Medical Policy
Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease

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Policy Number: 551
BCBSA Reference Number: 2.04.17A
NCD/LCD: NA

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

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
Inpatient
• For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
• For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

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<th>Outpatient</th>
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<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<td>Commercial PPO and Indemnity</td>
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<td>Medicare HMO BlueSM</td>
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<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes
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-neutrophilic 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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<td>2/2020</td>
<td>Policy updated with literature review through February 1, 2020, references added. Policy statements unchanged.</td>
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<tr>
<td>10/20/2010</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.

The Institute for Clinical Systems Improvement (ICSI) Technology Assessment. Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease (IBD): pANCA for Ulcerative Colitis (UC) and ASCA for Crohn’s Disease (CD). Released November 2002. No longer available on ICSI website.