

| TITLE: | COLONOSCOPY AND COLORECTAL SCREENING POLICY | |
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| POLICY #: | MM-PNP-006 | |
| VERSION #: | 01 | |
| DEPARTMENT: | MEDICAL MANAGEMENT | |
| ORIGINAL EFFECTIVE DATE: | 10/16/2023 | |
| CURRENT REVISION DATE: | N/A | |

1. PURPOSE

This Clinical Policy addresses colonoscopy and colorectal cancer screening

2. SCOPE

Medical UM Department

3. **DEFINITIONS**

3.1. N/A

4. POLICY

Medical Necessity

Routine Screening

Curative considers *any* of the following colorectal cancer screening tests medically necessary preventive services for average-risk members aged 45 years and older when these tests are recommended by their physician:

- Colonoscopy (considered medically necessary every 10 years for persons at average risk); or
- CT Colonography (virtual colonoscopy) (considered medically necessary every 5 years); or
- Double contrast barium enema (DCBE) (considered medically necessary every 5 years for persons at average risk); or
- Immunohistochemical or guaiac-based fecal occult blood test (FOBT) (considered medically necessary every year for persons at average risk); *or*
- Sigmoidoscopy (considered medically necessary every 5 years for persons at average risk); or
- Sigmoidoscopy (every 5 years) with annual immunohistochemical or guaiac-based fecal occult blood testing (FOBT); or
- Stool DNA (FIT-DNA, Cologuard) (considered medically necessary every 3 years).

Routine colorectal cancer screening for members 85 years of age or older is considered not medically necessary unless life expectancy is greater than or equal to 10 years.

Note: The U.S. Preventive Services Task Force (USPSTF) guidelines apply to routine screening. The USPSTF guidelines have no A or B recommendations for high-risk screening. The USPSTF guidelines explain: "This recommendation applies to asymptomatic adults 50 years and older who are at average risk of colorectal cancer and who do not have a family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer (such as Lynch syndrome or familial adenomatous polyposis), a personal history of inflammatory bowel disease, a previous adenomatous polyp, or previous colorectal cancer. When screening results in the diagnosis of colorectal adenomas or cancer, patients are followed up with a surveillance regimen, and recommendations for screening no longer apply. The USPSTF did not review or consider the evidence on the effectiveness of any particular surveillance regimen after diagnosis and removal of adenomatous polyps or colorectal cancer."

High-Risk Testing

Curative considers colorectal cancer testing with sigmoidoscopy, DCBE, or colonoscopy as frequently as every 2 years medically necessary for members with *any* of the following risk factors for colorectal cancer:

- A first-degree relative (sibling, parent, child) who has had colorectal cancer or adenomatous
 polyps (screening is considered medically necessary beginning at age 40 years, or 10 years
 younger than the earliest diagnosis in their family, whichever comes first); or
- Family history of familial adenomatous polyposis (screening is considered medically necessary beginning at puberty); or
- Family history of hereditary non-polyposis colorectal cancer (HNPCC) (screening is considered medically necessary beginning at age 20 years); or
- Family history of MYH-associated polyposis in siblings (screening is considered medically necessary beginning at age 25 years); *or*
- Diagnosis of Cowden syndrome (screening is considered medically necessary beginning at age 35 years).

Curative considers annual FOBT, alone or in conjunction with sigmoidoscopy, medically necessary for testing of members with any of the above risk factors for colorectal cancer.

Surveillance

Curative considers colorectal cancer surveillance with colonoscopy, flexible sigmoidoscopy or DCBE medically necessary as frequently as every year for members who meet *any* of the following criteria:

- Member has inflammatory bowel disease (including ulcerative colitis or Crohn's disease) (colorectal cancer surveillance is considered medically necessary as frequently as every year); or
- Personal history of adenomatous polyps (surveillance is considered medically necessary as frequently as every 2 years); or
- Personal history of colorectal cancer (surveillance is considered medically necessary as frequently as every year).

Curative considers annual FOBT, alone or in conjunction with sigmoidoscopy, medically necessary for surveillance of colorectal cancer.

Diagnostic Testing

Curative considers diagnostic testing with FOBT, colonoscopy, sigmoidoscopy and/or DCBE medically necessary for evaluation of members with signs or symptoms of colorectal cancer or other gastrointestinal diseases. Diagnostic upper endoscopy is considered medically necessary for evaluation of persons with signs and symptoms of upper gastrointestinal disease.

Biopsy of the Lower Gastro-Intestinal Tract

Curative considers biopsy of the lower gastro-intestinal tract medically necessary for the following indications:

- Microscopic colitis 8 or more biopsies are considered medically necessary in persons with symptoms suggestive of microscopic colitis (e.g., diarrhea and/or functional abdominal pain) (2 or more from the ascending, transverse, descending, and sigmoid colon);
- Inflammatory bowel disease, diagnosis 2 or more biopsies from 5 different locations, including the ileum and rectum;
- Inflammatory bowel disease, screening for dysplasia targeted biopsies, plus:
- Pancolitis biopsies from the 4 quadrants each 10 cm;
- Segmental colitis biopsies from the 4 quadrants each 10 cm limited to involved areas in previous examinations;
- Pouchitis multiple biopsies from the pouch and afferent loop;
- Colonic polyps biopsies of polyps that cannot be removed;
- Acute graft-versus-host disease:
 - Flexible sigmoidoscopy 4 or more biopsies from the rectum/sigmoid and 4 or more biopsies from the left colon;
 - Ileocolonoscopy 4 or more biopsies from the terminal ileum, ascending colon, transverse colon, descending colon, and rectum/sigmoid colon.

Experimental and Investigational

Colorectal Cancer Screening

Curative considers colorectal cancer screening with any of the following experimental and investigational because the effectiveness of these approaches has not been established:

- Stool molecular genetic tests other than Cologuard (e.g., ColoCaller Test, ColoSure, PreGen-Plus)
- Methylated Septin 9 (ColoVantage, Epi proColon)
- Whole-blood DNA methylation markers
- MicroRNAs

- Chromoendoscopy or narrow-band imaging optical colonoscopy
- Plasma/serum biomarkers (C-reactive protein, complement C3a anaphylatoxin, plasma GATA5 and SFRP2 methylation, serum CD26 (sCD26), serum matrix metalloproteinase-7 (MMP-7), and tissue inhibitor of metalloproteinases (TIMP-1))
- PolypDx (Atlantic DiagnosticLaboratories, LLC, Metabolomic Technologies Inc.)
- CD3 immuno-staining
- Full-spectrum endoscopy (FUSE) colonoscopy
- Stool-based protein biomarkers
- Blood-based protein biomarkers (e.g., BeScreened-CRC, Beacon Biomedical, Inc.)
- Capsule endoscopy
- Artificial intelligence-aided colonoscopy (including computer-aided colonoscopy)
- SimpliPro Colon Test
- Fecal volatile organic compounds
- Performance of multiple screening strategies simultaneously in the same individual (for example, virtual colonoscopy screening every 5 years plus stool DNA testing every 3 years)
- Screening begins at earlier than standard recommended ages for persons at increased risk due to smoking or obesity.

Anal Pap Smear

Curative considers screening for anal cytological abnormalities (anal Pap smear) or for anal human papilloma virus (HPV) infection experimental and investigational because of the lack of evidence that such screening improves clinical outcomes.

5. PROCEDURE

5.1. N/A

6. TRAINING REQUIREMENT

6.1. All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

7. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal and equitable remedies may apply.

8. DOCUMENTATION

N/A

9. REFERENCE DOCUMENTS AND MATERIALS

9.1. Regulatory Authority

9.1.1. N/A

- 9.2. Internal N/A
- 9.3. External N/A
- 10. COLLABORATING DEPARTMENTS
 - **10.1.** N/A
- 11. DOCUMENT CONTROL

| APPROVED BY: | | | | |
|----------------|--------|-------------|--|--|
| | | | | |
| (Printed Name) | (Date) | (Signature) | | |

| | REVISION HISTORY | | | | | |
|------|------------------|---------|-----------------|--|--|--|
| Date | Author | Version | Comments | | | |
| | | | Initial Version | | | |
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APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: