Genetic Testing for Celiac Disease

Humana®

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Policy Number: HUM-0544-010
Line of Business: Commercial

Medical Coverage Policy

Table of Contents

Related Medical/Pharmacy Coverage Policies

Genetic Testing

Description

Celiac disease is an autoimmune disorder with gastrointestinal (eg, abdominal pain, bloating, diarrhea, malabsorption, vomiting, weight loss) and variable non-gastrointestinal symptoms (eg, chronic fatigue, dermatitis herpetiformis, joint pain, migraines, vitamin deficiencies) that are triggered by eating foods that contain gluten, a grain protein (eg, barley, rye, wheat) found in many foods and in other products such as medications, toothpastes and vitamin supplements.

The diagnosis of celiac disease is based on celiac-specific serology (blood tests) and duodenal histopathology. *HLA-DQ2* and *HLA-DQ8* genetic testing is appropriate for certain clinical situations but should not be used routinely. A positive HLA-DQ2/DQ8 result is not diagnostic for celiac disease since a significant portion of the population have these alleles but do not have the disease. However, a negative result essentially excludes the diagnosis.

Except for an individual diagnosed with Down syndrome, genetic testing may not be warranted prior to serology or histopathology nor is it appropriate to perform combined or simultaneous genetic testing and serology. Examples of these types of tests include, but may not be limited to:

- Celiac HLA DQ Association with Reflex to Celiac Antibodies tTG IgA/IgG with DGP IgA/IgG Pos/Neg Combination Screen
- Celiac HLA DQ Association with Reflex to Celiac Antibodies tTG IgA, tTG IgG, DGP IgA, DGP IgG and Total IgA
- Prometheus Celiac PLUS

Coverage Determination

Any state mandates for genetic testing for celiac disease take precedence over this medical coverage policy.

Genetic testing may be excluded by certificate. Please consult the member's individual certificate regarding Plan coverage.

Apply General Criteria for Genetic and Pharmacogenomics Tests when disease- or gene-specific criteria are not available on a medical coverage policy. For information regarding **general criteria for genetic tests**, please refer to Genetic Testing Medical Coverage Policy.

Celiac Disease (*HLA-DQ2/HLA-DQ8*)
Humana members may be eligible under the Plan for ***HLA-DQ2/HLA-DQ8*** **testing to assist in diagnosing an individual with suspected celiac disease** when the following criteria are met:

- Pre- and post-test genetic counseling; **AND**
    - Individual currently on a gluten-free diet (GFD) and both celiac-specific serology***** and duodenal histology were not performed prior to beginning GFD; **OR**
    - Individual unable to undergo upper endoscopy (eg, unable to cooperate with procedure, presence of a known or suspected perforated viscus); **OR**
    - Individual with discordant celiac-specific serology***** and duodenal histology results; **OR**
    - Individual with Down syndrome regardless of celiac-specific serology***** or duodenal histology

*****Celiac-specific serology includes:

- Deamidated gliadin peptide antibody immunoglobulin A (DGP-IgA)
- Deamidated gliadin peptide immunoglobulin G (DGP-IgG)

- Endomysial antibody immunoglobulin A (EMA-IgA)
- Tissue transglutaminase antibody immunoglobulin A (tTG-IgA)
- Tissue transglutaminase antibody immunoglobulin G (tTG-IgG)
- Total serum IgA

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **genetic testing for celiac disease** for genes, indications or tests other than those listed above including, but may not be limited to:

- Performed prior to celiac-specific serology except for an individual diagnosed with Down syndrome including, but may not be limited to:
    - Celiac HLA DQ Association with Reflex to Celiac Antibodies tTG IgA/IgG with DGP IgA/IgG Pos/Neg Combination Screen
    - Celiac HLA DQ Association with Reflex to Celiac Antibodies tTG IgA, tTG IgG, DGP IgA, DGP IgG and Total IgA
- Performed prior to duodenal histology except for an individual diagnosed with Down syndrome or unable to undergo endoscopy (eg, unable to cooperate with procedure, presence of a known or suspected perforated viscus)
- Performed simultaneously to or in combination with celiac-specific serology including, but may not be limited to, Prometheus Celiac PLUS
- Unaffected (asymptomatic) individual

These are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81376	HLA Class II typing, low resolution (eg, antigen equivalents); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each	
81377	HLA Class II typing, low resolution (eg, antigen equivalents); one antigen equivalent, each	

81382	HLA Class II typing, high resolution (ie, alleles or allele groups); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each	**Not Covered if used to report any test outlined in Coverage Limitations section**
81383	HLA Class II typing, high resolution (ie, alleles or allele groups); one allele or allele group (eg, HLA-DQB1*06:02P), each	
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
S0265	Genetic counseling, under physician supervision, each 15 minutes	

References

1. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Diagnosis of celiac disease. https://effectivehealthcare.ahrq.gov. Published July 26, 2016.

2. American Academy of Pediatrics (AAP). Clinical report - health supervision for children with Down syndrome. https://www.aap.org. Published 2011. Updated January 2018.

3. American College of Gastroenterology (ACG). Practice Guidelines. ACG guidelines update: diagnosis and management of celiac disease. https://gi.org. Published May 2013. Updated January 2023.

4. American Gastroenterological Association (AGA). AGA clinical practice update on diagnosis and monitoring of celiac disease – changing utility of serology and histologic measures: expert review. https://gastro.org. Published December 19, 2018.

5. American Gastroenterological Association (AGA). AGA clinical practice update on management of refractory celiac disease: expert review. https://gastro.org. Published September 19, 2022.

6. ECRI Institute. ECRIgene. Celiac Genetics (Prometheus Laboratories Inc) for assessing risk of celiac disease. https://www.ecri.org. Published December 2019.

7. Hayes, Inc. Clinical Utility Evaluation. HLA-DQ2/DQ8 genotyping for celiac disease in asymptomatic individuals with type 1 diabetes. https://evidence.hayesinc.com. Published June 15, 2018. Updated July 16, 2022.

8. Hayes, Inc. Clinical Utility Evaluation. HLA-DQ2/DQ8 genotyping in asymptomatic relatives of individuals with celiac disease. https://evidence.hayesinc.com. Published June 15, 2018. Updated July 16, 2022.

9. Hayes, Inc. Clinical Utility Evaluation. HLA-DQ2/DQ8 genotyping to establish a non-biopsy diagnosis of celiac disease in symptomatic children. https://evidence.hayesinc.com. Published June 15, 2018. Updated July 16, 2022.

10. Hayes, Inc. Clinical Utility Evaluation. *HLA-DQ2/DQ8* genotyping to rule out celiac disease in symptomatic individuals with an uncertain diagnosis. https://evidence.hayesinc.com. Published June 15, 2018. Updated July 16, 2022.

11. MCG Health. Celiac disease – HLA testing. 27th edition. https://humanabh.access.mcg.com/index.

12. National Center for Biotechnology Information (NCBI). Genetic Testing Registry. Celiac disease. https://www.ncbi.nlm.nih.gov. Published July 3, 2008. Updated January 31, 2019.

13. National Institutes of Health (NIH). NIH Consensus and State-of-the-Science Statements. NIH consensus statement on celiac disease. https://www.nih.gov. Published June 2004.

14. North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN). Clinical Guideline. Guideline for the diagnosis and treatment of celiac disease in children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. https://www.naspghan.org. Published January 2005.

15. UpToDate, Inc. Diagnosis of celiac disease in adults. https://www.uptodate.com. Updated December 2023.

16. UpToDate, Inc. Diagnosis of celiac disease in children. https://www.uptodate.com. Updated December 2023.

17. UpToDate, Inc. Overview of upper gastrointestinal endoscopy (esophagogastroduodenoscopy). https://www.uptodate.com. Updated December 2023.

18. US Preventive Services Task Force (USPSTF). Recommendation Statement. Celiac disease: screening. https://www.uspreventiveservicestaskforce.org. Published March 2017.

Appendix

Pre- and Post-Test Genetic Counseling Criteria

Pre- and post-test genetic counseling performed by any of the following qualified medical professionals
Genetic counselor who is board-certified or board-eligible by the American Board of Medical Genetics and Genomics (ABMGG) or American Board of Genetic Counseling, Inc (ABGC) and is not employed by a commercial genetic testing laboratory; **OR**
Genetic clinical nurse (GCN) or advanced practice nurse in genetics (APNG) who is credentialed by the Genetic Nursing Credentialing Commission (GNCC) or the American of Nurses Credentialing Center (ANCC) and is not employed by a commercial genetic testing laboratory; **OR**
Medical geneticist who is board-certified or board-eligible by ABMGG; **OR**
Treating physician who has evaluated the individual to be tested and has completed a family history of three generations

Change Summary

- 01/25/2024 Annual Review, No Coverage Change.