# Dean Health Plan Coverage Policy

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| **Policy Name:** | **Genetic Testing: Hematologic Conditions (Non-Cancerous) MP9595** |
| **Effective Date:** | **January 1, 2025** |

**Important Information – Please Read Before Using This Policy**
These services may or may not be covered by Dean Health Plan. 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 Dean Health Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this medical policy see Provider Communications for additional information. https://deancare.com/Providers/Provider-communications

Dean Health Plan medical policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

## OVERVIEW

Genetic testing for hematologic (non-cancerous) conditions may be used to confirm a diagnosis in a patient who has signs and/or symptoms of a specific hematologic condition. Confirming the diagnosis may alter aspects of management and may eliminate the need for further diagnostic workup. This document addresses genetic testing for common hematologic (non-cancerous) conditions.

## POLICY REFERENCE TABLE

The tests, associated laboratories, CPT codes, and ICD codes contained within this document serve only as examples to help users navigate claims and corresponding coverage criteria; as such, they are not comprehensive and are not a guarantee of coverage or non-coverage. Please see the Concert Platform for a comprehensive list of registered tests.

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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| Coverage Criteria Sections | Example Tests (Labs) | Common CPT Codes | Common ICD Codes | Ref |
|---|---|---|---|---|
| **Inherited Thrombophilia** | | | | |
| Factor V Leiden (*F5*) and Prothrombin (*F2*) Variant Analysis for Inherited Thrombophilia | Factor V (Leiden) Mutation Analysis (Quest Diagnostics) | 81241 | D68.51, D68.2, D68.59, R79.1, Z86.2, I82.90 | 1, 5 |
| | Prothrombin (Factor II) 20210G>A Mutation Analysis (Quest Diagnostics) | 81240 | D68.52, D68.2, D68.59, R79.1, Z86.2, I82.90 | |
| **Hemoglobinopathies** | | | | |
| *HBA1*/*HBA2* and/or *HBB* Variant Analysis | Alpha Thalassemia Panel (Prevention Genetics, part of Exact Sciences) | 81259, 81269 | D56.0, D56.9, D53.9, R70.1, D56.3, D56.8, Z86.2 | 2, 3, 4, 6 |
| | Alpha-Globin Common Mutation Analysis (Quest Diagnostics) | 81257 | | |
| | Beta Globin (HBB) Sequencing (ARUP Laboratories) | 81364 | D57, D56.1, D64.9 | |
| | Beta Globin Gene Dosage Analysis (Quest Diagnostics) | 81363 | | |
| **Hemophilia** | | | | |
| Factor VIII (F8) and Factor IX (F9) Variant Analysis for Hemophilia A and B | Factor VIII (Hemophilia A) Genetic Analysis (Labcorp) | 81403, 81406, 81407 | D66, I62.9, M25, N92.2, R04.0, R31 | 8, 9 |
| | Factor IX (Hemophilia B) Genetic Analysis (Labcorp) | 81238 | D67, I62.9, M25, N92.2, R04.0, R31 | |
| **Glucose-6-Phosphate Dehydrogenase (*G6PD*) Deficiency** | | | | |
| *G6PD* Variant Analysis | G6PD Targeted Variant - Single Test (GeneDx)<br>G6PD Full Gene Sequencing and Deletion/Duplication (Invitae) | 81247, 81248, 81249, 81479 | D55.0 | 7, 14 |
| **von Willebrand Disease** | | | | |
| *VWF* Variant Analysis | Von Willebrand Disease Gene Sequencing (Quest) | 81408, 81479 | D68.0 | 10 |

| Coverage Criteria Sections | Example Tests (Labs) | Common CPT Codes | Common ICD Codes | Ref |
|---|---|---|---|---|
| **Other Covered Hematologic Conditions (non-cancerous)** | | | | |
| Other Covered Hematologic Conditions (non-cancerous) | See list below | 81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408 | | 11, 12, 13 |

## OTHER RELATED POLICIES

This policy document provides coverage criteria for Genetic Testing for Hematologic Conditions (Non-Cancerous). Please refer to:

- ***Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies*** for coverage criteria related to exome and genome sequencing of solid tumors and hematologic malignancies.
- ***Genetic Testing: Prenatal and Preconception Carrier Screening*** for coverage criteria related to carrier screening in the prenatal, preimplantation, and preconception setting.
- ***Genetic Testing: Prenatal Diagnosis (via amniocentesis, CVS, or PUBS) and Pregnancy Loss*** for coverage related to prenatal and pregnancy loss diagnostic genetic testing for tests intended to diagnose genetic conditions following amniocentesis, chorionic villus sampling or pregnancy loss.
- ***Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay*** for coverage criteria related to diagnostic genetic testing for conditions affecting multiple organ systems.
- ***Genetic Testing: Metabolic, Endocrine, and Mitochondrial Disorders*** for coverage criteria related to genetic testing for *MTHFR*.
- ***Genetic Testing: General Approach to Genetic and Molecular 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.

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## COVERAGE CRITERIA

### INHERITED THROMBOPHILIA

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

I. *F5* (81241) and *F2* (81240) 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 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* (81241) and *F2* (81240) 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).

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## HEMOGLOBINOPATHIES

### *HBA1*/*HBA2* and/or *HBB* Variant Analysis

I. *HBA1*/*HBA2* variant analysis (81257, 81259, 81269) and/or *HBB* variant analysis (81363, 81364) 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 (81257, 81259, 81269) and/or *HBB* variant analysis (81363, 81364) to confirm or establish a diagnosis of a hemoglobinopathy (alpha-thalassemia, beta-thalassemia, or sickle cell disease) is considered **investigational** for all other indications.

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## HEMOPHILIA

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

I. *F8* variant analysis (81403, 81406, 81407) and/or *F9* variant analysis (81238) 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 (81403, 81406, 81407) and/or *F9* variant analysis (81238, 81479) to confirm or establish a diagnosis of hemophilia A or B is considered **investigational** for all other indications.

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**GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY**

***G6PD* Variant Analysis**

I. *G6PD* variant analysis (81247, 81248, 81249, 81479) to confirm or establish a diagnosis* of glucose-6-phosphate dehydrogenase deficiency is considered **investigational**.

* Diagnosis of *G6PD* can be achieved by quantitative spectrophotometric analysis or, more commonly, by a rapid fluorescent spot test detecting the generation of NADPH from NADP.

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**VON-WILLEBRAND DISEASE**

***VWF* Variant Analysis**

I. *VWF* variant analysis (81408, 81479) to confirm or establish a diagnosis* of von-Willebrand disease is considered **investigational**.

* Diagnosis of von-Willebrand disease can be achieved by standard laboratory and biochemical testing.

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**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)
B. Complete Plasminogen Activator Inhibitor 1 Deficiency (PAI-1)
C. Diamond-Blackfan Anemia (DBA)
D. Hereditary Spherocytosis

E. Factor VII Deficiency
F. Factor X Deficiency
G. Factor XI Deficiency (Hemophilia C)
H. Factor XII Deficiency
I. Factor XIII Deficiency

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 Genetic and Molecular Testing* (see policy for coverage criteria).

*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.

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## DEFINITIONS

1. **Close relatives** include first, second, and third degree blood relatives on the same side of the family:
    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. **Nonsurgical transient risk factors** include 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.

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## PRIOR AUTHORIZATION

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

## BACKGROUND AND RATIONALE

**Factor V Leiden (*F5*) and Prothrombin (*F2*) Variant Analysis for Inherited Thrombophilia**
*American Society of Hematology (ASH)*
Evidence based guidelines published 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;
- individuals with a family history (first or second degree relative) of VTE when considering thromboprophylaxis for minor provoking risk factors and for guidance to avoid COCs/hormone replacement therapy;
- 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.

The panel also strongly recommends against thrombophilia testing in the general population before starting combined oral contraceptives. (p. 7101)

*American College of Obstetricians and Gynecologists (ACOG)*

ACOG also published Practice Bulletin 197 (2018) on Inherited Thrombophilias in Pregnancy which 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)

***HBA1/HBA2* and/or *HBB* Variant Analysis**

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 is as follows:

*GeneReviews: Alpha-Thalassemia*

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.

*GeneReviews: Beta-Thalassemia*

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.
*GeneReviews: Sickle Cell Disease*
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.
*Viprakasit V, Ekwattanakit S. Clinical classification, screening and diagnosis for thalassemia*
Viprakasit and Ekwattanakit (2018) 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)

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

*GeneReviews: Hemophilia A and Hemophilia B*
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)

### *G6PD* Variant Analysis

*American Academy of Family Physicians*

Frank (2005) published guidelines in American Family Physician for evaluating individuals for *G6PD* deficiency, including specific laboratory tests which notably do not include genetic testing: "The diagnosis of *G6PD* deficiency is made by a quantitative spectrophotometric analysis or, more commonly, by a rapid fluorescent spot test detecting the generation of NADPH from NADP. The test is positive if the blood spot fails to fluoresce under ultraviolet light." (p. 1278)

*UpToDate: Diagnosis and management of glucose-6-phosphate dehydrogenase (G6PD) deficiency*

Per this summary of G6PD diagnosis and management, the tests commonly used are semi-quantitative screening tests, some of which are done at the point-of-care. Positive screening tests should be followed up with a quantitative test that reports G6PD enzyme activity per gram of hemoglobin. If initial results are negative, testing should be repeated three months following resolution of the hemolytic episode. Confirmatory testing using molecular methods (DNA) is available; however, it is not used routinely and is not useful for those of African or Mediterranean ancestry.

### *VWF* Variant Analysis

*Centers for Disease Control and Prevention (CDC)*

Guidelines for diagnosis and management of von Willebrand disease (VWD) were developed by the CDC for practicing primary care and specialist clinicians - including family physicians, internists, obstetrician-gynecologists, pediatricians, and nurse-practitioners - as well as hematologists and laboratory medicine specialists, which included recommendations for laboratory tests to aid in the diagnosis of VWD, which notably do not include genetic testing.

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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.

| | Committee/Source | Date(s) |
|---|---|---|
| **Document Created:** | Medical Policy Committee/Health Services Division | November 16, 2022 |
| **Revised:** | Medical Policy Committee/Health Services Division | March 15, 2023 |
| | Medical Policy Committee/Health Services Division | August 16, 2023 |
| | Medical Policy Committee/Health Services Division | February 20, 2024 |
| **Reviewed:** | Medical Policy Committee/Health Services Division | March 15, 2023 |
| | Medical Policy Committee/Health Services Division | August 16, 2023 |
| | Medical Policy Committee/Health Services Division | February 20, 2024 |

# Dean Health Plan Coverage Policy

Re-Review Dates
December 19, 2024 Concert Genetics Effective Date: January 01, 2025 (V.1.2025)