Genetic Counseling

MEDICAL POLICY NUMBER: 316

Effective Date: 9/1/2023
Last Review Date: 8/2023
Next Annual Review: 8/2024

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. The genetic counseling requirement may be considered **fulfilled and met** for any of the following (A. or B. or C.) criteria:

   A. Genetic testing is requested for member with any of the following, for which genetic counseling is not required (i.e., no criteria for genetic counseling must be met):
      a. To guide pharmacologic treatment (i.e., drug selection including but not limited to chemotherapy selection); or
      b. Testing is performed on tumor tissue samples of any type; or
      c. Hematological cancer.
   B. Prenatal genetic testing for a fetus to assess risk of a genetic condition and there is clinical documentation of genetic counseling submitted with the request including all of the following (a. – d.):
      a. Counseling provider is either a prenatal care provider (e.g., board-certified OBGYN, Family Medicine physician, certified nurse midwife) with training and ongoing experience in genetics or a board-eligible or board-certified genetic counselor (see Policy Guidelines section below for complete list of appropriate providers); and
      b. Testing is for risk assessment due to ultrasound results, maternal age, family history, NIPT or other documented factor; and
      c. If condition is hereditary, a full personal and family history has been conducted and is documented; and
      d. Post-test counseling is required if inconclusive or positive results.
   C. Genetic testing is requested for situations not described above in criteria A. or B. and there is clinical documentation of genetic counseling submitted with the request including all of the following (a. – f.):

a. That genetic testing information and pre-test counseling has been provided; and
b. Provider is a board-eligible or board-certified genetic counselor or board-certified physician with training and ongoing experience in genetics* (see Policy Guidelines section below for complete list of appropriate providers); and
c. A full personal and family history has been conducted and is documented; and
d. Patient has undergone and signed informed consent for genetic testing;
e. Post-test counseling to review the test results and determine future evaluation, medical management and treatment plans has been discussed and will be scheduled, if applicable; and
f. Any one of the following are met:
    i. Individual has cancer (excluding hematological cancer which does not require Genetic Counseling) and testing is being done to understand if the cancer is due to a hereditary condition and results will guide treatment management based on a confirmed variant; or
    ii. Patient is asymptomatic but has a family history of cancer and testing is being done to understand if the patient is **at risk** for developing cancer; or
    iii. Testing to determine a diagnosis of a hereditary condition (based on symptoms and family history) and results will guide treatment management based on a confirmed variant.

II. The genetic counseling requirement is considered **not fulfilled and not met** if the above criteria are not met

Link to Evidence Summary

POLICY CROSS REFERENCES

- Genetic Testing: CADASIL Disease, MP238
- Genetic Testing: Hereditary Breast and Ovarian Cancer, MP 143
- Genetic Testing: Inherited Susceptibility to Colorectal Cancer, MP115
- Genetic Testing: Inherited Thrombophilias, MP266
- Genetic Testing: Myeloproliferative Diseases, MP72
- Genetic Testing: Non-Covered Genetic Panel Tests, MP213
- Genetic Testing: Reproductive Planning and Prenatal Testing, MP78
- Genetic Testing: Whole Exome, Whole Genome and Proteogenomic Testing, MP219

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

Genetic Counseling Requirements

Genetic studies and counseling are approved subject to benefits when there is a medical condition that requires genetic counseling and potential subsequent testing to diagnose or to aid in planning a treatment course. Identification of a genetic disorder should result in medical and/or surgical management that is corrective and/or therapeutic in nature.[1]

Prior to authorization of a genetic test, the member must have undergone pretest counseling by a certified genetic counselor or a provider trained in genetics.[2] A provider trained in genetics is defined as providing risk assessment on a regular basis and having received specialized ongoing training in genetics. Education limited to learning how to order a test is not considered adequate training for risk assessment and genetic counseling. The provider may be required to provide documentation of genetic training and ongoing continual medical education (CME). Examples of providers trained in genetic counseling or genetics are:

- Board-Eligible or Board-Certified Genetic Counselor (CGC)
- Advanced Genetics Nurse (AGN-BC), Genetic Clinical Nurse (GCN)
- Advanced Practice Nurse in Genetics (APNG)
- Board-Eligible or Board-Certified Clinical Geneticist
- Board-Certified physician with training and ongoing experience in genetics (e.g., obstetrician–gynecologist; surgical oncologist; medical oncologist; fellowship-trained surgeon, pediatrician, family medicine.)

The genetic counseling visit is expected to encompass the following:

1. Pretest counseling documenting:

    - Comprehensive family history/pedigree which includes first-, second- and third-degree relatives on both maternal and paternal side of the family; and
    - Evaluation of a patient's cancer risk; and
    - A differential diagnosis and documentation of having educated the member on inheritance patterns, penetrance, variable expressivity and the possibility of genetic heterogeneity; and
    - Documentation that the member has been prepared for possible outcomes of testing including positive, negative and uncertain findings; and
    - When possible, family members with cancer associated with inherited breast and/or ovarian cancer should be tested first, prior to testing unaffected members.
        - Documentation that testing an unaffected member has significant limitations on interpreting test results. Pre-test counseling note should document the reason why none of these members can be tested prior to testing an unaffected member; and
    - Informed consent for genetic testing was obtained.

    Additional pretest counseling requirements for noninvasive prenatal screening only (based on recommendations by the American College of Obstetricians and Gynecologists [ACOG]):[3]

    Patients should be counseled that:

- Cell-free DNA screening does not replace the precision obtained with diagnostic tests, such as chorionic villus sampling or amniocentesis and, therefore, is limited in its ability to identify all chromosome abnormalities.
- Cell-free DNA screening does not assess risk of fetal anomalies such as neural tube defects or ventral wall defects.
- Cell-free DNA screening test should not be considered in isolation from other clinical findings and test results.
- Management decisions, including termination of the pregnancy, should not be based on the results of the cell-free DNA screening alone.
- A negative cell-free DNA test result does not ensure an unaffected pregnancy

2. Posttest counseling will be scheduled and expected to provide the following:[4]

- Results along with their significance and impact and recommended medical and/or surgical management options; and
- Interpretation of results in context of personal and family history of cancer; and
- Informing and recommending testing of at-risk family members; and
- Providing available resources such as disease-specific support groups and research studies; and
- Appropriate referral to medical specialties to assist with long term medical management and risk reduction strategies
- If a mutation is found, post-test counseling will include not only the affected member but recommendations regarding inherited risk to relatives and options for risk assessment and management
- If a mutation is found in a patient of reproductive age, post-test counseling will also include reproductive decision-making and/or risk assessment and management.

Additional posttest counseling requirements for noninvasive prenatal screening only (based on recommendations by ACOG):[5]

- Patients with a positive screening test for fetal aneuploidy should undergo genetic counseling and a comprehensive ultrasound evaluation with an opportunity for diagnostic testing to confirm results
- Patients with a negative screening test result should be made aware that this substantially decreases their risk of the targeted aneuploidy but does not ensure that the fetus is unaffected. The potential for a fetus to be affected by genetic disorders that are not evaluated by the screening or diagnostic test should also be reviewed. Even if patients have a negative screening test result, they may choose diagnostic testing later in pregnancy, particularly if additional findings become evident such as fetal anomalies identified on ultrasound examination.
- Patients whose cell-free DNA screening test results are not reported by the laboratory or are uninterpretable (a no-call test result) should be informed that test failure is associated with an increased risk of aneuploidy, receive further genetic counseling and be offered comprehensive ultrasound evaluation and diagnostic testing.
- If an enlarged nuchal translucency or an anomaly is identified on ultrasound examination, the patient should be offered genetic counseling and diagnostic testing for genetic

conditions as well as a comprehensive ultrasound evaluation including detailed ultrasonography at 18–22 weeks of gestation to assess for structural abnormalities.

Clinical Utility

Clinical utility of any genetic test is established by evaluating the following components of the test:

- Eliminates the need for further clinical workup or invasive testing
- Leads to changes in clinical management of the condition that improve outcomes
- Leads to discontinuation of interventions that are unnecessary and/or ineffective
- Leads to initiation of effective medication(s) and/or changes in dosing of a medication that is likely to improve outcomes
- Leads to discontinuation of medications that are ineffective or harmful

Provides prognostic information not revealed by standard laboratory and/or clinical testing that reclassifies patients into clinically relevant prognostic categories for which there are different treatment strategies

DOCUMENTATION REQUIREMENTS

In order to determine the clinical utility of a genetic test, the following documentation must be provided at the time of the request. Failure to submit complete documentation may affect the outcome of the review.

- Specific gene, trade or proprietary name of the test, or if a custom-built test, include every gene(s) and/or component of the test
- Name of laboratory where the testing is being conducted or was conducted
- Clinical notes to include the following:
  - Documentation of genetic counseling as required in the policy criteria below which includes how test results will impact clinical decision making
  - Reason (indication) for performing test, including the suspected condition
  - Existing signs and/or symptoms related to reason for current test request
  - Prior test/laboratory results related to reason for current test request
  - Family history, if applicable
  - How results from current test request will impact clinical decision making
- All relevant CPT/HCPCS codes billed

REFERENCES

1. Directors ABo. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. *Genet Med.* 2015;17(6):505-507.
2. Directors ABo. Points to consider in the clinical application of genomic sequencing. *Genet Med.* 2012;14(8):759-761.
3. Practice Bulletin No. 163 Summary: Screening for Fetal Aneuploidy. *Obstet Gynecol.* 2016;127(5):979-981.
4. David KL, Best RG, Brenman LM, et al. Patient re-contact after revision of genomic test results: points to consider-a statement of the American College of Medical Genetics and Genomics (ACMG). *Genet Med.* 2019;21(4):769-771.

5. American College of O, Gynecologists' Committee on Practice B-O, Committee on G, Society for Maternal-Fetal M. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. *Obstet Gynecol.* 2020;136(4):e48-e69.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
9/2023	Annual update. No changes to criteria