IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Inflammatory Bowel Disease (IBD) Serology	**Guideline #**	UM_DIA 11
		Original Effective Date	11/18/2005
Section	Diagnostic	**Revision Date**	11/20/2023

COVERAGE POLICY

The IEHP Utilization Management Subcommittee considers inflammatory bowel disease (IBD) serology testing to be investigational and experimental in the screening, diagnosis, and management of this condition, and therefore not a medical necessity. Indeed, a recent review of literature revealed no conclusive scientific data supporting the routine use of serologic testing.

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

Center for Medicare and Medicaid Coverage (CMS), Local Coverage Determination (LCD)
MolDX: Prometheus IBD sgi Diagnostic Policy (37299)
This assay does not meet Medicare's reasonable and necessary criteria for coverage. Additionally, each of the individual components that comprise this assay, except ASCA-IgA, ASCA-IgG, and atypical perinuclear anti-neutrophil cytoplasmic antibody, are additionally non-covered for the diagnosis of IBD.

Medi-Cal
Does not comment on serologic testing for IBD.

MCG
Care planning needs for patient not requiring admission may include diagnostic tests [such as] perinuclear antineutrophil cytoplasmic antibody (pANCA) [and]anti-Saccharomyces cerevisiae antibody (ASCA).

Apollo
Testing for anti-neutrophil cytoplasmic antibodies (ANCA) [and] anti-saccharomyces cerevisiae antibodies (ASCA)…[are] experimental and investigational to diagnosis inflammatory bowel disease, to distinguish Ulcerative Colitis from Crohn's Disease and for all other indications because their effectiveness has not been established.

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 ulcerative colitis disease evolution and prognosis (Rubin et.al, 2019).

The ACG Clinical Guideline for Crohn's Disease recommends that routine use of serologic markers of IBD to establish the diagnosis of Crohn's disease is not indicated. Genetic testing is not indicated to establish the diagnosis of Crohn's disease.

REFERENCES

1. Apollo Medical Review Criteria Guidelines for Managing Care, 22nd edition, 10th online edition, 2023. GI 137C Inflammatory Bowel Disease (IBD) Markers.
2. Apollo Medical Review Criteria Guidelines for Managing Care, 22nd edition, 10th online edition, 2023. GI 187 Inflammatory Bowel Disease (IBD); Crohn's, Ulcerative (Regional) Colitis.
3. Labcorp. Inflammatory Bowel Disease (IBD) Expanded Profile. https://www.labcorp.com/tests/162045/inflammatory-bowel-disease-ibd-expanded-profile#:~:text=The%20most%20commonly%20employed%20serological,predominantly%20in%20patients%20with%20UC. Accessed November 20, 2023.
4. Lichtenstein, Gary R, Edward V Loftus, Kim L Isaacs, Miguel D Regueiro, Lauren B Gerson, Bruce E Sands. 2018. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 113(4): 481-517. https://journals.lww.com/ajg/Fulltext/2018/04000/ACG_Clinical_Guideline__Management_of_Crohn_s.10.aspx?context=FeaturedArticles&collectionId=2. Accessed November 20, 2023.
5. MCG Health Inpatient and Surgical Care, 26th edition, 2023. M-565 Inflammatory Bowel Disease.
6. Medicare Local Coverage Determination (LCD). MolDX: Prometheus IBD sgi Diagnostic Policy L37299. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37299&ver=21&keyword=L37299&keywordType=starts&ar

eaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed November 20, 2023.
7. Rubin David T, Ashwin N Ananthakrishnan, Corey A Siegel, Bryan G Sauer, Millie D Long. 2019. ACG Clinical Guideline- Ulcerative Colitis in Adults. Am J Gastroenterol;114 (3): 384-413. https://journals.lww.com/ajg/Fulltext/2019/03000/ACG_Clinical_Guideline__Ulcerative_Colitis_in.10.aspx?context=FeaturedArticles&collectionId=2. Accessed November 20, 2023.

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.