



IEHP UM Subcommittee Approved Authorization Guideline			
<b>Guideline</b>	Inflammatory Bowel Disease (IBD) Serology	<b>Guideline #</b>	UM_DIA 11
		<b>Original Effective Date</b>	11/18/2005
<b>Section</b>	Diagnostic	<b>Revision Date</b>	03/28/2019

### COVERAGE POLICY

The IEHP Utilization Management Subcommittee adopts the opinions below and considers inflammatory bowel disease (IBD) serology testing to be investigational and experimental, and therefore not a medical necessity.

A recent review of literature revealed no conclusive scientific data supporting the routine use of serologic testing in the screening, diagnosis or management of IBD.

### COVERAGE LIMITATIONS AND EXCLUSIONS

Not applicable

### ADDITIONAL INFORMATION

Inflammatory bowel disease (IBD) can be subdivided into ulcerative colitis (UC) and Crohn’s disease (CD), both which present with symptoms of diarrhea and abdominal pain. The definitive diagnosis can usually be established by a combination of x-rays, endoscopy, and microscopic tissue analysis. For some of the patients (10% - 15%), however, distinction between UC and CD cannot be made with certainty. Two serum antibodies, anti-neutrophilic cytoplasmic antibodies (ANCA) and anti-Saccharomyces cerevisiae (ASCA), have been known to be associated with IBD and have thus been studied.

Tests with serum antibodies have the potential to be used as diagnostic tools. A second possible use may be to classify subtypes of IBDs that may provide more prognostic information. It has been proposed that these serologic markers also may predict response to anti-tumor necrosis factor (TNF) therapy or to identify susceptible family members to IBD. Prometheus Therapeutics and Diagnostics offers diagnostic testing that combines serology, genetic and inflammation markers to differentiate IBD from other causes of diarrhea and abdominal pain and differentiate UC from Crohn’s Disease. MicroRNAs (miRNAs) are small, 22-nucleotide, noncoding, single-stranded RNA involved in post-transcriptional regulation of protein coding genes. Unique expression profiles have been described in epithelial cells of patients with active UC and Crohn’s Disease. However, current evidence suggests that these markers lack sufficient sensitivity to be recommended for use as diagnostic or screening tools. Evidence is also unavailable to support their cases as prognostic indications (Ruben, 2019).

## CLINICAL/REGULATORY RESOURCE

### Medicare

Clinical validity has not been established for the use of the Prometheus IBD sgi diagnostic test in distinguishing ulcerative colitis (UC) from Crohn's Disease (CD). This assay does not meet Medicare reasonable and necessary criteria for coverage (L37299 2018).

### Medi-Cal

Does not comment on serologic testing for IBD.

### MCG

A0839-MicroRNA Detection-Inflammatory Bowel Disease states that there are currently no clinical indications for the use of MicroRNA detection

M-565- Inflammatory Bowel Disease notes that the alternative care plan for patients not requiring hospitalization may include C-reactive protein, erythrocyte sedimentation rate, liver function tests, perinuclear antineutrophil cytoplasmic antibody (pANCA), iron studies, and testing for cytomegalovirus.

### American College of Gastroenterology (ACG):

The ACG Clinical Guideline for ulcerative colitis states that the individual and pooled sensitivity pANCA and anti-Saccharomyces cerevisiae antibodies (ASCA) for the diagnosis of UC versus CD is low and that such markers are not useful for establishing or ruling out a diagnosis.

ACG also states that there is currently no role for tests of pANCA in determining the likelihood of disease evolution and prognosis (Rubin et.al, 2019).

## REFERENCES

1. Local Coverage Determination (LCD): MolDX: Prometheus IBD sgi Diagnostic Policy (L327299). <https://www.cms.gov/medicare-coverage-database/details/Icd-details.aspx?LCDId=37299&ver=9&Date=03%2f20%2f2019&DocID=L37299&bc=iAA AABAAAAAA&>. Accessed 3/10/2019.
2. MCG Health 22<sup>nd</sup> edition, Ambulatory Care, 2018. A-0839 MicroRNA Detection-Inflammatory Bowel Disease.
3. MCG Health 22<sup>nd</sup> edition, Inpatient and Surgical Care, 2018. M-565 Inflammatory Bowel Disease
4. Rubin D, AN Ananthakrishnan, CA Siegel, BG Sauer, MD Long. ACG Clinical Guideline- Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114 (3): 384-413. [https://journals.lww.com/ajg/Fulltext/2019/03000/ACG\\_Clinical\\_Guideline\\_\\_Ulcerative\\_Colitis\\_in.10.aspx](https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline__Ulcerative_Colitis_in.10.aspx)
5. Sushila, SR and JH Kwon. The Role of MicroRNA in Inflammatory Bowel Disease. Gastroenterol Hepatol (NY) 2010 Nov, 6(11): 714-722. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3033542/>

**DISCLAIMER**

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.