Medical Policy
Serological Diagnosis of Celiac Disease

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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 Blue℠
Prior authorization is NOT required.

Medicare Members: PPO Blue℠
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**

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<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>2/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td></td>
<td>Changes made to policy statement.</td>
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<tr>
<td>9/1/2011</td>
<td>Reviewed BCBS National Policy Revised policy statement</td>
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**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**