



# MASSACHUSETTS

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

## Medical Policy

### Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease

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#### Policy Number: 551

BCBSA Reference Number: 2.04.17A (For Plan internal use only)

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 Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> 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**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

#### 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-neutrophilcytoplasmic 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**

<b>Date</b>	<b>Action</b>
11/2022	Annual policy review. Policy updated with literature review through October 2022. No references added. Policy statements unchanged.
2/2020	Policy updated with literature review through February 1, 2020, references added. Policy statements unchanged.
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 GI, Nutrition and Organ Transplantation. No changes to policy statements.
10/20/2010	New policy effective 10/20/10 describing ongoing non-coverage.

## **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.
2. Reese GE, Constantinides VA, Simillis C et al. Diagnostic precision of anti- *Saccharomyces cerevisiae* antibodies and perinuclear antineutrophil cytoplasmic antibodies in inflammatory bowel disease. *Am J Gastroenterol* 2006; 101(10):2410-22.
3. Joossens S, Reinisch W, Vermeire S et al. The value of serologic markers in indeterminate colitis: a prospective follow-up study. *Gastroenterology* 2002; 122(5):1242-7.
4. Mow WS, Vasiliauskas EA, Lin YC et al. Association of antibody responses to microbial antigens and complications of small bowel Crohn's disease. *Gastroenterology* 2004; 126(2):414-24.
5. Russell RK, Ip B, Aldhous MC. Anti- *Saccharomyces cerevisiae* antibody status is associated with oral involvement and disease severity in Crohn disease. *J Pediatr Gastroenterol Nutr* 2009; 48(2):161-7.
6. Sutton CL, Yang H, Li Z et al. Familial expression of anti- *Saccharomyces cerevisiae* mannan antibodies in affected and unaffected relatives of patients with Crohn's disease. *Gut* 2000; 46(1):58-63.
7. Annese V, Andreoli A, Andriulli A et al. Familial expression of anti- *Saccharomyces cerevisiae* Mannan antibodies in Crohn's disease and ulcerative colitis: a GISC study. *Am J Gastroenterol* 2001; 96(8):2407-12.
8. Zholudev A, Zurakowski D, Young W et al. Serologic testing with ANCA, ASCA and anti-OmpC in children and young adults with Crohn's disease and ulcerative colitis: diagnostic value and correlation with disease phenotype. *Am J Gastroenterol* 2004; 99(11):2235-41.
9. Schoepfer AM, Trummler M, Seeholzer P et al. Discriminating IBD from IBS: comparison of the test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. *Inflamm Bowel Dis* 2008; 14(1):32-9.
10. Papp M, Norman GL, Altorjay I et al. Utility of serological markers in inflammatory bowel diseases: gadget or magic? *World J Gastroenterol* 2007; 13(14):2028-36.  
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.