Medica Central Coverage Policy

Policy Name: Genetic Testing – Specialty Testing: Hematology

Effective Date: 01/01/2026

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

OVERVIEW

This policy addresses the use of diagnostic tests for benign (non-cancerous) hematologic conditions.

For additional information see the Rationale and References section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for additional registered tests.

POLICY REFERENCE TABLE

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Inherited Thrombophilia			
Factor V Leiden (*F5*) and Prothrombin (*F2*) Variant Analysis for Inherited Thrombophilia	Factor V (Leiden) Mutation Analysis (Quest Diagnostics)	81240, 81241, D68.2, D68.51, D68.59, I82.90, R79.1, Z86.2	Rationale/ References
	Prothrombin (Factor II) 20210G>A Mutation Analysis (Quest Diagnostics)		
Hemoglobinopathies			

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
HBA1/HBA2 and/or *HBB* Variant Analysis	Alpha Thalassemia Panel (Prevention Genetics, part of Exact Sciences)	81257, 81259, 81269, 81361, 81362, 81363, 81364, D56.0, D56.1, D56.3, D56.8, D56.9, D57, D64.9, R70.1, Z86.2	Rationale/ References
	Alpha-Globin Common Mutation Analysis (Quest Diagnostics)		
	Beta Globin (HBB) Sequencing (ARUP Laboratories)		
	Beta Globin Gene Dosage Analysis (Quest Diagnostics)		
Hemophilia			
Factor VIII (*F8*) and Factor IX (*F9*) Variant Analysis for Hemophilia A and B	Factor VIII (Hemophilia A) Genetic Analysis (LabCorp)	81238, 81403, 81406, 81407, D66, D67, I62.9, M25, N92.2, R04.0, R31	Rationale/ References
	Factor IX (Hemophilia B) Genetic Analysis (LabCorp)		
Fanconi Anemia			
Fanconi Anemia Multigene Panel	FancZoom (DNA Diagnostic Laboratory - Johns Hopkins Hospital)	81162, 81242, 81307, 81479, C92, D46.9, D61.09, D61.89, D61.9, L81.3, L81.4 Q02, R62.52	Rationale/ References
Other Covered Hematologic Conditions (non-cancerous)			
Other Covered Hematologic Conditions (non-cancerous)	See list below	81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408	Additional References

RELATED POLICIES

This policy document provides coverage criteria for benign (non-cancerous) hematologic conditions. Please refer to:

- ***Oncology Testing: Solid Tumor Molecular Diagnostics*** for coverage criteria related to molecular profiling of a known or suspected cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic / fusion testing).
- ***Specialty Testing: Nutrition and Metabolism*** for coverage criteria related to diagnostic and serum biomarker tests for nutritional status and biochemical disorders.

- ***General Approach to Laboratory Testing*** for coverage criteria related to genetic testing for non-cancerous hematologic disorders that are not specifically discussed in this or another non-general policy, including known familial variant testing.

back to top

COVERAGE CRITERIA

INHERITED THROMBOPHILIA

Factor V Leiden (*F5*) and Prothrombin (*F2*) Variant Analysis for Inherited Thrombophilia

I. *F5* and *F2* variant analysis to confirm or establish a diagnosis of an inherited thrombophilia is considered **medically necessary** when:

A. The member had a venous thromboembolism (VTE) that meets at least one of the following:

1. Provoked by a nonsurgical major transient risk factor, **OR**
2. Provoked by pregnancy or postpartum, **OR**
3. Provoked by combination oral contraceptive use, **OR**

B. The member is planning to discontinue anticoagulation after venous thromboembolism (VTE), **AND**

1. The member has a personal history of one of the following:

a) Cerebral venous thrombosis, **OR**

b) Splanchnic venous thrombosis, **OR**

C. The member has a minor provoking risk factor for VTE (e.g. immobility, minor injury, illness, infection), **AND**

1. The member has two first- or second-degree relatives with VTE, **OR**
2. The member meets both of the following:

a) At least one of the relatives had VTE under age 50, **AND**

b) The relative's thrombophilia status is unknown, **OR**

D. The member is a female planning a pregnancy, **AND**

1. Has a first- or second-degree relative who is known to be homozygous for factor V Leiden, **OR**
2. Has a first- or second-degree relative who is known to be a compound heterozygote for factor V Leiden and prothrombin (F2) mutation, **OR**

E. The member is receiving systemic cancer treatment, **AND**

1. Does not have a personal history of VTE, **AND**
2. Has a first-degree relative with VTE.

II. *F5* and *F2* variant analysis to confirm or establish a diagnosis of an inherited thrombophilia is considered **investigational** for all other indications, including:

A. Fetal loss or adverse pregnancy outcomes (examples: placental abruption, fetal growth restriction, or preeclampsia).

view rationale

back to top

HEMOGLOBINOPATHIES

HBA1/HBA2 and/or *HBB* Variant Analysis

I. *HBA1*/*HBA2* variant analysis and/or *HBB* variant analysis to confirm or establish a diagnosis of a hemoglobinopathy (alpha-thalassemia, beta-thalassemia, or sickle cell disease) is considered **medically necessary** when:

A. The member's hematologic screening results (examples: MCV, MCH, CBC, hemoglobin electrophoresis, or dichlorophenol indophenol (DCIP)) are positive for a hemoglobinopathy, **OR**

B. The member's hematologic screening results (examples: MCV, MCH, CBC, hemoglobin electrophoresis, or dichlorophenol indophenol (DCIP)) do not conclusively diagnose or rule out a hemoglobinopathy.

II. *HBA1*/*HBA2* variant analysis and/or *HBB* variant analysis to confirm or establish a diagnosis of a hemoglobinopathy (alpha-thalassemia, beta-thalassemia, or sickle cell disease) is considered **investigational** for all other indications.

view rationale

back to top

HEMOPHILIA

Factor VIII (*F8*) and Factor IX (*F9*) Variant Analysis for Hemophilia A and B

I. *F8* variant analysis and/or *F9* variant analysis to confirm or establish a diagnosis of hemophilia A or B is considered **medically necessary** when:

A. The member has any of the following clinical features of hemophilia:

1. Hemarthrosis (especially with mild or no antecedent trauma), **OR**
2. Deep-muscle hematomas, **OR**
3. Intracranial bleeding in the absence of major trauma, **OR**
4. Neonatal cephalohematoma or intracranial bleeding, **OR**
5. Prolonged oozing or renewed bleeding after initial bleeding stops following tooth extractions, mouth injury, or circumcision, **OR**
6. Prolonged, delayed bleeding, or poor wound healing following surgery or trauma, **OR**
7. Unexplained GI bleeding or hematuria, **OR**
8. Heavy or prolonged menstrual bleeding (especially with onset at menarche), **OR**

9. Prolonged nosebleeds, especially recurrent and bilateral, **OR**
10. Excessive bruising (especially with firm, subcutaneous hematomas), **OR**

B. The member has the following laboratory features:

1. Normal platelet count, **AND**
2. Prolonged activated partial thromboplastin time (aPTT), **AND**
3. Normal prothrombin time (PT).

II. *F8* variant analysis and/or *F9* variant analysis to confirm or establish a diagnosis of hemophilia A or B is considered **investigational** for all other indications.

view rationale

back to top

FANCONI ANEMIA

Fanconi Anemia Multigene Panel

I. Multigene panel analysis to establish or confirm a genetic diagnosis of Fanconi anemia is considered **medically necessary** when:

A. The member had a positive or inconclusive result via chromosome breakage analysis, **AND**

B. The member displays at least one of the following:

1. Prenatal and/or postnatal short stature, **OR**
2. Abnormal skin pigmentation (e.g., café au lait macules, hyper- or hypopigmentation), **OR**
3. Skeletal malformations (e.g., hypoplastic thumb, hypoplastic radius, vertebral anomalies), **OR**
4. Microcephaly, **OR**
5. Ophthalmic anomalies, **OR**
6. Genitourinary tract anomalies (e.g., horseshoe kidney, hypospadias, bicornuate uterus), **OR**
7. Macrocytosis, **OR**
8. Increased fetal hemoglobin (often precedes anemia), **OR**
9. Cytopenia (especially thrombocytopenia, leukopenia and neutropenia), **OR**
10. Progressive bone marrow failure, **OR**
11. Adult-onset aplastic anemia, **OR**
12. Myelodysplastic syndrome (MDS), **OR**
13. Acute myelogenous leukemia (AML), **OR**

14. Early-onset solid tumors (e.g., squamous cell carcinomas of the head and neck, esophagus, and vulva; cervical cancer; and liver tumors), **OR**

15. Inordinate toxicities from chemotherapy or radiation.

II. Multigene panel analysis to establish or confirm a genetic diagnosis of Fanconi anemia is considered **investigational** for all other indications.

view rationale

back to top

OTHER COVERED HEMATOLOGIC CONDITIONS (NON-CANCEROUS)

Other Covered Hematologic Conditions (non-cancerous)

The following is a list of conditions that have a known genetic association. Due to their relative rareness, it may be appropriate to cover these genetic tests to establish or confirm a diagnosis.

I. Genetic testing to establish or confirm one of the following hematologic conditions (non-cancerous) to guide management is considered **medically necessary** when the member demonstrates clinical features consistent with the disorder (the list is not meant to be comprehensive, see II below):

A. Atypical Hemolytic-Uremic Syndrome (aHUS) (*C3, CD46, CFB, CFH, CFHR1, CFHR3, CFHR4, CFHR5, CFI, DGKE, THBD, VTN)*

B. Complete Plasminogen Activator Inhibitor 1 Deficiency (PAI-1) (*SERPINE1)*

C. Diamond-Blackfan Anemia (DBA) (*GATA17, RPL5, RPL9, RPL11, RPL15, RPL18, RPL26, RPL27, RPL31, RPL35, RPL35A, RPS7, RPS10, RPS15A, RPS17, RPS19, RPS24, RPS26, RPS27, RPS28, RPS29, TSR2)*

D. Hereditary Spherocytosis (*ANK1, EPB42, SLC4A1, SPTA1, SPTB*)

E. Factor VII Deficiency (*F7*)

F. Factor X Deficiency (*F10*)

G. Factor XI Deficiency (Hemophilia C) (*F11*)

H. Factor XII Deficiency (*F12*)

I. Factor XIII Deficiency (*F13A1)*

II. Genetic testing to establish or confirm the diagnosis of all other non-cancerous hematologic conditions not specifically discussed within this or another medical policy will be evaluated by the criteria outlined in *General Approach to Laboratory Testing* (see policy for coverage criteria).

NOTE: Clinical features for a specific disorder may be outlined in resources such as GeneReviews, OMIM, National Library of Medicine, Genetics Home Reference, or other scholarly source.

back to top

RATIONALE AND REFERENCES

Factor V Leiden (*F5*) and Prothrombin (*F2*) Variant Analysis for Inherited Thrombophilia

American Society of Hematology (ASH)

Evidence based guidelines published by ASH in 2023 provide recommendations for testing for thrombophilia, including hereditary and acquired types. These recommendations are helpful to guide anticoagulation treatment for patients with a personal or family history of venous thromboembolism (VTE).

The panel provided conditional recommendations for thrombophilia testing in the following scenarios:

- Patients with VTE associated with nonsurgical major transient or hormonal risk factors;
- Patients with cerebral or splanchnic venous thrombosis, in settings where anticoagulation would otherwise be discontinued;
- Pregnant women with a family history (first or second degree relative) of high-risk thrombophilia types;
- Patients with cancer receiving systemic therapy at low or intermediate risk of thrombosis and with a family history (first or second degree relative) of VTE (p. 7102-7104).

Recommendation 13 of the guideline says that “thrombophilia testing may be considered if a patient has multiple family members with VTE, if the family member with VTE was young…A positive history is defined as having a first or second degree relative with VTE” (p. 7121).

The panel does not address or recommend testing for patients with cancer who have a personal history of VTE or who are at high risk of VTE (p. 7132). The panel also strongly recommends against thrombophilia testing in the general population before starting combined oral contraceptives (p. 7101).

Middeldorp S, Nieuwlaat R, Baumann Kreuziger L, et al. American Society of Hematology 2023 guidelines for management of venous thromboembolism: thrombophilia testing. Blood Adv. 2023;7(22):7101-7138. doi:10.1182/bloodadvances.2023010177

American College of Obstetricians and Gynecologists (ACOG)

ACOG practice bulletin No. 197 (2018, reaffirmed 2022) on inherited thrombophilias in pregnancy states that “...screening for inherited thrombophilias is not recommended for women with a history of fetal loss or adverse pregnancy outcomes including abruption, preeclampsia, or fetal growth restriction because there is insufficient clinical evidence that antepartum prophylaxis with unfractionated heparin or low-molecular-weight-heparin prevents recurrence in these patients, and a causal association has not been established” (p. e23).

American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Obstetrics. ACOG Practice Bulletin No. 197: Inherited Thrombophilias in Pregnancy [published correction appears in Obstet Gynecol. 2018 Oct;132(4):1069. (Reaffirmed 2022). Obstet Gynecol. 2018;132(1):e18-e34. doi:10.1097/AOG.0000000000002703 doi:10.1097/AOG.0000000000002924.

back to top

HBA1/HBA2 and/or *HBB* Variant Analysis

GeneReviews: Alpha-Thalassemia

GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.

The recommended hemoglobinopathy evaluation testing for Alpha-Thalassemia, Beta-Thalassemia, and Sickle Cell Disease are as follows:

Hemoglobin Bart hydrops fetalis (Hb Bart) syndrome, which is caused by deletion or inactivation of all four alpha globin genes, exhibits the following hematologic findings: severe macrocytic hypochromic anemia (in the absence of ABO or Rh blood group incompatibility), reticulocytosis (may be >60%), and peripheral blood smear with large, hypochromic red cells, severe anisopoikilocytosis, and numerous nucleated red cells. In addition, hemoglobin analysis will typically display decreased amounts or complete absence of hemoglobin A and increased amounts of Hb Bart.

Hemoglobin H disease (HbH disease), which is caused by deletion or inactivation of three alpha globin genes, exhibits the following hematologic findings: mild-to-moderate (rarely severe) microcytic hypochromic hemolytic anemia, moderate reticulocytosis (3%-6%), Peripheral blood smear with anisopoikilocytosis, and very rarely nucleated red blood cells, Red blood cell supravital stain showing HbH inclusions (β4 tetramers) in 5%-80% of erythrocytes following incubation of fresh blood smears with 1% brilliant cresyl blue for one to three hours. In addition, hemoglobin analysis will typically display the presence of 0.8%-40% HbH and 60%-90% hemoglobin A.

Tamary H, Dgany O. Alpha-Thalassemia. 2005 Nov 1 [Updated 2024 May 23]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1435/

GeneReviews: Beta-Thalassemia

GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.

Beta-Thalassemia typically displays the following hematologic findings: microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and decreased or complete absence of hemoglobin A (HbA) and increased hemoglobin A2 (HbA2) and often hemoglobin F (HbF) on hemoglobin analysis.

Langer, A. Beta-Thalassemia. 2000 Sep 28 [Updated 2024 February 8]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1426/

GeneReviews: Sickle Cell Disease

GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.

Laboratory features of sickle cell disease include: normocytic anemia; sickle cells, nucleated red blood cells, target cells, and other abnormal red blood cells on peripheral blood smear; Howell-Jolly bodies indicate hyposplenism; presence of hemoglobin S (HbS) on a hemoglobin assay (e.g., high-performance liquid chromatography [HPLC], isoelectric focusing, cellulose acetate electrophoresis, citrate agar electrophoresis) with an absence or diminished amount of HbA.

Bender MA and Carlberg, K. Sickle Cell Disease. 2003 Sep 15 [Updated 2025 Feb 13]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1377/

Viprakasit et al

In 2018, Viprakasit and Ekwattanakit published a clinical classification, screening and diagnosis for thalassemia article that states:

In general, these mutation analyses would be critical for the confirmation of thalassemia diagnoses in only a few selected cases for whom the basic hematology and Hb analysis described

could not provide a conclusive diagnosis. However, these molecular analyses would be indispensable in a program for the prevention and control of thalassemia syndromes because the mutation data would be required for genetic counseling, genetic risk calculation in the offspring, and prenatal and preimplantation genetic diagnosis. In addition, DNA analysis could help in predicting the clinical severity and guiding clinical management; milder b-globin mutations (b1-thal) usually are associated with milder phenotypes, as has been shown in HbE/b-thalassemia (p. 207).

Viprakasit V, Ekwattanakit S. Clinical Classification, Screening and Diagnosis for Thalassemia. Hematol Oncol Clin North Am. 2018;32(2):193-211. doi:10.1016/j.hoc.2017.11.006

back to top

Factor VIII (*F8*) and Factor IX (*F9*) Variant Analysis for Hemophilia A and B

GeneReviews: Hemophilia A and Hemophilia B

GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.

The recommended hemoglobinopathy evaluation testing for Hemophilia A and Hemophilia B is as follows:

Individuals with Hemophilia A (factor VIII deficiency) or Hemophilia B (factor IX deficiency) can exhibit the following clinical symptoms:

- Hemarthrosis, especially with mild or no antecedent trauma
- Deep-muscle hematomas
- Intracranial bleeding in the absence of major trauma
- Neonatal cephalohematoma or intracranial bleeding
- Prolonged oozing or renewed bleeding after initial bleeding stops following tooth extractions, mouth injury, or circumcision
- Prolonged or delayed bleeding or poor wound healing following surgery or trauma
- Unexplained GI bleeding or hematuria
- Heavy menstrual bleeding, especially with onset at menarche
- Prolonged nosebleeds, especially recurrent and bilateral
- Excessive bruising, especially with firm, subcutaneous hematomas

The following are laboratory findings in individuals with Hemophilia A or Hemophilia B:

- Normal platelet count
- Prolonged activated partial thromboplastin time (aPTT) (Note: in mild hemophilia B, aPTT may be normal or mildly prolonged)
- Normal prothrombin time (PT)

Konkle BA, Nakaya Fletcher S. Hemophilia A. 2000 Sep 21 [Updated 2023 Jul 27]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1404/

Konkle BA, Nakaya Fletcher S. Hemophilia B. 2000 Oct 2 [Updated 2023 Feb 9]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1495/

back to top

Fanconi Anemia Multigene Panel

Fanconi Anemia Research Foundation

In 2020, the Fanconi Anemia Research Foundation issued guidelines on diagnosis and management of the disease, which stated the following in regard to genetic testing:

If the results from the chromosome breakage test are positive, genetic testing should be performed to identify the specific FA-causing variants. Genetic testing enables accurate diagnosis and improves clinical care for individuals with anticipated genotype/phenotype manifestations and for relatives who are heterozygous carriers of FA gene variants that confer increased risk for malignancy (p. 28, additional testing methodologies pages 29-45).

Sroka I, Frohnmayer L, Van Ravenhorst S, Wirkkula L, eds. Fanconi Anemia: Guidelines for Diagnosis and Management. 5th ed. Fanconi Anemia Research Foundation; 2020:21-33.

GeneReviews: Fanconi Anemia

GeneReviews is an expert-authored review of current literature on a genetic disease, and goes through a rigorous editing and peer review process before being published online.

Fanconi anemia (FA) should be suspected in individuals with the following clinical and laboratory features:

Physical features (in ~75% of affected persons):

- Prenatal and/or postnatal short stature
- Abnormal skin pigmentation (e.g., café au lait macules, hypopigmentation)
- Skeletal malformations (e.g., hypoplastic thumb, hypoplastic radius)
- Microcephaly
- Ophthalmic anomalies
- Genitourinary tract anomalies

Laboratory findings:

- Macrocytosis
- Increased fetal hemoglobin (often precedes anemia)
- Cytopenia (especially thrombocytopenia, leukopenia, and neutropenia)

Pathology findings:

- Progressive bone marrow failure
- Adult-onset aplastic anemia
- Myelodysplastic syndrome (MDS)
- Acute myelogenous leukemia (AML)
- Early-onset solid tumors (e.g., squamous cell carcinomas of the head and neck, esophagus, and vulva; cervical cancer; liver tumors)
- Inordinate toxicities from chemotherapy or radiation

Mehta PA, Tolar J. Fanconi Anemia. 2002 Feb 14 [Updated 2021 Jun 3]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1401/

back to top

DEFINITIONS

1. **Close relatives** include first, second, and third degree blood relatives:

    a. **First-degree relatives** are parents, siblings, and children

    b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings

c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins

2. A **Nonsurgical major transient risk factor** includes confinement to bed in the hospital with acute illness for at least 3 days, or a combination of minor transient risk factors such as admission of less than 3 days with acute illness or confinement to bed outside of hospital for at least 3 days, or leg injury associated with decreased mobility for at least 3 days.

back to top

ADDITIONAL REFERENCES

1. MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US). Available from: https://medlineplus.gov/genetics/.
2. Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1116/
3. Online Mendelian Inheritance in Man, OMIM. McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University (Baltimore, MD). World Wide Web URL: https://omim.org/

back to top

Note: The Health Plan uses the genetic testing clinical criteria developed by Concert Genetics, an industry-leader in genetic testing technology assessment and policy development.

back to top

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