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INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines
Inflammatory Bowel Disease (IBD) Serology

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 performed January 2017 by ECRI, a paid health technology assessment information service, revealed no conclusive scientific data supporting the routine use of serologic testing in the screening, diagnosis or management of IBD.

US Department of Health and Human Services 2016 (US DHHS NGCH):

The U.S. Department of Health and Human Services National Guideline Clearing House does not comment on serologic testing for IBD.

American College of Gastroenterology 2012:

The American College of Gastroenterology noted that the low sensitivity of pANCA and ANCA for the diagnosis of UC and CD, respectively, prevent them from serving as useful diagnostic tools.

American Academy of Pediatrics 2010 (Pediatrics):

The American Academy of Pediatrics noted that despite its recent inclusion of an antitropodinin assay, the IBD7 panel has a lower predictive value than routine lab tests.

Blue Cross Blue Shield 2012:

BCBS does not provide coverage for the determination of anti-neutrophil cytoplasmic antibody (ANCA) and anti-Saccharomyces cerevisiae antibody (ASCA) serology in the workup and monitoring of patients with IBD. It is considered experimental/investigational and therefore not a covered benefit. (2/14/2012)

10801 Sixth St, Suite 120, Rancho Cucamonga, CA 91730
Tel (909) 890-2000 Fax (909) 890-2003
Visit our web site at: www.iehp.org

A Public Entity

IEHP UM Subcommittee Approved Authorization Guidelines

Inflammatory Bowel Disease Serology

Page 2 of 4

CIGNA 2016:

CIGNA does not serologic testing for the diagnosis of IBD or to differentiate ulcerative colitis from Crohn's . All serologic tests/test panels including, but not limited to ANCA, pANCA, ASCA, Prometheus IBD sgi Diagnostic, Prometheus Crohn's Prognostic are considered experimental, investigational or unproven.

Aetna 2012:

Aetna considers only one of the following per member lifetime medically necessary prior to initiation of 6-mercaptopurine or azathioprine therapy: TMPT gene mutation or TMPT phenotypic assays (e.g. Prometheus TMPT Genetics, Prometheus TMPT Enzyme). Testing for anti-neutrophil cytoplasmic antibodies (ANCA), anti-Saccharomyces cerevisiae antibodies (ASCA) experimental and investigational to diagnose IBD or to distinguish ulcerative colitis from Crohn's disease because their clinical value has not been established. Aetna does not cover serological testing for IBD. (5/25/2012)

Background:

The Blue Cross Blue Shield Corporate Medical Policy describes the Procedure or Service as follows: 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.

These tests with serum antibodies have the potential to be used as improved diagnostic tools differentiating types of IBDs with accuracy that may decrease some of the diagnostic workups. 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. However, evidences have shown that these markers are neither sufficiently sensitive nor specific to be recommended for use as diagnostic or screening tools in current guidelines. (Amer J of Gastroenterology, 2009, 2010; American Academy of Pediatrics, 2010); U.S. Department of Health and Human Services, National Guideline Clearing House (NGC-5604, 2007).

Effective Date: *November 18, 2005*

Reviewed Annually: *November 9, 2016*

Revised:

November 14, 2012

February 8, 2017

IEHP UM Subcommittee Approved Authorization Guidelines

Inflammatory Bowel Disease Serology

Page 3 of 4

Bibliography:

1. Amer J of Gastroenterology: Management of Crohn's Disease in Adults (2009)
2. Amer J of Gastroenterology: Ulcerative Colitis Practice Guidelines in Adults (2010):
3. American Academy of Pediatrics: Shortcomings of the Inflammatory Bowel Disease Serology 7 Panel (2010)
4. US Department of Health and Human Services: Evidence-based care guideline for management of pediatric moderate/severe inflammatory bowel disease (IBD). (2007)
5. BCBS: Laboratory Studies for Diagnosing and Managing Inflammatory Bowel Disease (2/14/2012).
6. CIGNA. Serological Testing for Inflammatory Bowel Disease. Cigna Medical Coverage Policy. Effective date (8/15/2016). Retrieved from:
[https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0121_coveragepositioncrit
eria_serological_testing_for_ibd.pdf](https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0121_coveragepositioncriteria_serological_testing_for_ibd.pdf)
7. Aetna. Inflammatory Bowel Disease: Serologic Markers and Pharmacogenomic and Metabolic Assessment of Thiopurine Therapy. Policy Number 0249. Last Review: 5/24/2016 Retrieved from:
http://www.aetna.com/cpb/medical/data/200_299/0249.html

This guideline was developed using the following information: Blue Cross Blue Shield of North Carolina (BCBSNC) Corporate Policy (2012), CIGNA Healthcare Coverage Position (2011), Aetna Clinical Policy (2012), U.S. Department of Health and Human Services (2007), American College of Gastroenterology (2012), American Academy of Pediatrics (2010).

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.

IEHP UM Subcommittee Approved Authorization Guidelines*Inflammatory Bowel Disease Serology*

Page 4 of 4

ATTACHMENT:**Current IBD Guidelines and policies**

Organization	Recommendation/Coverage	Serologic Markers	Date	Comments
CMS	No specific guidelines established			
MediCal	No specific guidelines established			
CIGNA	Cigna does not cover testing markers for the diagnosis or management of IBD because it is considered experimental, investigational or unproven thus not covered.	ANCA pANCA ASCA Anti-OmpC Ab Anti-CBir1 Ab	7/15/2011	Sustained from prior review
BCBS	Blue Cross Blue Shield stated that serological markers for the diagnosis or management of IBD are considered experimental/ investigational thus not covered.	ANCA pANCA ASCA Anti-OmpC Ab Anti-CBir1 Ab	2/14/2012	The authors concluded that a combination of ESR and Hb has a higher positive predictive value for IBD and is more sensitive and specific than commercial testing.
Aetna	Aetna considers the following tests experimental and investigational because their clinical value has not been established thus not covered.	eXaIBD (genetest) Myeloperoxidase Proteinase-3AB Raman spectroscopy for IBD	5/25/2012	Aetna considers the Prometheus IBD sgi diagnostic panel and IBS panel experimental and investigational.
AC GI	American college of gastroenterology noted that the low sensitivity of pANCA and ANCA for Dx of UC and CD , respectively, prevent them from serving as a useful Dx tool.	ANCA pANCA	1/12/2012	Independent study
Pediatrics	American Academy of Pediatrics noted that despite its recent inclusion of anti-flagellin assay, IBD7 panel has lower predictive value than routine lab tests.	Anti-CBir1 Anti-OmpC ASCA IgA ASCA IgG pANCA	6/2010	IBD7 testing was performed at Prometheus Laboratories between 1/2006 and 11/2008.
US DHHS NGCH	US Department of Health and Human Services National Guideline Clearing House does not comment or mention about serologic testing for IBD in pediatric patients.	N/A	10/12/2011	The NGC summary was completed by ECRI Institute on June 6, 2007 and updated by ECRI Institute on 10/12/2011.
IEHP	IEHP UM Subcommittee adopts these opinions and considers IBD Serology investigational and experimental and therefore not a medical necessity.		11/18/2005, Reviewed 11/9/2011, Updated 11/14/2012	Concurrent with above studies and recommendations IEHP does not recognize serologic testing as a medical necessity.