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*Easy Choice Health Plan*

*Harmony Health Plan of Illinois*

*Missouri Care*

*'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona*

*OneCare (Care1st Health Plan Arizona, Inc.)*

*Staywell of Florida*

*WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)*

*WellCare Prescription Insurance*

## Serological Testing for Inflammatory Bowel Disease

Policy Number: HS-191

Original Effective Date: 10/21/2010

Revised Date(s): 9/15/2011; 10/4/2012;  
10/3/2013; 10/2/2014; 10/1/2015; 10/6/2016;  
8/3/2017

### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at [www.wellcare.com](http://www.wellcare.com). All guidelines can be found at this site as well but selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### BACKGROUND

Inflammatory bowel diseases (IBDs), which include ulcerative colitis and Crohn's disease, affect approximately one million Americans, and the incidence and prevalence of these diseases is increasing in western societies. Both diseases are characterized by an uncontrolled inflammatory response at the mucosal level that results in tissue damage. While most cases of Crohn's disease and ulcerative colitis can be diagnosed readily based on clinical, radiological, or endoscopic and histological criteria, these diseases have overlapping clinicopathologic features. Furthermore, in 10% of cases in which only the colon is affected, the correct diagnosis cannot be made and the colitis is classified as indeterminate. There is evidence from cross-sectional studies that ASCA and pANCA are strongly

associated with Crohn's disease and ulcerative colitis, respectively, and that combining the tests may be useful as an adjunct to conventional diagnostic techniques for patients with suspected Crohn's disease and ulcerative colitis, and may aid in classifying patients with indeterminate colitis. However, there is insufficient evidence from prospective studies that serologic testing improves patient management or health outcomes for patients with IBD, and there are unanswered questions regarding the most accurate type of assay. Due to the lack of prospective studies in asymptomatic individuals at risk, there is no evidence at this time regarding the usefulness of these markers in population screening for IBD. Likewise, there is no evidence regarding the use of ASCA or pANCA for predicting response to treatment.<sup>1,2,3</sup>

#### Professional Organizations

The American College of Gastroenterology Practice Guidelines for Management of Crohn's Disease in Adults state, "serological studies evaluating antibodies against *Saccharomyces cerevisiae*, antineutrophil cytoplasmic antibodies, antibodies directed against CBir1, OmpC are evolving to provide adjunctive support for the diagnosis of Crohn's disease, but are not sufficiently sensitive or specific to be recommended for use as a screening tool".<sup>4</sup>

The American College of Gastroenterology Ulcerative Colitis Practice Guidelines in Adults states that pANCA has been found in 60-70% of UC patients and nearly 40% of patients with CD. "These pANCA-positive CD patients typically have a clinical phenotype resembling left-sided UC patients, so ANCA detection alone is of little value in distinguishing between UC and Crohn's colitis" therefore demonstrating that due to the low sensitivity of pANCA it is not a reliable diagnostic measure.<sup>5</sup> Such tests may be useful in patients who do not have other clinical or pathologic features, allowing a differential diagnosis between UC and Crohn's colitis.

According to the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the Crohn's and Colitis Foundation of America, differentiating UC from CD in children and young adults is a continued area for study with attention on the role of surrogate laboratory markers (genetics, serology, microbiology). Hayes has found a lack of evidence supporting the efficacy of serological testing.<sup>1</sup>

## POSITION STATEMENT

### Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Testing for serological markers for the diagnosis or management of inflammatory bowel disease, which includes Crohn's disease and ulcerative colitis, **is considered experimental and investigational and is NOT a covered benefit.** Types of Serological Marker Assays (list not all-inclusive) for Inflammatory Bowel Disease include:

- anti-neutrophilic cytoplasmic antibody (ANCA), perinuclear anti-neutrophilic cytoplasmic antibody (pANCA)
- anti-saccharomyces cerevisiae antibody (ASCA)
- anti-outer membrane porin C (anti-OmpC) antibody
- anti-CBir1 flagellin (anti-CBir1) antibody

NOTE: These tests may be medically necessary for the diagnosis or treatment of other conditions.

## CODING

### Non-Covered CPT® Codes (this list may not be all inclusive)

- 83516** Immunoassay for analyte other than infectious agent antibody or infectious agent antigen, qualitative or semiquantitative; multiple step method
- 83520** Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified.
- 86021** Antibody identification; leukocyte antibodies
- 86255** Fluorescent noninfectious agent antibody; screen, each antibody
- 86256** Fluorescent noninfectious agent antibody; titer, each antibody
- 86671** Antibody; fungus, not elsewhere specified
- 88346** Immunofluorescence, per specimen; initial single antibody stain procedure

**88350** Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)

**HCPCS Level II© Codes** – No applicable codes.

**ICD-9-CM Procedure Codes** – No applicable codes.

**ICD-10-PCS Codes** – No applicable codes.

**ICD-10-CM Diagnosis Codes**

**K50.00 – K50.919** Crohn’s disease (regional enteritis)

**K51.80 - K51.919** Ulcerative colitis

**K58.0 - K58.9** Irritable bowel syndrome

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**

1. Serologic assays for the diagnosis and management of inflammatory bowel disease: ulcerative colitis. Hayes Directory Web site. <http://www.hayesinc.com>. Published April 4, 2013 (reviewed March 17, 2017). Accessed July 12, 2017.
2. North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition; Colitis Foundation of America; Bousvaros A, Antonioli DA, Colletti RB, Dubinsky MC, et al. Differentiating ulcerative colitis from Crohn disease in children and young adults: report of a working group of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the Crohn's and Colitis Foundation of America. *Journal of Pediatric Gastroenterology and Nutrition*. 2007; 44(5):653-74.
3. Anand V, Russell AS, Tsuyuki R, Fedorak R. Perinuclear antineutrophil cytoplasmic autoantibodies and anti-Saccharomyces cerevisiae antibodies as serological markers are not specific in the identification of Crohn's disease and ulcerative colitis. *Canadian Journal of Gastroenterology*. 2008; 22(1):33-36.
4. Lichtenstein GR, Hanauer SB, Sandborn WJ, Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. *American Journal of Gastroenterology*. 2009; 104(2):465-83.
5. Kornbluth A, Sachar DB, Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *American Journal of Gastroenterology*. 2010; 105(3):501-523.

**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

Date	Action
8/3/2017, 10/6/2016, 10/1/2015, 10/2/2014, 10/3/2013, 10/4/2012	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
12/1/2011	<ul style="list-style-type: none"> <li>• New template design approved by MPC.</li> </ul>
9/15/2011	<ul style="list-style-type: none"> <li>• Approved by MPC. Added section “Professional Organizations” with 2 new references.</li> </ul>