

## COLORECTAL CANCER (CRC) SCREENING PROTOCOL v1

Approved 9/28/2021

### PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to provide education and information specific to Colorectal Cancer and when appropriate, initiate noninvasive, stool-based colorectal cancer (CRC) screening using fecal immunochemical test (FIT) or stool DNA test (e.g., sDNA-FIT).

### PHARMACIST EDUCATION AND TRAINING

Prior to initiating noninvasive, stool-based CRC screening under this protocol, pharmacist(s) shall have received education and training in CRC screening, including review of the most recent: 1) Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement<sup>1</sup> and 2) the American Cancer Society's Colorectal Cancer Screening Guideline for Average-Risk Adults<sup>2</sup> from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

### CRITERIA

Pharmacist(s) authorized to initiate the dispensing of noninvasive stool-based CRC shall follow the most current ACS/USPSTF Guidelines for CRC screening.<sup>1,2</sup>

Inclusion criteria (All criteria must be met):

- Patient is between 45 and 85 years of age
  - For patients 76 through 85 years of age the decision to be screened shall be based on a person's preference, life expectancy, overall health, and prior screening history using shared decision making between the pharmacist and the patient.

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<sup>1</sup> Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238

- Patient is at average risk for colorectal cancer (CRC) as defined by inclusion and exclusion criteria
- Patient is able and willing to undergo a screening completion colonoscopy [if positive results are obtained from the stool-based screening tests]

Exclusion criteria:

- A person with active signs or symptoms of CRC including, but not limited to rectal bleeding, unexplained bowel habit changes (diarrhea or constipation), unexplained abdominal pain, unexplained anemias, or unexplained recent weight loss.
- A personal history of colorectal cancer or adenomatous colon polyps
- A family history of colorectal cancer in first or 2<sup>nd</sup> degree relatives
- A personal history of inflammatory bowel disease (IBD, e.g. ulcerative colitis or Crohn's disease)
- A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC)
- A personal history of getting radiation to the abdomen (belly) or pelvic area to treat a prior cancer
- Patient is not due for colorectal cancer screening based on USPSTF/ACS guidelines for CRC screening
  - Patient has had a colonoscopy in the last 10 years
  - Patient has had CT-colonography or flexible sigmoidoscopy (flex sig) in the last 5 years
  - Patient has received a FOBT, or FIT test in the past year
    - Patient has received sDNA-FIT in the past 3 years
- Patient has been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-associated Polyposis (MAP), Garner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis

## **PROCEDURES FOR DISPENSING, MONITORING AND FOLLOW UP**

Upon initiation of the protocol, the pharmacist will initiate the appropriate test according to the USPSTF/ACW Guidelines (see Appendix 1).

In the case when results from screening tests are received by the initiating pharmacists, pharmacists shall report the results, positive or negative, to the patient's designated primary care provider. The pharmacist shall follow up with patients within two (2) business days to provide results and direct the patient to their primary care provider as needed. In the case

of any positive results, patients shall be directed to their primary care provider for follow up and timely scheduling of a screening completion colonoscopy.

When it is determined that the patient meets criteria for colonoscopy-based CRC screening rather than stool-based screening, the pharmacist shall notify the patient and the primary care provider for a screening colonoscopy.

In the case the patient has signs or symptoms of CRC, a pharmacist shall direct the patient urgently to their primary care provider or endoscopy provider to evaluate for diagnostic colonoscopy.

In the case where the patient has attested that they do not have a primary care provider, the patient shall be directed to the authorizing prescriber for follow-up as indicated above.

In the case when results from screening tests are received by the authorizing prescriber and not the initiating pharmacist, no specific follow up procedures for the initiating pharmacist are required.

### **EDUCATION REQUIREMENTS**

Individuals, or their guardian/caregiver, receiving a noninvasive stool-based CRC screening kit under the protocol shall receive education regarding:

- Directions regarding how to use the specific screening kit ordered and dispensed
- Information regarding need for follow-up screening completion colonoscopy in the case of positive screening test results
- Information regarding high-risk populations requiring colonoscopy-based screenings and signs and symptoms of CRC requiring immediate diagnostic evaluation.

### **DOCUMENTATION**

Pharmacist(s) shall document via prescription record with each person who receives a CRC screening under this protocol including:

- (a) Prescription documentation as required in 201 KAR 2:171
- (b) Documentation that the individual receiving CRC screening was provided with required education pursuant to this administrative regulation.
- (c) Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and referral.

**NOTIFICATION**

Pharmacist(s) shall ask all persons receiving CRC screening under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the screening modality dispensed under the protocol to the identified primary care provider within two (2) business days. Once screening results are obtained, pharmacist(s) shall notify the patient's primary care provider of the screening results within two (2) business days of receipt.

In the case when results from screening tests are received by the authorizing prescriber and not the initiating pharmacist, no specific notification procedures for the initiating pharmacist are required.

Any individual affirmatively stating that the individual does not have a primary care provider may still receive CRC screening under this protocol provided all other applicable requirements of the protocol are met. In this circumstance, pharmacist(s) shall notify the authorizing prescriber of the patient and identify the screening modality dispensed within 7 days and, once results are obtained, pharmacists shall notify the authorizing prescriber of the screening results within two (2) business days of receipt.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving CRC screening under this protocol within 7 days]

**TERMS**

This protocol is effective as of the date all parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty (60) days.

**SIGNATURES**

\_\_\_\_\_  
Prescriber Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescriber Signature

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Pharmacist Name

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Date

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Pharmacist Signature

## Appendix 1

### USPSTF 2021/ACS 2018 Recommended CRC Screening Modalities

Recommendations	USPSTF 2021 <sup>1</sup>	ACS 2018 <sup>2</sup>	
<b>Choice of test</b>	Screening for CRC with several different methods can accurately detect early-stage CRC and adenomatous polyps	High-sensitivity stool-based test or a structural (visual) exam, depending on patient preference and test availability; <b>All positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy</b>	
Direct Visualization Examination	<b>Colonoscopy</b>	Every 10 years	Every 10 years
	<b>CT colonography</b>	Every 5 years	Every 5 years
	<b>Flexible sigmoidoscopy (FS)</b>	Every 5 years	Every 5 years
	<b>FS with FIT</b>	FS every 10 years with annual FIT	--
	<b>Capsule colonoscopy</b>	--	--
Stool-based, noninva	<b>gFOBT or hs-gFOBT</b>	Annual gFOBT	Annual hs-gFOBT
	<b>Fecal immunochemical test (FIT)</b>	Annual	Annual
	<b>mt-sDNA (Cologuard)</b>	Every 1 to 3 years	Every 3 years

#### References:

- Davidson KW, Barry MJ, Mangione CM, et al. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238
- Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2018;68(4):250-281.
- Exact Sciences Corporation. Cologuard(R) Physician Brochure. Madison, WI.

#### Additional Resources

[Cologuard HCP Resources https://www.cologuardhcp.com/resources](https://www.cologuardhcp.com/resources)  
[Link to NEJM Pivotal Study \(DeeP-C\)](#)