ACTION:
☐ New Policy  ☒ Revising Policy Number: CMS06.03
☐ Superseding Policy Number
☐ Archiving Policy Number
☐ Retiring Policy Number

Effective Date: 08/23/2005
Review Dates: 10/17/06, 03/03/08, 03/02/09, 06/04/10, 10/07/11, 06/07/13, 12/04/15, 12/01/17

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.

POLICY:

For Advantage MD, see Medicare Coverage Database:
National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3)

I. When benefits are provided under the member’s contract, JHHC considers colorectal cancer (CRC) screening using stool DNA (sDNA) samples, (E.g., Cologuard) medically necessary for men or women who meet ALL of the following requirements:
   A. Are ≥ 50 years of age
   B. Have an average risk of CRC, AND;
   C. Have not had a positive result from another CRC screening test.

   Note ~ When benefits are provided under the member’s contract, JHHC considers colorectal cancer (CRC) screening using stool DNA (sDNA) samples, (E.g., Cologuard) medically necessary at a frequency of once every three years when all of the above criteria are met.

II. Unless specific benefits are provided under the member’s contract, JHHC considers colorectal cancer (CRC) screening using stool DNA (sDNA) samples, (E.g., Cologuard) experimental and investigational for all other indications, as it does not meet Technology Evaluation Criteria (TEC) #2-5.

BACKGROUND:

Fecal or stool DNA testing is a noninvasive screening technique used primarily for the detection of cancer and precancerous tumors. In particular, fecal DNA testing is known to be effective in detecting colorectal cancer and other conditions affecting the colon. Currently, Cologuard™ is the only FDA-approved stool DNA test in the United States.
Testing of the stool allows physicians and researchers to identify genetic changes in DNA using biomarkers associated with colorectal cancer and other premalignant colorectal adenomas. Detection of biomarker is possible using a PCR-based method known as Quantitative Allele-specific Real-time Target and Signal (QuARTS), which analyzes specific gene variants for changes. Positive test results of a stool sample indicate that there is an abnormal gene sequence or an elevated presence of Hb levels.

**CODING INFORMATION:**

*CPT Copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.*

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.

**NO PRE-AUTHORIZATION REQUIRED**

*Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits*

<table>
<thead>
<tr>
<th>Employer Health Programs (EHP)</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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**CPT ® CODES**

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>81528</td>
<td>Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result.</td>
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ICD10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY

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<tr>
<th>ICD10 CODES</th>
<th>DESCRIPTION</th>
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<tr>
<td>Z12.10</td>
<td>Encounter for screening for malignant neoplasm of intestinal tract, unspecified</td>
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<tr>
<td>Z12.11</td>
<td>Encounter for screening for malignant neoplasm of colon</td>
</tr>
<tr>
<td>Z12.12</td>
<td>Encounter for screening for malignant neoplasm of rectum</td>
</tr>
<tr>
<td>Z15.09</td>
<td>Genetic susceptibility to other malignant neoplasm</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:


