- Original requisition form submission is required
- Confirming the diagnosis by genetic testing would alter or significantly influence the medical management or drug therapy of the member;
- A medically acceptable and medically necessary treatment or intervention exists for the target disease, and the member would be an appropriate candidate for such treatment or the test does one or more of the following:
 - Change health monitoring
 - Provide prognosis
 - Provide information needed for genetic counseling for patient, or patient's parent, sibling, or child
- The tests and/or the treatments are not investigational or experimental, as defined in the member benefit book or by PacificSource Health Plans Policy New Technologies and Operational Criteria
- Pharmacogenetic: In addition to items 2a-d, pharmacogenetic testing coverage requires that the therapeutic drug target and genetic biomarker or gene mutation relationship is supported by evidence-based medicine
- Expanded Panels:
 - Each gene on panel must meet items 2a-d
 - Panel is considered to be experimental/investigational/unproven if one or more of the panel genes or gene mutations is determined to be experimental/investigational/unproven
 - Original requisition form will be used for determination of panel size (i.e., number of genes).

Experimental/Investigational/Unproven

PacificSource considers the following genetic tests Experimental/Investigational/Unproven

Genetic Test	CPT/HCPCS Codes
4K Score testing for prostate cancer	0010M, 81539
Afirma Genomic Sequencing Classifier (GSC)	No specific code 81210, 81275, 81311, 81401, 81406, 81455
Agendia Breast Cancer Test Suite (MammaPrint and Blueprint)	No specific code S3854, 81521, 81599
Ambry Genetic™ PancNext panel	No specific code
Anser IFX & Anser ADA, Anser UST, Anser VDZ, Infliximab, adalimumab, ustekinumab, vedolizumab antibody detection	No specific code, 84999, 80299
BluePrint Breast Cancer genomic profile	No specific code S3854, 81599
Boston Heart Cardiovascular Risk Panel – Genetic test	No specific code 81400
Boston Heart Labs Statin-induced myopathy genotype testing	No specific code 81400
BRCPlus Ambry Genetics™	No specific codes
Breast Cancer Index (BCI)	Code not specific to test: 81479, S3854
BreastNext Generation Ambry Genetics	No specific codes

BROCA Cancer Risk Panel	No specific codes
Cardiac Panel of Molecular Tests (Vantari Genetics, LLC)	No specific codes
CardioNext	No specific code 81280, 81282, 81403, 81404, 81405,
Cell Culture Drug Resistance Testing (CCDRT) Chemoresistance assay	86152 86153, 89240, S3711
Chromosome Analysis, High Resolution (Telomere Analysis)	88289
ColoNext (Ambry Genetics)	No specific code
ColonSentry	No specific codes 81479, 81599
ConfirmMDx for Prostate Cancer (MDxHealth)	No specific code 81479, 88387
Corus® CAD gene expression test	No specific code: 84999, 81599
Counsyl Foresight™ Carrier Screen (formerly Counsyl Family Prep Screen)	No specific code 81200, 81205, 81209, 81220, 81242, 81250, 81251, 81255, 81260, 81290, 81330, 81332, 81400, 81401, 81479
Counsyl Reliant Hereditary Cancer Screen	No specific code 81162, 81201, 81202, 81203, 81211, 81212, 81213, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81317, 81318, 81319, 81321, 81322, 81323, 81401, 81403, 81404, 81405, 81406 81408, 81479
Decision Dx-GBM (Castle Biosciences) gene expression profile test	No specific code 81479
Decision DX-Melanoma (Castle Biosciences) gene expression profile test	No specific code 84999
Fibrotest/Actitest	81596
FoundationOne™ and FoundationOne Heme	No specific codes
FoundationOne CDx	81201, 81206, 81210, 81211, 81235, 81242, 81245, 81270, 81275, 81292, 81295, 81298, 81310, 81315, 81321, 81455, 81479, 88360, 0037U no specific code
Genecept™ (Genomind LLC) saliva genetic assay for neuropsychiatric disorders	No specific code
GeneDX comprehensive brain malformations panel (whole exome sequencing)	No specific code 81404, 81405, 81406, 81407, 81408
GeneSight® ADHD assay	No specific Code 81225, 81226, 81227,

	81401,81479, 81599
GeneSightRx® Psychotropic assay	Codes not specific 81225, 81226, 81227, 81401, 81479,
Genetic Testing for Spinocerebellar Ataxia	No specific code
GeneTrails AML, MDS Genotyping Panel (Knight Diagnostic Laboratory)	No specific code 81403, 81404, 81405, 81479
gMS Dx anti-glycan antibody testing (Glycominds)	No specific code: 8499
Guardant360 (Guardant Health Inc.)	No specific code
HE4 Assay	86305
HERmark Breast Cancer Assay (Monogram Biosciences Inc.)	No specific code 84999
Inflammatory Bowel Disease Markers pANCA (perinuclear anti-neutrophil cytoplasmic antibodies) and ASCA (anti-saccharomyces cerevisiae antibodies)	No specific codes
Invitae Hyperparathyroid panel (genetic testing for CASR, CDC73, CDKN1B, MEN1, and RET)	81445, 81479, 81404, 81401, 81211, 81201, 81162
Medical Management Panel (Vantari Genetics)	No specific code 81225, 81226, 81227, 81240, 81241, 81291, 81355, 81401
Millennium PGT pharmacogenetic laboratory testing	No specific code 81225, 81226, 81227, 81291, 81401, 81479
Morphometric analysis of tumors (e.g. Extreme Drug Resistance Assay chemoresistance and chemosensitivity (EDR) by Oncotech and ChemoFX).	81535, 81536 88358
MTHFR for all indications	81291
MuSK (muscle specific Kinase) antibody	No specific code, 83519
Myeloid Molecular Profile (MMP)	No specific code 81270 81450
NxtPanel (Progenity)	No specific codes 81401, G0452, 81246
OncoGeneDx - Hereditary Pancreatic Cancer Panel	No specific code 81211, 81213, 81201, 81203, 81292, 81294, 81295, 81404
OncoGeneDx High/Moderate Risk Panel	No specific code 81211, 81213, 81294, 81292
OncoPanel	No specific code 81403
Oncotype DX Colon Cancer Assay	No specific code: 84999
Oncotype DX DCIS	No specific code
OncoVue Breast Cancer Risk Test	No specific code
PCA3 Detection Test for Prostate Cancer	S3721, 81313 Non-specific codes 84999, 81479
Percepta bronchial genomic classifier	No specific code 81479
PGXL Lab CYP1A2 Drug Metabolism Gene Assay	Non-specific codes 81225, 81226, 81227, 81401, 81479
PGxOne Plus (pharmacogenetics gene panel)	81479,81400, 81401, 81381, 81291, 81355, 81350, 81227, 81226, 81225

Preparent Standard Panel (genetic testing for procreative management)	No specific code 81220, 81209, 81200, 81251, 81260, 81242, 81290, 81330, 81255, 81250, 81401, 81243, 81257, 81205
Prolaris Test for Prediction of Prostate Cancer Progression	No specific code 84999 or 81599, 81541
Prometheus Anser UST test, ustekinumab antibody detection	no specific code, 84999, 80299
Prometheus Anser VDZ Test, vedolizumab antibody detection	84999 unlisted chemistry procedure
Prometheus IBD sgi diagnostic testing	No specific code 81479
Proove Narcotics Risk Genetic Profile, Proove Drug Metabolism	No specific codes 81225, 81226, 81227
Proove Pain Perception and comprehensive Genetic Profile panels	81291, 81355 81401, 81402 81479
RAD50 genetic testing	No specific code, 81479
Riscover Hereditary Cancer panel	No specific code 81403, 81404, 81405, 81406, 81407, 81432, 81433, 81435, 81436, 81479
SelectMDx (MDxHealth Inc.) for prostate cancer	No specific codes 81479
SensiGene Fetal RHD Genotyping	No specific codes 81479
ST2 Assay	83006
STA2R SureGene Test	No specific codes
Symphony Personalized Breast Cancer Genomic Profile (MammaPrint, BluePrint, TargetPrint, and TheraPrint)	No specific code: S3854 81599
TAADNext – Next Generation Sequencing (Ambry Genetics)	Non-specific codes 81405, 81406, 81408, 81479
ThyGenX	no specific code 81445,81479
ThyraMir oncogene panel	0018U
Vectra DA (multi-biomarker blood test)	81490
VeriStrat Test (Biodesix)	81538 No specific code 84999, 81599

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HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS)

Related Policies

Clinical Criteria Used in UM Decisions

New and Emerging Technologies_ Coverage Status

References

AIM® Genetic Testing Guidelines

MCG Guidelines 24th Edition.

Oregon Health Plans Prioritized List Guideline Notes D1 and D17.

Washington State Health Care Authority. Health technology reviews, 2020

<https://www.hca.wa.gov/about-hca/health-technology-assessment/health-technology-reviews>

Appendix

Policy Number:

Effective: 6/1/2020

Next review: 1/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s):

Commercial Ops: 5/2021

Government Ops: 5/2021