

Title

Immunochemical Fecal Occult Blood Testing¹

Description

Colorectal cancers and some precancerous adenomas often bleed periodically. Consequently, a small amount of blood in the stool (fecal occult blood) in the absence of other explanatory conditions is a marker for neoplasia. Immunochemical fecal occult blood tests (iFOBTs) are used for colorectal cancer screening by employing antibodies to detect the globin portion of human hemoglobin in stool. Because globin is degraded during passage through the upper gastrointestinal tract, the iFOBT is specific for bleeding that is limited to the colon and rectum.

The primary risk factor for colorectal cancer is age; more than 90% of cases are diagnosed in adults over age 50. It is estimated that at age 50 a person has about a 5% remaining lifetime risk of being diagnosed with colorectal cancer. About 20% of cases occur in persons with specific risk factors (e.g., inflammatory bowel disease), and about 6% arise in persons with uncommon genetic syndromes such as familial adenomatous polyposis. The incidence also is increased in individuals with a personal or family history of colorectal cancer or polyps.

Colorectal cancer in the early stages is largely asymptomatic and frequently cured by surgery alone. Survival rates are much better when diagnosed and treated at an early stage. Thus, screening for early colorectal cancer is recommended beginning at age 50 for those with no risk factors other than age. Guaiac fecal occult blood testing (gFOBT) has been the standard test used for screening but requires complicated dietary and drug restrictions prior to testing, and sampling instructions may limit patient compliance. iFOBTs offer testing without dietary or drug restrictions and may offer simpler sampling instructions.

A number of iFOBTs have been approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States. These are InSure™ (Enterix, Inc.), Instant-View® (Alpha Scientific Designs, Inc.), immoCARE (Care Products, Inc.), and MonoHaem® (Chemicon International, Inc.). The tests require sample collection from 1 (Instant-View®, immoCARE), 2 (InSure™), or 3 stools (MonoHaem®). The test formats for several iFOBTs require minimal processing and involve developing a test strip with controls and reading a color reaction. In the case of the InSure™ iFOBT, all tests are developed by Quest Diagnostic Laboratories through an exclusive arrangement. For InSure™, a dry stool specimen is not required, and the sample may be collected by brushing the surface of the stool while in the toilet bowl water, which may be more agreeable to the patient.

Review of the FDA Web site indicated that a number of additional iFOBTs have been cleared through the 510(k) process. Some (not the entire list) of these include Hema-Screen Specific (Immunostics), Innovacon Flipcard Fecal Occult Blood Test (Innovacon), OC Auto Micro FOB Test (Polymedco and Eiken), FlexSure OBT (SmithKline Diagnostics), Teco Rapid FOB Card Test (TECO Diagnostics), and InSure II (Enterix, Inc.). In addition, the iScreen FOB is noted to be cleared by FDA and waived under Clinical Laboratory Improvement Amendments (CLIA), and thus available for point-of-care testing.

When services are covered for commercial products and Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx

We cover immunochemical fecal occult blood testing for colorectal cancer screening.

When services are not covered for commercial products or Medicare HMO Blue, Medicare PPO Blue, and Medicare PFFS PlusRx

We do not cover immunochemical fecal occult blood testing for any indications other than colorectal cancer screening.²

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
Provider Appeals
PO Box 986065
Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
Case Creation/Medical Policy
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-327-6716
Fax: 1-888-641-5330

Authorization Information

For Managed Care members:

- No authorization is required for this service; *see Managed Care Guidelines for additional requirements.*

For Indemnity and PPO members:

- No authorization is required for this service; *see Indemnity and PPO Guidelines for additional requirements.*

Managed Care Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- **For Medicare HMO Blue members:** The service must meet the criteria for coverage noted in this policy, be medically necessary, prescribed by a plan physician and provided by a network provider.
- **For Medicare HMO Blue members:** Referrals are required for all visits to a specialist.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorization is required for an inpatient admission.

Indemnity and PPO Guidelines

All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description, however;

- Authorization is required for an inpatient admission.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

CPT codes:

- **82274:** Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations

HCPCS codes:

- **G0328** Colorectal cancer screening; fecal-occult blood test, 1-3 immunoassay, 1-3 simultaneous determinations

Policy update history

New policy, effective 11/01/09.

References

References for footnote 1:

1. 2004 TEC Assessments; Tab 5.
2. U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2008; 149(9):627-637.
3. Levin B, Lieberman DA, McFarland B et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin* 2008; 58(3):130-60. Accessible online at: <http://caonline.amcancersoc.org/cgi/reprint/58/3/130>.
4. Whitlock EP, Lin JS, Liles E et al. Screening for colorectal cancer: a targeted, updated systematic review for the US Preventive Services Task Force. *Ann Intern Med* 2008; 149(9):638-58.
5. Allison JE, Sakoda LC, Levin TR et al. Screening for colorectal neoplasms with new fecal occult blood tests: update on performance characteristics. *J Natl Cancer Inst* 2007; 99(19):1462-70. Accessible online at: <http://jnci.oxfordjournals.org/cgi/reprint/99/19/1462>.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Footnotes

¹ Based on BCBSA policy # 2.01.66, Immunochemical Fecal Occult Blood Testing.

² ICD-9 diagnosis codes: V76.51, screening for malignant neoplasm of colon or colorectal