

The Department of Vermont Health Access Clinical Criteria

Subject: Hereditary Hemochromatosis Genetic Testing

Last Review: February 10, 2023*

Past Revisions: January 31, 2022, November 20, 2020, August 11, 2016

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Hereditary hemochromatosis (HH), also called genetic hemochromatosis, is one of the most commonly identified genetic disorders in Caucasians. HH alters the body's ability to regulate iron absorption. The mechanism for regulating iron absorption is faulty and the body absorbs too much iron from food. Over time the excess iron is deposited into cells of the liver, heart, pancreas, joints, and pituitary gland, leading to diseases such as cirrhosis of the liver, liver cancer, diabetes, heart disease or failure, and joint disease. Hereditary hemochromatosis is associated with mutations of several genes, but most commonly the HFE gene, which is responsible for producing the HFE protein. The two most common mutations found in the HFE gene related to HH are the C282Y and H63D mutations. In individuals affected by HH related to mutations of the HFE gene, one mutated HFE gene is inherited from each parent. Genetic testing can reveal whether these mutations exist in the HFE gene. It is important to note that not everyone who inherits a copy of the HFE gene with the C282Y and/or H63D mutation from each parent develops clinical features associated with HH.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 7405 Laboratory and Radiology Services
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services



Coverage Position

HH gene analysis may be covered for members:

- When HH gene analysis is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding HH gene analysis testing and results and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

Coverage Criteria

HH may be covered for a member with one or more of the following:

1. Who have abnormal iron study results indicating iron overload, even in the absence of symptoms. **OR**
2. With suggestive symptoms (examples: abdominal pain, weakness, lethargy, arthralgias, impotence, weight loss), physical findings (examples: cirrhosis of the liver, liver cancer, diabetes, heart disease or failure, joint disease, osteoporosis) AND an elevated transferrin saturation or serum ferritin test. **OR**
3. A family history of HH in a first degree relative. **OR**
4. Recommended screening (iron studies and HFE mutation analysis) of first-degree relatives of member's with HFE-related HH or evidence of active liver disease to detect early disease and prevent complications.

Definition: A first degree blood relative shares 50 % DNA (father, mother, brother, sister, daughter, or son).

Both genotype (HFE mutation analysis) and phenotype (ferritin and Transferrin saturation (TS) should be performed simultaneously at a single visit.

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Subsequent HH genetic testing is not **considered medically** necessary and will not be covered.

Type of service or procedure not covered (this list may not be all inclusive)

Average risk population screening for HH is not recommended.

References

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