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**	12/15/2021

COVERAGE POLICY

The IEHP Utilization Management Subcommittee 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

The Promethius IBD sgi Diagnostic test is not covered. Local Coverage Determination notes clinical validity has not been established for the use of this test in distinguishing ulcerative colitis (UC) from Crohn's Disease (CD). This assay does not meet Medicare reasonable and necessary criteria for coverage.

Medi-Cal

Does not comment on serologic testing for IBD.

MCG

The MCG guideline on MicroRNA Detection-Inflammatory Bowel Disease states that there are currently no clinical indications for the use of MicroRNA detection

The MCG guideline on Inflammatory Bowel Disease notes that the alternative care plan for patients not requiring hospitalization may include C-reactive protein, erythrocyte sedimentation rate, liver and renal function tests, perinuclear antineutrophil cytoplasmic antibody (pANCA), anti-Saccharomyces cerevisiae antibody (ASCA), iron studies, and testing for cytomegalovirus.

Apollo

MicroRNA tests are not addressed. Aetna policies that consider antibody and genetic testing experimental and investigational to diagnose inflammatory bowel disease and distinguish ulcerative colitis from Crohn's disease are listed. The effectiveness and clinical value has not been established for these tests.

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

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