



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent
Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Serological Diagnosis of Celiac Disease

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 138

BCBSA Reference Number: 2.04.30

Related Policies

- Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon [#185](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Serologic measurement may be **MEDICALLY NECESSARY** to treat the following conditions:

- Tissue transglutaminase or antiendomysial antibodies in patients with signs or symptoms suggestive of celiac disease
- Antigliadin antibodies in children less than 24 months of age with signs or symptoms suggestive of celiac disease, and
- HLA-DQ2 and HLA-DQ8 testing to rule out celiac disease in patients with discordant serologic and histologic (biopsy) findings or if persistent symptoms warrant testing despite negative serology and histology.

Serologic measurement of deamidated gliadin peptide antibodies in patients with signs or symptoms suggestive of celiac disease is **INVESTIGATIONAL**.

Screening of asymptomatic at risk patient groups or population screening for celiac disease using one or more serologic IgA or IgG measures is **INVESTIGATIONAL**.

Prior Authorization Information

Commercial Members: Managed Care (HMO and POS)

Prior authorization is **NOT** required.

Commercial Members: PPO, and Indemnity

Prior authorization is **NOT** required.

Medicare Members: HMO BlueSM

Prior authorization is **NOT** required.

Medicare Members: PPO BlueSM

Prior authorization is **NOT** required.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Description

Celiac disease, which may be referred to as celiac sprue or gluten-sensitive enteropathy, is defined as inflammation of the small intestine resulting from an immunologic intolerance to gluten (i.e., the proteins derived from wheat, barley, and rye). The diagnosis criteria reflects a positive biopsy at presentation, in conjunction with consistent history and serologic results, followed by a clinical response to a gluten-free diet, and relapse when dietary gluten is reintroduced.

Clinical symptoms are variable, nonspecific, and are often overlooked. In addition, the disease may develop at any time in life, from infancy to very old age. While a positive biopsy result is considered the gold standard for diagnosis, serologic evaluation of patients with possible celiac disease can be used to triage the large numbers of patients with nonspecific symptoms for biopsy.

Serologic diagnosis is focused on the detection of IgA antibodies, such as antigliadin, antiendomysial, and tissue transglutaminase. Antigliadin antibodies (AGA) can be detected using an enzyme-linked immunosorbent assay (ELISA) test. Another serologic study is to test for the presence of antiendomysial antibodies (EMA) also with an ELISA-based test, and a dot blot procedure that can be performed in the physician's office. The newest serologic tests are deamidated gliadin peptide (DGP) antibody tests whose presence is believed to be more specific to celiac disease than native peptides.

Examples of antibody testing for celiac disease are widely available from laboratories such as Quest, LabCorp, and Prometheus. All antibody tests for celiac disease are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

Summary

Use of serology tests, if accurate, reduces the need for multiple biopsies. Evidence from systematic reviews and head-to-head comparative studies using biopsy as the gold standard concludes that there is sufficient evidence that tissue transglutaminase and antiendomysial antibody tests are reasonably accurate for identifying celiac disease in patients with signs or symptoms of the disease. One study found that, in children under 18 months old, serologic measurement of antigliadin antibodies is more sensitive than either of the other 2 tests. For these reasons, these tests for the defined population may be considered medically necessary.

There is insufficient evidence on the newer deamidated gliadin peptide (DGP) tests; fewer studies have been published, and the DGP tests have not consistently been found to be as sensitive as the tTG and antiendomysial antibody (EMA) tests. Moreover, national organizations that recommend the use of tTG and EMA tests do not yet have recommendations on DGP tests. These tests are investigational.

The evidence is also insufficient that serology testing of asymptomatic high-risk individuals or population screening of asymptomatic individuals improves the net health outcome.

Policy History

Date	Action
2/2013	New references from BCBSA National medical policy.
2/2013	BCBS Association National Policy Review. Changes made to policy statement.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition/ Organ Transplantation No changes to policy statements.
9/1/2011	Reviewed BCBS National Policy Revised policy statement
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition/ Organ Transplantation No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition/ Organ Transplantation No changes to policy statements.
11/01/2009	New policy effective 11/01/2009.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

- Green PH, Cellier C. Celiac disease. N Engl J Med 2007; 357(17):1731-43.
- Walker-Smith JA GS, Schmitz J et al. Revised criteria for diagnosis of coeliac disease. Report of Working Group of European Society of Paediatric Gastroenterology and Nutrition. Arch Dis Child 1990; 65(8):909-11.
- NIH consensus development conference on celiac disease. Consensus development conference statement. 2004. Available online at:
<http://consensus.nih.gov/2004/2004CeliacDisease118.html.htm>. . Last accessed March 2010.
- AGA Institute Medical Position Statement on the Diagnosis and Management of Celiac Disease. Gastroenterology 2006; 131(6):1977-80.
- Hill ID, Dirks MH, Liptak GS et al. Guideline for the diagnosis and treatment of celiac disease in children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr 2005; 40(1):1-19.
- Lewis NR, Scott BB. Meta-analysis: deamidated gliadin peptide antibody and tissue transglutaminase antibody compared as screening tests for coeliac disease. Aliment Pharmacol Therap 2010; 31(1):73-81.
- Hill ID. What are the sensitivity and specificity of serologic tests for celiac disease? Do sensitivity and specificity vary in different populations? Gastroenterology 2005; 128(4 Suppl 1):S25-32.
- Zintzaras E, Germeis AE. Performance of antibodies against tissue transglutaminase for the diagnosis of celiac disease: meta-analysis. Clin Vaccine Immunol 2006; 13(2):187-92.
- Naiyer AJ, Hernandez L, Ciaccio EJ et al. Comparison of commercially available serologic kits for the detection of celiac disease. J Clin Gastroenterol 2009; 43(3):225-32.
- Vermeersch P, Geboes K, Marien G et al. Diagnostic performance of IgG anti-deamidated gliadin peptide antibody assays is comparable to IgA anti-tTG in celiac disease. Clin Chim Acta 2010; 411(13-14):931-5.

11. Sugai E, Moreno ML, Hwang HJ et al. Celiac disease serology in patients with different pretest probabilities: is biopsy avoidable? *World J Gastroenterol* 2010; 16(25):3144-52.
12. Lagerqvist C, Dahlbom I, Hansson T et al. Antigliadin immunoglobulin A best in finding celiac disease in children younger than 18 months of age. *J Pediatr Gastroenterol Nutr* 2008; 47(4):428-35.
13. Foucher B, Johanet C, Jego-Desplat S et al. Are Immunoglobulin A anti-gliadin antibodies of any help in the diagnosis of coeliac disease in children below 2 years-old? a French multicenter study. *J Pediatr Gastroenterol Nutr* 2012; 54(1):110-2.
14. Panetta F, Torre G, Colistro F et al. Clinical accuracy of anti-tissue transglutaminase as screening test for celiac disease under 2 years. *Acta Paediatr* 2011; 100(5):728-31.
15. Mubarak A, Gmelig-Meyling FH, Wolters VM et al. Immunoglobulin G antibodies against deamidated-gliadin-peptides outperform anti-endomysium and tissue transglutaminase antibodies in children <2 years age. *APMIS* 2011; 119(12):894-900.
16. Hojsak I, Mozer-Glassberg Y, Segal Gilboa N et al. Celiac disease screening assays for children younger than 3 years of age: the performance of three serological tests. *Dig Dis Sci* 2012; 57(1):127-32.
17. Hopper AD, Hadjivassiliou M, Hurlstone DP et al. What is the role of serologic testing in celiac disease? A prospective, biopsy-confirmed study with economic analysis. *Clin Gastroenterol Hepatol* 2008; 6(3):314-20.
18. Katz KD, Rashtak S, Lahr BD et al. Screening for celiac disease in a North American population: sequential serology and gastrointestinal symptoms. *Am J Gastroenterol* 2011; 106(7):1333-9.
19. Basso D, Guariso G, Bozzato D et al. New screening tests enrich anti-transglutaminase results and support a highly sensitive two-test based strategy for celiac disease diagnosis. *Clin Chim Acta* 2011; 412(17-18):1662-7.
20. Mubarak A WV, Gmelig-Meyling FH, et al. Tissue transglutaminase levels above 100 U/ml and celiac disease: a prospective study. *World J Gastroenterol* 2012; 18(32):4399-403.
21. Alessio MG TE, Brusca I, et al. Correlation between IgA tissue transglutaminase antibody ratio and histological finding in celiac disease. *J Pediatr Gastroenterol Nutr* 2012; 55(1):44-49.
22. Catassi C, Kryszak D, Louis-Jacques O et al. Detection of celiac disease in primary care: a multicenter case-finding study in North America. *Am J Gastroenterol* 2007; 102(7):1454-60.
23. Korponay-Szabo IR, Szabados K, Pusttai J et al. Population screening for coeliac disease in primary care by district nurses using a rapid antibody test: diagnostic accuracy and feasibility study. *BMJ* 2007; 335(7632):1244-7.