



Population Health Services

WellSpan Laboratory Utilization Committee Recommendation

Exact Sciences - Cologuard colon cancer screening

June 2018

S: Request from WellSpan Medical Group practice to begin use of Cologuard DNA Stool Testing for Colorectal Cancer Screening.

B: April 3, 2014 publication in NEJM touted Cologuard Multitarget Stool DNA testing to be superior to FIT testing (sensitivity of 92% vs 73%, respectively). One collection every 3 years.

A: The WellSpan Preventive Health Task Force endorses the use of colonoscopy first and lower cost FIT if the patient does not want a colonoscopy, prior to considering Cologuard. Hayes Technology gives Cologuard an evidence rating of C (Dec 5, 2017). Claims by company of frequency of once/3 yr is unsubstantiated. CMS is requiring the company to monitor product results in relation to outcomes until 2020 to determine frequency. Exact Sciences charges patients \$599. The Medicare fee schedule for 2017 is \$512.43, however, PA Medicaid is not covered and other payers have coverage and network limitations and exclusions. It is recommended that patients contact their insurer directly to confirm what the payer will pay, what to expect the patient will pay, and if any paperwork is required before the patient uses the test. Those payers not covering the service consider testing to be experimental and investigational and likely will not be reimbursed at this time.

R: *Not recommended as first choice CRC Screening tool at this time for non-Medicare patients due to proven lower cost alternative, FIT. In addition, frequency of testing has not been proven, so this testing should only be offered to Medicare patients who have declined other forms of testing. If Cologuard is prescribed to the patient, the following caveats should be discussed with the patient:*

- 1. Cologuard has been shown to be slightly more sensitive than FIT, but less specific, causing about 15% more false positive results when compared to FIT. All Cologuard positive test results must be followed-up with a diagnostic colonoscopy.*
- 2. The frequency of testing proposed by Cologuard (every 3 years) is unsubstantiated in peer reviewed literature at this time.*
- 3. Cologuard's charge is covered by Medicare, but not by all payers, so the patient should check with their payor to make sure of benefits covered by their plan.*

Payer reimbursement guidance will be monitored yearly.