Genetic Testing

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

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 Guideline Notes D1 and D17. https://www.oregon.gov/oha/HPA/CSIHERC/PrioritizedList/4-1-2018%20Prioritized%20List%20of%20Health%20Services.pd
        - **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:

a) Original requisition form submission is required
b) Confirming the diagnosis by genetic testing would alter or significantly influence the medical management or drug therapy of the member;
c) 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:
   i. Change health monitoring
   ii. Provide prognosis
   iii. Provide information needed for genetic counseling for patient, or patient's parent, sibling, or child

d) 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

e) 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
f) Expanded Panels:
   i. Each gene on panel must meet items 2a-d
   ii. 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
   iii. Original requisition form will be used for determination of panel size (i.e., number of genes)

Related Policies

Clinical Criteria Used in UM Decisions

New and Emerging Technology_ Coverage Status

References

AIM® Genetic Testing Guidelines

MCG Guidelines 24th Edition.

Oregon Health Plans Prioritized List Guideline Notes D1 and D17.

Appendix

Policy Number: [Policy Number]

Effective: 6/1/2020 **Next review:** 6/1/2021

Policy type: Enterprise

Depts: Health Services

Applicable regulation(s): N/A

External entities affected: N/A