

Reimbursement Policy

Celiac Disease Testing

[POLICY DESCRIPTION](#) | [INDICATIONS AND/OR LIMITATIONS OF COVERAGE](#) | [APPLICABLE STATE AND FEDERAL REGULATIONS](#) | [APPLICABLE CPT/HCPCS PROCEDURE CODES](#) | [EVIDENCE-BASED SCIENTIFIC REFERENCES](#) | [REVISION HISTORY](#)

I. Policy Description

Celiac disease is a hereditary, chronic autoimmune disorder that affects one in 100 individuals worldwide. It is triggered by the ingestion of gluten, a protein found in wheat, rye, and barley. When an individual with celiac disease ingests gluten, the body mounts an immune response that attacks the small intestine. These attacks lead to damage on the villi within the small intestine, inhibiting nutrient absorption.¹

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For individuals who have been diagnosed with celiac disease and who are IgA sufficient, serologic testing with IgA anti-tissue transglutaminase (TTG) **MEETS COVERAGE CRITERIA** at the following intervals:
 - a) At the first follow-up visit 3-6 months after diagnosis.
 - b) Every 6 months until normalization of anti-TTG levels has occurred.
 - c) Every 12-24 months thereafter.
- 2) For individuals who have been diagnosed with celiac disease and who are IgA deficient, testing for IgG endomysial antibodies, IgG deamidated gliadin peptide, **or** IgG TTG **MEETS COVERAGE CRITERIA** at the following intervals:
 - a) At the first follow-up visit 3-6 months after diagnosis.
 - b) Every 6 months until normalization of IgG levels has occurred.
 - c) Every 12-24 months thereafter.

Reimbursement Policy

- 3) For individuals with signs and symptoms of celiac disease (see Note 1), serologic testing with the IgA anti-TTG **and** the total IgA test for the diagnosis of celiac disease **MEETS COVERAGE CRITERIA**.
- 4) For individuals at risk for celiac disease (see Note 1), when IgA anti-TTG is negative or weakly positive, testing for IgA endomysial antibodies **MEETS COVERAGE CRITERIA**.
- 5) For individuals with clinical suspicion of celiac disease (see Note 1) with an IgA deficiency, testing for IgG endomysial antibodies, IgG deamidated gliadin peptide, **or** IgG TTG **MEETS COVERAGE CRITERIA**.
- 6) Testing for IgA and IgG antibodies to deamidated gliadin peptides **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) For individuals under 2 years of age with a clinical suspicion of celiac disease (see Note 1).
 - b) For individuals over 2 years of age as a substitute for anti-TTG testing.
- 7) For confirmation of celiac disease in individuals at high risk for celiac disease, regardless of the result of celiac disease serology testing, pathological examination of tissue obtained from a biopsy of the small intestine **MEETS COVERAGE CRITERIA**.
- 8) Rapid antigen point-of-care testing for anti-TTG **DOES NOT MEET COVERAGE CRITERIA**.
- 9) Panel testing, multiplex testing, or multi-analyte testing (for more than two analytes) for the diagnosis or evaluation of celiac disease **DOES NOT MEET COVERAGE CRITERIA**.
- 10) For asymptomatic individuals not at an increased risk for developing celiac disease (see Note 1), testing for celiac disease **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

- 11) For the diagnosis of celiac disease, testing for anti-reticulin antibodies **DOES NOT MEET COVERAGE CRITERIA**.
- 12) For the evaluation of celiac disease, testing of stool or saliva samples **DOES NOT MEET COVERAGE CRITERIA**.
- 13) Serologic testing using an HLA-DQ-gluten tetramer-based assay, including flow cytometry-based HLA-DQ-gluten tetramer assays, **DOES NOT MEET COVERAGE CRITERIA**.

Reimbursement Policy

NOTES:

Note 1: Signs and symptoms of celiac disease may include, but are not limited to, the following: unexplained chronic or intermittent diarrhea; unexplained weight loss; unexplained chronic or intermittent abdominal pain or bloating; recurrent nausea or vomiting; unexplained iron deficiency anemia; unexplained vitamin B12 or folate deficiency; unexplained liver transaminase elevations; autoimmune hepatitis; dermatitis herpetiformis; type 1 diabetes; intestinal blockages; unexplained subfertility or miscarriage; unexplained osteoporosis, osteomalacia, or low bone density; and/or primary biliary cirrhosis. Individuals with Down syndrome, Turner syndrome, or Williams-Beuren syndrome are also at high risk for celiac disease. Additionally, in pediatric patients, fatty stools, delayed puberty, amenorrhea, failure to thrive, stunted growth, and/or short stature may also be associated with celiac disease.²⁻⁴

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

The Quanta Lite Celiac Screen ELISA test for tissue transglutaminase/gliadin and the Quanta Lite Celiac DGP Screen by Inova Diagnostics, Inc. were approved by the FDA on 01/28/1999 and 12/13/2006, respectively. Quanta Plex Celiac IgA and IgG profiles by Inova Diagnostics, Inc. were approved on 03/14/2007 and 06/20/2007.

EliA Celikey IgG for use with the EliA Celikey IgG Immunoassay by Phadia US, Inc. was approved by the FDA on 12/26/2006.

Reimbursement Policy

The FIDIS Celiac on the FIDS Analyser and FIDIS CELIAC kit by Biomedical Diagnostics S.A. were approved by the FDA on 09/24/2004 and 03/29/2006, respectively.

The IMMULISA CELIAC ELISA testing systems for gliadin IgA/IgG and TTG IgA/IgG by IMMCO Diagnostics, Inc. were approved on 02/04/2010 and 03/10/2010. IMMCO's IMMULISA enhanced celiac fusion (TTG/DGP) IgA/IgG antibody ELISA system was approved on 10/25/2013.

Bio-Rad Laboratories' Bioplex 2200 Celiac IgA IgG kits were approved on 09/19/2013. The IgX Plex Celiac qualitative assay and Ig Plex Celiac DG panel by SQI diagnostics systems, Inc. were approved by the FDA on 06/02/2011 and 11/06/2014, respectively.

SQI Diagnostics received FDA clearance for the Ig plex Celiac DGP which detects IgA and IgG antibodies to deamidated gliadin peptide (DGP) and tissue transglutaminase (tTG) in human serum. This was approved by the FDA on Nov 06, 2014.⁴⁰

Inova Diagnostics received FDA clearance on June 16, 2021, for the Aptiva Celiac Disease IgA Reagent, which is an "immunoassay utilizing particle-based multi-analyte technology for the semi-quantitative determination of anti-tissue transglutaminase IgA autoantibodies and anti-deamidated gliadin peptide IgA antibodies in human serum." They also received approval for an IgG Reagent in 2021. It can be used to diagnose celiac disease and dermatitis herpetiformis.⁴¹

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82784	Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
86231	Endomysial antibody (EMA), each immunoglobulin (Ig) class
86255	Fluorescent noninfectious agent antibody; screen, each antibody
86256	Fluorescent noninfectious agent antibody; titer, each antibody
86258	Gliadin (deamidated) (DGP) antibody, each immunoglobulin (Ig) class
86364	Tissue transglutaminase, each immunoglobulin (Ig) class
88305	Level IV - Surgical pathology, gross and microscopic examination, colon biopsy

Current Procedural Terminology© American Medical Association. All Rights reserved.

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

Reimbursement Policy

V. Evidence-based Scientific References

1. CDF. What is Celiac disease? Celiac Disease Foundation. <https://celiac.org/celiac-disease/understanding-celiac-disease-2/what-is-celiac-disease/>
2. Husby S, Koletzko S, Korponay-Szabó I, et al. European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease 2020. *J Pediatr Gastroenterol Nutr.* Jan 2020;70(1):141-156. doi:10.1097/mpg.0000000000002497
3. NICE. Coeliac disease overview. <https://pathways.nice.org.uk/pathways/coeliac-disease>
4. NIDDK. Symptoms & Causes of Celiac Disease. U.S. Department of Health and Human Services. Updated October 2020. <https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/symptoms-causes>
5. Kelly CP. Diagnosis of celiac disease in adults. Updated March 14, 2025. <https://www.uptodate.com/contents/diagnosis-of-celiac-disease-in-adults>
6. Nellikall SS, Hafed Y, Larson JJ, Murray JA, Absah I. High Prevalence of Celiac Disease Among Screened First-Degree Relatives. *Mayo Clin Proc.* Sep 2019;94(9):1807-1813. doi:10.1016/j.mayocp.2019.03.027
7. Caio G, Volta U, Sapone A, et al. Celiac disease: a comprehensive current review. *BMC Med.* Jul 23 2019;17(1):142. doi:10.1186/s12916-019-1380-z
8. NIDDK. Definition & Facts for Celiac Disease. National Institute of Diabetes and Digestive and Kidney Diseases. Updated October 2020. <https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/definition-facts>
9. Brown NK, Guandalini S, Semrad C, Kupfer SS. A Clinician's Guide to Celiac Disease HLA Genetics. *Am J Gastroenterol.* Oct 2019;114(10):1587-1592. doi:10.14309/ajg.0000000000000310
10. Tye-Din JA, Galipeau HJ, Agardh D. Celiac Disease: A Review of Current Concepts in Pathogenesis, Prevention, and Novel Therapies. *Frontiers in pediatrics.* 2018;6:350. doi:10.3389/fped.2018.00350
11. Stankovic B, Radlovic N, Lekovic Z, et al. HLA genotyping in pediatric celiac disease patients. *Bosnian journal of basic medical sciences.* Aug 16 2014;14(3):171-6. doi:10.17305/bjbms.2014.3.28
12. Paul SP, Hoghton M, Sandhu B. Limited role of HLA DQ2/8 genotyping in diagnosing coeliac disease. *Scottish medical journal.* Feb 2017;62(1):25-27. doi:10.1177/0036933016689008
13. Sarna VK, Lundin KEA, Morkrid L, Qiao SW, Sollid LM, Christophersen A. HLA-DQ-Gluten Tetramer Blood Test Accurately Identifies Patients With and Without Celiac Disease in Absence of Gluten Consumption. *Gastroenterology.* Mar 2018;154(4):886-896.e6. doi:10.1053/j.gastro.2017.11.006
14. Lau MS, Mooney P, White W, et al. Pre-endoscopy point of care test (Simtomax- IgA/IgG-Deamidated Gliadin Peptide) for coeliac disease in iron deficiency anaemia: diagnostic

Reimbursement Policy

- accuracy and a cost saving economic model. *BMC Gastroenterol.* Sep 15 2016;16:115. doi:10.1186/s12876-016-0521-5
15. FDA. Decision Summary. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160026.pdf
16. Olen O, Gudjonsdottir AH, Browaldh L, et al. Antibodies against deamidated gliadin peptides and tissue transglutaminase for diagnosis of pediatric celiac disease. *J Pediatr Gastroenterol Nutr.* Dec 2012;55(6):695-700. doi:10.1097/MPG.0b013e3182645c54
17. Sakly W, Mankai A, Ghdes A, Achour A, Thabet Y, Ghedira I. Performance of anti-deamidated gliadin peptides antibodies in celiac disease diagnosis. *Clinics and research in hepatology and gastroenterology.* Dec 2012;36(6):598-603. doi:10.1016/j.clinre.2012.01.008
18. Bufler P, Heilig G, Ossianer G, Freudenberg F, Grote V, Koletzko S. Diagnostic performance of three serologic tests in childhood celiac disease. *Zeitschrift für Gastroenterologie.* Feb 2015;53(2):108-14. doi:10.1055/s-0034-1385704
19. Silvester JA, Kurada S, Sz wajcer A, Kelly CP, Leffler DA, Duerksen DR. Tests for Serum Transglutaminase and Endomysial Antibodies Do Not Detect Most Patients With Celiac Disease and Persistent Villous Atrophy on Gluten-free Diets: a Meta-analysis. *Gastroenterology.* Sep 2017;153(3):689-701.e1. doi:10.1053/j.gastro.2017.05.015
20. Selleski N, Almeida LM, Almeida FC, Pratesi CB, Nobrega YKM, Gandolfi L. PREVALENCE OF CELIAC DISEASE PREDISPOSING GENOTYPES, INCLUDING HLA-DQ2.2 VARIANT, IN BRAZILIAN CHILDREN. *Arquivos de gastroenterologia.* Jan-Mar 2018;55(1):82-85. doi:10.1590/s0004-2803.201800000-16
21. Mubarak A, Spierings E, Wolters V, van Hoogstraten I, Kneepkens CM, Houwen R. Human leukocyte antigen DQ2.2 and celiac disease. *J Pediatr Gastroenterol Nutr.* Apr 2013;56(4):428-30. doi:10.1097/MPG.0b013e31827913f9
22. Vijzelaar R, van der Zwan E, van Gammeren A, et al. Rapid Detection of the Three Celiac Disease Risk Genotypes HLA-DQ2.2, HLA-DQ2.5, and HLA-DQ8 by Multiplex Ligation-Dependent Probe Amplification. *Genetic testing and molecular biomarkers.* Mar 2016;20(3):158-61. doi:10.1089/gtmb.2015.0233
23. Bajor J, Szakács Z, Farkas N, et al. Classical celiac disease is more frequent with a double dose of HLA-DQB1*02: A systematic review with meta-analysis. *PloS one.* 2019;14(2):e0212329. doi:10.1371/journal.pone.0212329
24. Tangermann P, Branchi F, Itzlinger A, et al. Low Sensitivity of Simtomax Point of Care Test in Detection of Celiac Disease in a Prospective Multicenter Study. *Clin Gastroenterol Hepatol.* Aug 2019;17(9):1780-1787.e5. doi:10.1016/j.cgh.2018.09.032
25. Profaizer T, Pole A, Monds C, Delgado JC, Lázár-Molnár E. Clinical utility of next generation sequencing based HLA typing for disease association and pharmacogenetic testing. *Hum Immunol.* Jul 2020;81(7):354-360. doi:10.1016/j.humimm.2020.05.001
26. Gould MJ, Mahmud FH, Clarke ABM, et al. Accuracy of Screening Tests for Celiac Disease in Asymptomatic Patients With Type 1 Diabetes. *Am J Gastroenterol.* Jul 1 2021;116(7):1545-1549. doi:10.14309/ajg.0000000000001193

Reimbursement Policy

27. Rubio-Tapia A, Hill ID, Semrad C, et al. American College of Gastroenterology Guidelines Update: Diagnosis and Management of Celiac Disease. *Am J Gastroenterol*. Jan 1 2023;118(1):59-76. doi:10.14309/ajg.0000000000002075
28. 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;156(4):885-889. doi:10.1053/j.gastro.2018.12.010
29. Green PHR, Paski S, Ko CW, Rubio-Tapia A. AGA Clinical Practice Update on Management of Refractory Celiac Disease: Expert Review. *Gastroenterology*. Nov 2022;163(5):1461-1469. doi:10.1053/j.gastro.2022.07.086
30. Mearin ML, Agardh D, Antunes H, et al. ESPGHAN Position Paper on Management and Follow-up of Children and Adolescents With Celiac Disease. *J Pediatr Gastroenterol Nutr*. Sep 1 2022;75(3):369-386. doi:10.1097/mpg.0000000000003540
31. Hill ID, Fasano A, Guandalini S, et al. NASPGHAN Clinical Report on the Diagnosis and Treatment of Gluten-related Disorders. *J Pediatr Gastroenterol Nutr*. Jul 2016;63(1):156-65. doi:10.1097/mpg.0000000000001216
32. NICE. Coeliac disease: recognition, assessment and management. National Institute for Health and Care Excellence. <https://www.nice.org.uk/guidance/ng20/resources/coeliac-disease-recognition-assessment-and-management-pdf-1837325178565>
33. NICE. Coeliac disease. National Institute for Health and Care Excellence. <https://www.nice.org.uk/guidance/qs134/resources/coeliac-disease-pdf-75545419042501>
34. Bibbins-Domingo K, Grossman DC, Curry SJ, et al. Screening for Celiac Disease: US Preventive Services Task Force Recommendation Statement. *Jama*. Mar 28 2017;317(12):1252-1257. doi:10.1001/jama.2017.1462
35. Bai JC, Ciacci C. World Gastroenterology Organisation Global Guidelines: Celiac Disease February 2017. *Journal of clinical gastroenterology*. Oct 2017;51(9):755-768. doi:10.1097/mcg.0000000000000919
36. Al-Toma A, Volta U, Auricchio R, et al. European Society for the Study of Coeliac Disease (ESsCD) guideline for coeliac disease and other gluten-related disorders. *United European gastroenterology journal*. Jun 2019;7(5):583-613. doi:10.1177/2050640619844125
37. Ludvigsson JF, Bai JC, Biagi F, et al. Diagnosis and management of adult coeliac disease: guidelines from the British Society of Gastroenterology. *Gut*. Aug 2014;63(8):1210-28. doi:10.1136/gutjnl-2013-306578
38. Pelkowski TD, Viera AJ. Celiac disease: diagnosis and management. *Am Fam Physician*. Jan 15 2014;89(2):99-105.
39. AAFP. Screening for Celiac Disease: Recommendation Statement. *Am Fam Physician*. Sep 15 2017;96(6):Online.
40. FDA. Ig_Plex Celiac DGP Panel. <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm?db=pmn&id=K140691>
41. FDA. Aptiva Celiac Disease IgA Reagent. https://www.accessdata.fda.gov/cdrh_docs/reviews/K193604.pdf

Reimbursement Policy

VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria. The following changes were made for clarity and consistency: Removed CC7, which referred to genetic testing, as the focus of this policy is routine testing for the diagnosis of celiac disease. Removed CPT code 81376, 81377, 81382, 81383