JOHNS HOPKINS HEALTHCARE

Medical Policy: Serum Antibodies Assays for the Diagnosis of Inflammatory Bowel Disease
Department: Health Services
Lines of Business: EHP, USFHP, PPMCO, ADVANTAGE MD

Policy Number CMS19.06

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ACTION:
☐ New Policy
☐ Revising Policy Number
☐ Superseding Policy Number
☒ Archiving Policy Number: CMS19.06
☐ Retiring Policy Number

Effective Date: 11/30/2004
Review Dates: 11/21/05, 10/21/06, 06/25/08, 06/04/09, 01/07/11, 09/06/13, 09/02/16

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

ACTIVE AND ARCHIVED

This document has been archived as of 09/06/2013 and is no longer scheduled for review for either one or more of the following reasons:
1. This document is either primarily administrative in nature AND/OR
2. It addresses operational issues only AND/OR
3. It is mandated by statute or regulation AND/OR
4. It is unlikely that further published literature would change the determination

ARCHIVED POLICIES REMAIN ACTIVE FOR THE PURPOSE OF MEDICAL NECESSITY DETERMINATION

SCOPE:

This policy addresses anti-neutrophil cytoplasmic antibody (ANCA) and anti-Saccharomyces cerevisiae antibody (ASCA).

POLICY:

I. Unless specific benefits are provided under the member’s contract, JHHC considers anti-neutrophil cytoplasmic antibody (ANCA) and anti-Saccharomyces cerevisiae antibody (ASCA) experimental and investigational in the work-up and monitoring of patients with inflammatory bowel disease for all other indications, as they do not meet Technology Evaluation Criteria (TEC) #2-5.
BACKGROUND:

Inflammatory bowel disease (IBD) can be subdivided into ulcerative colitis and Crohn’s disease, both of which present with symptoms of diarrhea and abdominal pain. The definitive diagnosis can usually be established by a combination of radiographic, endoscopic and histological criteria, although in 10-15% of cases the distinction cannot be made with certainty. Two serum antibodies, anti-neutrophilic cytoplasmic antibodies (ANCA) and anti-Saccharomyces cerevisiae (ASCA) have been investigated as a technique to improve the efficiency and accuracy of diagnosing IBD.

Hayes, Inc. has assigned a C Rating to ASCA and pANCA serologic tests when used for the management of patients with IBD or for predicting response to treatment and population screening in asymptomatic individuals. They conclude: “Findings from a large body of low-quality evidence indicate that serological assays, specifically those incorporating perinuclear antineutrophil cytoplasmic antibodies (pANCA) and anti-Saccharomyces cerevisiae antibodies (ASCA), have high specificity (typically ≥ 85%) for diagnosis of ulcerative colitis (UC), suggesting that a positive finding from such an assay may be useful for confirming a diagnosis of the disease. In contrast, the sensitivity of assays with these serological antibodies is too low (typically ≤ 50%) to be effective for identifying the disease in question, indicating that the test is likely not useful for screening. There is also limited, low-quality evidence that the presence of pANCA can predict disease phenotype or progression of UC. Furthermore, there is limited evidence regarding the use of serological antibodies for predicting response to treatment. Although there is currently no evidence from prospective studies that serological testing improves patient management or health outcomes for patients with UC, such improvements are likely if cross-sectional studies confirm the high specificity for UC. 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 UC.”

CODING INFORMATION:

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage and referral requirements. All inpatient admissions require pre-authorization.
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ICD10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY

<table>
<thead>
<tr>
<th>Employer Health Programs (EHP) <strong>See Specific Summary Plan Description (SPD)</strong></th>
<th>Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply policy criteria</th>
<th>US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria</th>
<th>Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria</th>
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<tr>
<th>ICD10 CODES</th>
<th>DESCRIPTION</th>
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<tr>
<td>K58.0 – K58.9</td>
<td>Irritable bowel syndrome</td>
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REFERENCE STATEMENT:

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

REFERENCES:


Higuchi, L.M., Bousvaros, A. (2011). UpToDate: Diagnosis of Inflammatory Bowel Disease in Children and Adolescents.


