

Genetic testing: gastroenterologic disorders (non-cancerous)

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for the following services:

- Genetic testing for Inflammatory Bowel Disease
- Genetic testing for Celiac Disease
- Non-invasive Liver Fibrosis Serum Tests
- Testing that is associated with a procedure code listed in "Box A", below.

Prior authorization is not required for the following:

- Genetic testing for Hereditary Pancreatitis
- Genetic testing for Hereditary Hemochromatosis

The following genetic tests do not require prior authorization because they are considered investigational/experimental and, therefore, not covered:

Inflammatory bowel disease/Crohn's disease diagnostic and prognostic algorithmic tests

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

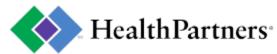
Box A: Genetic testing procedure codes that require prior authorization	
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)	
Unlisted multianalyte assays (CPT 81599)	
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test	

CPT Copyright American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes		
Celiac Disease					
HLA-DQ Genotyping Analysis	Celiac HLA DQ Association (Labcorp)	81375, 81376, 81377, 81382, 81383	K90.0, R10.0-R10.13, R10.3-R10.829, R10.84-R10.9		
	HLA Typing for Celiac Disease (Quest Diagnostics)				
Hereditary Hemochromatos	is				
HFE C282Y and H63D Genotyping	Hereditary Hemochromatosis DNA Mutation Analysis (Quest Diagnostics)	81256	E83.110, E83.118, E83.119, R79.0, E83.19, R16.0		
	HFE Targeted Variant - Single Test (GeneDx)				
Hereditary Pancreatitis					
Hereditary Pancreatitis Multigene Panel	Hereditary Pancreatitis Panel (GeneDx)	81222, 81223, 81404, 81405, 81479	K85.0-K85.9, K86.1, Z83.79		
Inflammatory Bowel Diseas	e				
Inflammatory Bowel Disease / Crohn's Disease Diagnostic Algorithmic Tests	Prometheus IBD sgi Diagnostic (Prometheus Laboratories)	81479, 82397, 83520, 86140, 88346	K50-K52		



Inflammatory Bowel Disease / Crohn's Disease Prognostic Algorithmic Tests	Prometheus Crohn's Prognostic (Prometheus Laboratories)	81401, 83520, 88346	K50-K52		
Hereditary Inflammatory Bowel Disease / Crohn's Disease Panel Tests	Monogenic Inflammatory Bowel Disease Panel (Invitae)	81479, 81321, 81406, 81407	K50-K52		
	Very Early Onset Inflammatory Bowel (VEO-IBD) Genomic Panel (Children's Hospital of Philadelphia-Division of Genomic Diagnostics)				
Non-invasive Liver Fibrosis Disease Serum Tests					
Non-invasive Liver Fibrosis Serum Tests	ASH FibroSURE (LabCorp) NASH FibroSURE (LabCorp)	0002M, 0003M	K76.0, R74.8, R94.5, R79.89, I10		
	FIB-4 Index Panel with Reflex to Enhanced Liver Fibrosis (ELF) Score (Quest Diagnostics)	84450, 84460, 85049			
	Enhanced Liver Fibrosis (ELF) Test (Siemens Health Care Diagnostics)	81517			

CPT Copyright American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Coverage

Celiac Disease

HLA-DQ Genotyping Analysis

- 1. *HLA-DQA1* and *HLA-DQB1* genotyping analysis to rule out celiac disease (CD) is considered **medically necessary** when:
 - A. The member is being evaluated for celiac disease, and
 - Had an inconclusive serology (antibody) result, or
 - ii. Had an inconclusive histology (biopsy) result, or
 - iii. Started a gluten-free diet before evaluation for celiac disease, and
 - B. *HLA-DQA1* and *HLA-DQB1* genotyping analysis has not been previously performed.
- 2. *HLA-DQA1* and *HLA-DQB1* genotyping analysis to rule out celiac disease is considered **investigational** for all other indications.

Back to top

Hereditary Hemochromatosis *HFE* C282Y and H63D Genotyping

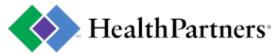
- 1. *HFE* C282Y and H63D genotyping to establish a diagnosis of hereditary hemochromatosis is considered **medically necessary** when:
 - A. The member has abnormal serum iron indices, defined as transferrin saturation greater than or equal to 45% and/or elevated ferritin, indicating iron overload, **or**
 - B. The member has a first-degree relative with a diagnosis of hereditary hemochromatosis.
- 2. *HFE* C282Y and H63D genotyping to establish a diagnosis of hereditary hemochromatosis is considered **investigational** for all other indications, including general population screening for hereditary hemochromatosis.

Back to top

Hereditary Pancreatitis

Hereditary Pancreatitis Multigene Panel

- 1. Hereditary pancreatitis multigene panel analysis to establish a diagnosis of hereditary pancreatitis is considered **medically necessary** when:
 - A. The member has a personal history of pancreatitis, and
 - B. The member meets at least one of the following:
 - i. Unexplained episode of acute pancreatitis in childhood (18 years or younger), or
 - ii. Recurrent (two or more separate, documented) acute attacks of pancreatitis for which there is no explanation (i.e., anatomical anomalies, ampullary or main pancreatic strictures, trauma, viral infection, gallstones, alcohol, drugs, hyperlipidemia, etc.), **or**
 - iii. Chronic pancreatitis of unknown cause, particularly with onset before age 35 years without a history of heavy alcohol use, **or**
 - iv. At least one close relative with recurrent acute pancreatitis, chronic pancreatitis of unknown cause, or childhood pancreatitis of unknown cause, **and**



- C. The panel includes, at a minimum, the following genes: *PRSS1*, *SPINK*, *CFTR*, and *CTRC*.
- 2. Hereditary pancreatitis multigene panel analysis to establish a diagnosis of hereditary pancreatitis is considered **investigational** for all other indications.

Back to top

Inflammatory Bowel Disease

Inflammatory Bowel Disease / Crohn's Disease Diagnostic Algorithmic Tests

1. Inflammatory bowel disease diagnostic algorithmic tests are considered investigational.

Inflammatory Bowel Disease / Crohn's Disease Prognostic Algorithmic Tests

1. Inflammatory bowel disease prognostic algorithmic tests are considered investigational.

Hereditary Inflammatory Bowel Disease / Crohn's Disease Panel Tests

- 1. Genetic testing for hereditary inflammatory bowel disease, including Crohn's disease, via a multigene panel is considered **medically necessary** when:
 - A. The member was diagnosed with infantile-onset inflammatory bowel disease (Infantile-IBD) before age 2 years, **or**
 - B. The member was diagnosed with very early onset inflammatory bowel disease (VEO-IBD) before age 6 years, and
 - i. At least one of the following:
 - a) The member has congenital multiple intestinal atresias, **or**
 - b) The member has congenital diarrhea, or
 - c) The member has a diagnosis or malignancy under age 25, **or**
 - d) The member has features of an inborn error of immunity such as susceptibility to infections, **or**
 - e) The member has complex autoimmune features, or
 - f) The member has a close relative meeting any of the above criteria, **or**
 - g) The member is undergoing stem cell transplant, or
 - h) The member has a history of multiple intestinal resections.
- 2. Genetic testing for inflammatory bowel disease, including Crohn's disease, via a multigene panel is considered **investigational** for all other indications.

Back to top

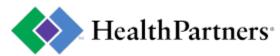
Non-invasive Liver Fibrosis Serum Tests

- 1. Non-invasive liver fibrosis serum tests to rule out liver fibrosis are considered **medically necessary** when:
 - A. The member has one of the following:
 - i. Nonalcoholic fatty liver disease (NAFLD), also known as metabolic dysfunction-associated steatotic liver disease (MASLD) **or**
 - ii. Nonalcoholic steatohepatitis (NASH), or
 - iii. Type 2 diabetes, or
 - iv. Obesity (BMI >25), or
 - v. Abnormal liver function tests, or
 - vi. A history of alcohol use, and
 - B. The member had previous fibrosis-4 index (FIB-4) testing with a score of greater than 1.3.
- 2. Non-invasive liver fibrosis serum tests to rule out liver fibrosis are considered **investigational** for all other indications.

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. **Infantile-onset inflammatory bowel disease (Infantile-IBD)** is defined as clinical manifestations and/or receiving the diagnosis when younger than 2 years of age. (Ouahed, et al)
- 3. Very early onset inflammatory bowel disease (VEO-IBD) is defined as clinical manifestations and/or receiving the diagnosis when younger than 6 years of age. (Ouahed, et al)
- 4. **Fibrosis-4 index (FIB-4)** is a blood test that measures the probability of advanced liver fibrosis based on AST, ALT, platelets, and age.

Products

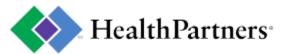


This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee: 6/15/2021; Revised: 4/15/2022, 3/17/23, 9/12/23, 03/08/2024, 9/10/2024; Reviewed: 12/2021, 1/2022, 1/2023, 7/2023, 1/2024, 7/2024, 1/2025

References

- Kowdley KV, Brown KE, Ahn J, Sundaram V. ACG Clinical Guideline: Hereditary Hemochromatosis [published correction appears in Am J Gastroenterol. 2019 Dec;114(12):1927]. Am J Gastroenterol. 2019;114(8):1202-1218. doi:10.14309/ajg.00000000000315
- Conwell DL, Lee LS, Yadav D, et al. American Pancreatic Association Practice Guidelines in Chronic Pancreatitis: evidence-based report on diagnostic guidelines. Pancreas. 2014;43(8):1143-1162. doi:10.1097/MPA.0000000000000237
- Tenner S, Baillie J, DeWitt J, Vege SS; American College of Gastroenterology. American College of Gastroenterology guideline: management of acute pancreatitis [published correction appears in Am J Gastroenterol. 2014 Feb;109(2):302]. Am J Gastroenterol. 2013;108(9):1400-1416. doi:10.1038/ajg.2013.218
- Rubio-Tapia, Alberto MD1; Hill, Ivor D. MD2; Semrad, Carol MD3; Kelly, Ciarán P. MD4; Greer, Katarina B. MD, MS5; Limketkai, Berkeley N. MD, PhD, FACG6; Lebwohl, Benjamin MD, MS7. American College of Gastroenterology Guidelines Update: Diagnosis and Management of Celiac Disease. The American Journal of Gastroenterology 118(1):p 59-76, January 2023. | DOI: 10.14309/ajg.0000000000002075
- Husby S, Murray JA, Katzka DA. AGA Clinical Practice Update on Diagnosis and Monitoring of Celiac Disease. Changing Utility of Serology and Histologic Measures: Expert Review. Gastroenterology. 2019 Mar;156(4):885-889. doi:10.1053/j.gastro. 2018.12.010. Epub 2018 Dec 19. PMID: 30578783; PMCID: PMC6409202.
- US Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, et al. Screening for Celiac Disease: US Preventive Services Task Force Recommendation Statement. JAMA. 2017;317(12):1252-1257. doi:10.1001/jama.2017.1462
- 7. Barton JC, Edwards CQ. HFE Hemochromatosis. 2000 Apr 3 [Updated 2018 Dec 6]. In: 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/NBK1440/
- Higuchi LM and Bousvaros A. Clinical presentation and diagnosis of inflammatory bowel disease in children. In UpToDate. UpToDate, Connor RF (Ed), Wolters Kluwer. Accessed March 21, 2024. https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-inflammatory-bowel-disease-in-children
- Kammermeier J, Lamb CA, Jones KDJ, et al. Genomic diagnosis and care coordination for monogenic inflammatory bowel disease in children and adults: consensus guideline on behalf of the British Society of Gastroenterology and British Society of Paediatric Gastroenterology, Hepatology and Nutrition. *Lancet Gastroenterol Hepatol.* 2023;8 (3):271-286.
- Lichtenstein, Gary R et al. "ACG Clinical Guideline: Management of Crohn's Disease in Adults." The American Journal of Gastroenterology Vol. 113,4 (2018): 481-517. doi:10.1038/ajg.2018.27
- 11. Rubin, David T et al. "ACG Clinical Guideline: Ulcerative Colitis in Adults." The American Journal of Gastroenterology Vol. 114,3 (2019): 384-413. doi:10.14309/aig.00000000000152
- 12. Magro F, Gionchetti P, Eliakim R, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 1: Definitions, Diagnosis, Extra-intestinal Manifestations, Pregnancy, Cancer Surveillance, Surgery, and Ileo-anal Pouch Disorders. J Crohns Colitis. 2017;11(6):649-670.doi:10.1093/ecco-jcc/ijx008
- 13. Verstockt, Bram et al. "Results of the Seventh Scientific Workshop of ECCO: Precision Medicine in IBD Disease Outcome and Response to Therapy." Journal of Crohn's & colitis vol. 15,9 (2021): 1431-1442. doi:10.1093/ecco-icc/jiab050
- 14. Porto G, Brissot P, Swinkels DW, et al. EMQN best practice guidelines for the molecular genetic diagnosis of hereditary hemochromatosis (HH). Eur J Hum Genet. 2016;24(4):479-495. doi:10.1038/ejhg.2015.128
- Gardner, Timothy B. MD, MS, FACG1; Adler, Douglas G. MD, FACG2; Forsmark, Chris E. MD, FACG3; Sauer, Bryan G. MD, MSc (Clin Res), FACG (GRADE Methodologist)4; Taylor, Jason R. MD5; Whitcomb, David C. MD, PhD, FACG6. ACG Clinical Guideline: Chronic Pancreatitis. The American Journal of Gastroenterology 115(3):p 322-339, March 2020.
- 16. Shelton C, LaRusch J, Whitcomb DC. Pancreatitis Overview. 2014 Mar 13 [Updated 2020 Jul 2]. In: Adam MP, Mirzaa GM, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK190101/
- Canivet CM, Boursier J. Screening for Liver Fibrosis in the General Population: Where Do We Stand in 2022?. Diagnostics (Basel). 2022;13(1):91. Published 2022 Dec 28. doi:10.3390/diagnostics13010091
- Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). Endocr Pract. 2022;28(5):528-562. doi:10.1016/j.eprac.2022.03.010
- Wattacheril JJ, Abdelmalek MF, Lim JK, Sanyal AJ. AGA Clinical Practice Update on the Role of Noninvasive Biomarkers in the Evaluation and Management of Nonalcoholic Fatty Liver Disease: Expert Review. Gastroenterology. 2023;165(4):1080-1088. doi:10.1053/j.gastro.2023.06.013
- Rinella, Mary E.1; Neuschwander-Tetri, Brent A.2; Siddiqui, Mohammad Shadab3; Abdelmalek, Manal F.4; Caldwell, Stephen5; Barb, Diana6; Kleiner, David E.7; Loomba, Rohit8. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology 77(5):p 1797-1835, May 2023. | DOI: 10.1097/HEP.0000000000000323



21. Ouahed J, Spencer E, Kotlarz D, et al. Very Early Onset Inflammatory Bowel Disease: A Clinical Approach With a Focus on the Role of Genetics and Underlying Immune Deficiencies. Inflamm Bowel Dis. 2020;26(6):820-842. doi:10.1093/ibd/izz259