Medical Policy

Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease

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Policy Number: 551
BCBSA Reference Number: 2.04.17A

Related Policies
- Pharmacogenomic and Metabolite Markers for Patients Treated with Thiopurines, #096
- 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
The determination of anti-neutrophil cytoplasmic antibody (ANCA) and anti-Saccharomyces cerevisiae antibody (ASCA) in the workup and monitoring of patients with inflammatory bowel disease is INVESTIGATIONAL.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Medical Plan</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<td>Medicare PPO BlueSM</td>
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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
Inflammatory bowel disease (IBD) can be subdivided into ulcerative colitis and Crohn’s disease, both of which present with symptoms of diarrhea and abdominal pain. The definitive diagnosis can usually be established by a combination of radiographic, endoscopic, and histologic criteria, although in 10–15%, the distinction between ulcerative colitis and Crohn’s disease cannot be made with certainty.

Two serum antibodies, anti-neutrophil cytoplasmic antibodies (ANCA) and anti-Saccharomyces cerevisiae antibodies (ASCA) have been associated with IBD.

It has been suggested that these antibodies can be used as diagnostic tests to improve the efficiency and accuracy of diagnosing IBD. They might also be useful in differentiating between ulcerative colitis and Crohn’s disease in cases of indeterminate colitis. Another potential use is to classify subtypes of IBD by location of disease (i.e., proximal vs. distal bowel involvement) or by disease severity, thereby providing prognostic information. It has also been proposed that these markers may predict response to anti-tumor necrosis factor therapy or identify susceptibility to IBD among family members of an affected individual.

An example of serum antibody testing for the diagnosis of inflammatory bowel disease is the Prometheus© IBD Serology 7 from Prometheus© Inc. All serum antibody testing for the diagnosis of inflammatory bowel disease is considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Summary
Systematic reviews have found relatively low sensitivity and moderately high specificity. Moreover, the clinical utility of these assays has not been demonstrated. No studies demonstrated these markers could be used in lieu of a standard workup for IBD. No studies demonstrated an actual decrease in the number of invasive tests through use of serum markers. Given the insufficient evidence to evaluate the impact on net health outcome, these technologies are investigational for the diagnosis and monitoring of inflammatory bowel.

Policy History

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<th>Date</th>
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<tr>
<td>10/2010</td>
<td>New policy effective 10/20/10 describing ongoing non-coverage.</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
1. 1999 TEC Assessments; Tab 12.