
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 5

Date: DECEMBER 19, 2003

CHANGE REQUEST 2996

I. SUMMARY OF CHANGES: Medicare coverage is being expanded for screening for early detection of colorectal cancer by adding an additional fecal occult blood test (iFOBT, immunoassay-based) that can be used as an alternative to the existing gFOBT, guaiac-based test. Medicare coverage continues to allow for one FOBT per year for beneficiaries aged 50 and over.

NEW/REVISED MATERIAL –

EFFECTIVE DATE: January 1, 2004

***IMPLEMENTATION DATE:** January 5, 2004 (for coverage & HCPCS codes)

***IMPLEMENTATION DATE:** April 5, 2004 (for frequency edits only)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1 - Table of Contents/National Coverage Determinations
N	1/210.3 - Colorectal Cancer Screening Tests

(This revision to §210.3 of Pub. 100-03 is an NCD. NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

***III. FUNDING:** These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Medicare contractors only

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

Table of Contents (Rev. 5, 12-19-03)

Foreword - Purpose for National Coverage Determinations Manual

A - Purpose

B - Organization

C - CMS Coverage Web site

10 - Anesthesia and Pain Management - Not Yet Available

10.1 - Use of Visual Tests Prior to and General Anesthesia during Cataract Surgery - Not Yet Available

10.2 - Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain - Not Yet Available

10.3 - Inpatient Hospital Pain Rehabilitation Programs - Not Yet Available

10.4 - Outpatient Hospital Pain Rehabilitation Programs - Not Yet Available

10.5 - Autogenous Epidural Blood Graft - Not Yet Available

10.6 - Anesthesia in Cardiac Pacemaker Surgery - Not Yet Available

20 - Cardiovascular System - Not Yet Available

20.1 - Vertebral Artery Surgery - Not Yet Available

20.2 - Extracranial - Intracranial (EC-IC) Arterial Bypass Surgery - Not Yet Available

20.3 - Thoracic Duct Drainage (TDD) in Renal Transplants - Not Yet Available

20.4 - Implantable Automatic Defibrillators - Not Yet Available

20.5 - Extracorporeal Immunoabsorption (ECI) Using Protein A Columns - Not Yet Available

20.6 - Transmyocardial Revascularization (TMR) - Not Yet Available

20.7 - Percutaneous Transluminal Angioplasty (PTA) - Not Yet Available

20.8 - Cardiac Pacemakers - Not Yet Available

20.8.1 - Cardiac Pacemaker Evaluation Services - Not Yet Available

20.8.1.1 - Transtelephonic Monitoring of Cardiac Pacemakers - Not Yet Available

20.8.2 - Self-Contained Pacemaker Monitors - Not Yet Available

20.8.3 - Anesthesia in Cardiac Pacemaker Surgery - Not Yet Available

20.9 - Artificial Hearts and Related Devices

20.10 - Cardiac Rehabilitation Programs - Not Yet Available

20.11 - Intraoperative Ventricular Mapping - Not Yet Available

- 20.12 - Diagnostic Endocardial Electrical Stimulation (Pacing) - Not Yet Available
- 20.13 - HIS Bundle Study - Not Yet Available
- 20.14 - Plethysmography - Not Yet Available
- 20.15 - Electrocardiographic Services - Not Yet Available
- 20.16 - Cardiac Output Monitoring by Electrical Bioimpedance - Not Yet Available
- 20.17 - Noninvasive Tests of Carotid Function - Not Yet Available
- 20.18 - Carotid Body Resection/Carotid Body Denervation - Not Yet Available
- 20.19 - Ambulatory Blood Pressure Monitoring - Not Yet Available
- 20.20 - External Counterpulsation (ECP) for Severe Angina - Not Yet Available
- 20.21 - Chelation Therapy for Treatment of Atherosclerosis - Not Yet Available
- 20.22 - Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis - Not Yet Available
- 20.23 - Fabric Wrapping of Abdominal Aneurysms - Not Yet Available
- 20.24 - Displacement Cardiography - Not Yet Available
- 20.25 - Cardiac Catheterization Performed in Other Than a Hospital Setting - Not Yet Available
- 20.26 - Partial Ventriculectomy - Not Yet Available
- 20.27 - Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test - Not Yet Available
- 20.28 – Therapeutic Embolization - Not Yet Available
- 20.29 – Hyperbaric Oxygen Therapy - Not Yet Available
- 30 - Complementary and Alternative Medicine - Not Yet Available
 - 30.1 - Biofeedback Therapy - Not Yet Available
 - 30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence - Not Yet Available
 - 30.2 - Thermogenic Therapy - Not Yet Available
 - 30.3 - Acupuncture - Not Yet Available
 - 30.4 - Electrosleep Therapy - Not Yet Available
 - 30.5 - Transcendental Meditation - Not Yet Available
 - 30.6 - Intravenous Histamine Therapy - Not Yet Available
 - 30.7 - Laetrile and Related Substances - Not Yet Available
 - 30.8 - Cellular Therapy - Not Yet Available
 - 30.9 - Transillumination Light Scanning, or Diaphanography - Not Yet Available
- 40 - Endocrine System and Metabolism - Not Yet Available
 - 40.1 - Diabetes Outpatient Self-Management Training - Not Yet Available
 - 40.2 - Home Blood Glucose Monitors - Not Yet Available
 - 40.3 - Closed-Loop Blood Glucose Control Device (CBGCD) - Not Yet Available

- 40.4 - Insulin Syringe - Not Yet Available
- 40.5 - Treatment of Obesity - Not Yet Available
- 50 - Ear, Nose, and Throat (ENT)
 - 50.1 - Speech Generating Devices
 - 50.2 - Electronic Speech Aids
 - 50.3 - Cochlear Implantation
 - A - General
 - B - Adults
 - C - Children
 - 50.4 - Tracheostomy Speaking Valve
 - 50.5 - Oxygen Treatment of Inner Ear/Carbon Therapy
 - Not Covered
 - 50.6 - Tinnitus Masking
 - 50.7 - Cochleostomy With Neurovascular Transplant for Meniere's Disease
 - Not Covered
 - 50.8 - Ultrasonic Surgery
- 60 - Emergency Medicine
- 70 - Evaluation and Management of Patients - Office/hospital/home
 - 70.1 - Consultations With a Beneficiary's Family and Associates
 - 70.2 - Consultation Services Rendered by a Podiatrist in a Skilled Nursing Facility
 - 70.2.1 - Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy With Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy)
 - 70.3 - Physician's Office Within an Institution - Coverage of Services and Supplies Incident to a Physician's Services
 - 70.4 - Pronouncement of Death
 - 70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures
- 80 - Eye
 - 80.1 - Hydrophilic Contact Lens for Corneal Bandage
 - 80.2 - Photodynamic Therapy
 - Ocular photodynamic therapy (OPT)
 - 80.3 - Photosensitive Drugs
 - 80.4 - Hydrophilic Contact Lenses
 - 80.5 - Scleral Shell
 - 80.6 - Intraocular Photography
 - 80.7 - Refractive Keratoplasty
 - Not Covered
 - 80.7.1 - Keratoplasty

- 80.8 - Endothelial Cell Photography
- 80.9 - Computer Enhanced Perimetry
- 80.10 - Phaco-Emulsification Procedure - Cataract Extraction
- 80.11 - Vitrectomy
- 80.12 - Intraocular Lenses (IOLs)
- 90 - Genetics - Not Yet Available
- 100 - Gastrointestinal System
 - 100.1 - Gastric Bypass Surgery for Obesity
 - 100.2 - Endoscopy
 - 100.3 - 24-Hour Ambulatory Esophageal pH Monitoring
 - 100.4 - Esophageal Manometry
 - 100.5 - Diagnostic Breath Analyses
 - 100.6 - Gastric Freezing
 - 100.7 - Colonic Irrigation
 - Not Covered
 - 100.8 - Intestinal Bypass Surgery
 - Not Covered
 - 100.9 - Implantation of Anti-Gastroesophageal Reflux Device
 - 100.10 - Injection Sclerotherapy for Esophageal Variceal Bleeding
 - 100.11 - Gastric Balloon for Treatment of Obesity
 - Not Covered
 - 100.12 - Gastrophotography
 - 100.13 - Laproscopic Cholecystectomy
- 110 - Hematology/Immunology/Oncology - Not Yet Available
 - 110.1 - Hyperthermia for Treatment of Cancer - Not Yet Available
 - 110.2 - Certain Drugs Distributed by the National Cancer Institute - Not Yet Available
 - 110.3 - Anti-Inhibitor Coagulant Complex (AICC) - Not Yet Available
 - 110.4 - Extracorporeal Photopheresis - Not Yet Available
 - 110.5 - Granulocyte Transfusions - Not Yet Available
 - 110.6 - Scalp Hypothermia During Chemotherapy to Prevent Hair Loss - Not Yet Available
 - 110.7 - Blood Transfusions - Not Yet Available
 - 110.8 - Blood Platelet Transfusions- Not Yet Available
 - 110.8.1 - Stem Cell Transplantation - Not Yet Available
 - 110.9 - Antigens Prepared for Sublingual Administration - Not Yet Available
 - 110.10 - Intravenous Iron Therapy - Not Yet Available
 - 110.11 - Food Allergy Testing and Treatment - Not Yet Available
 - 110.12 - Challenge Ingestion Food Testing - Not Yet Available

- 110.13 - Cytotoxic Food Tests - Not Yet Available
- 110.14 - Apheresis (Therapeutic Pheresis) - Not Yet Available
- 110.15 - Ultrafiltration, Hemoperfusion and Hemofiltration - Not Yet Available
- 110.16 - Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation - Not Yet Available
- 120 - Infectious Diseases
- 130 - Mental Health - Not Yet Available
 - 130.1 - Inpatient Hospital Stays for the Treatment of Alcoholism - Not Yet Available
 - 130.2 - Outpatient Hospital Services for Treatment of Alcoholism - Not Yet Available
 - 130.3 - Chemical Aversion Therapy for Treatment of Alcoholism - Not Yet Available
 - 130.4 - Electrical Aversion Therapy for Treatment of Alcoholism - Not Yet Available
 - 130.5 - Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic - Not Yet Available
 - 130.6 - Treatment of Drug Abuse (Chemical Dependency) - Not Yet Available
 - 130.7 - Withdrawal Treatments for Narcotic Addictions - Not Yet Available
 - 130.8 - Hemodialysis for Treatment of Schizophrenia - Not Yet Available
- 140 - Miscellaneous Surgical Procedures
 - 140.1 - Abortion
 - 140.2 - Breast Reconstruction Following Mastectomy
 - 140.3 - Transsexual Surgery
 - 140.4 - Plastic Surgery to Correct "Moon Face"
Not Covered
 - 140.5 - Laser Procedures
- 150 - Musculoskeletal System - Not Yet Available
 - 150.1 - Manipulation - Not Yet Available
 - 150.2 - Osteogenic Stimulator - Not Yet Available
 - 150.3 - Bone (Mineral) Density Studies - Not Yet Available
 - 150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy - Not Yet Available
 - 150.5 - Diathermy Treatment - Not Yet Available
 - 150.6 - Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot - Not Yet Available
 - 150.7 - Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections With Sclerosing Agents - Not Yet Available
 - 150.8 - Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders - Not Yet Available

- 160 - Nervous System - Not Yet Available
 - 160.1 - Induced Lesions of Nerve Tracts - Not Yet Available
 - 160.2 - Treatment of Motor Function Disorders With Electric Nerve Stimulation - Not Yet Available
 - 160.3 - Assessing Patients Suitability for Electrical Nerve Stimulation - Not Yet Available
 - 160.4 - Stereotactic Cingulotomy as a Means of Psychosurgery - Not Yet Available
 - 160.5 - Stereotaxic Depth Electrode Implantation - Not Yet Available
 - 160.6 - Carotid Sinus Nerve Stimulator - Not Yet Available
 - 160.7 - Electrical Nerve Stimulators - Not Yet Available
 - 160.7.1 - Assessing Patients Suitability for Electrical Nerve Stimulation Therapy - Not Yet Available
 - 160.8 - Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature - Not Yet Available
 - 160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery - Not Yet Available
 - 160.10 - Evoked Response Tests - Not Yet Available
 - 160.11 - Osteogenic Stimulator - Not Yet Available
 - 160.12 - Neuromuscular Electrical Stimulator (NMES) - Not Yet Available
 - 160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) - Not Yet Available
 - 160.14 - Invasive Intracranial Pressure Monitoring - Not Yet Available
 - 160.15 - Electrotherapy for Treatment of Facial Nerve Palsy (Bell's Palsy) - Not Yet Available
 - 160.16 - Vertebral Axial Decompression (VAX-D) - Not Yet Available
 - 160.17 - L-Dopa - Not Yet Available
 - 160.18 - Vagus Nerve Stimulation for Treatment of Seizures - Not Yet Available
 - 160.19 - Phrenic Nerve Stimulator - Not Yet Available
 - 160.20 - Transfer Factor for Treatment of Multiple Sclerosis - Not Yet Available
 - 160.21 - Telephone Transmission of EEGs - Not Yet Available
 - 160.22 - Ambulatory EEG Monitoring - Not Yet Available
 - 160.23 - Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) - Not Yet Available
 - 160.24 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease - Not Yet Available
 - 160.25 - Multiple Electroconvulsive Therapy (MECT) - Not Yet Available
- 170 - Nonphysician Practitioner Services (PT/OT/SLP/Audiologists/CRNA)
 - 170.1 - Institutional and Home Care Patient Education Programs

- 170.2 - Melodic Intonation Therapy
- 170.3 - Speech Pathology Services for the Treatment of Dysphagia
- 180 - Nutrition
 - 180.1 - Medical Nutrition Therapy
 - 180.2 - Enteral and Parenteral Nutritional Therapy
 - Covered As Prosthetic Device
 - Parenteral Nutrition Therapy
 - Enteral Nutrition Therapy
 - Nutritional Supplementation
- 190 - Pathology and Laboratory - Not Yet Available
 - 190.1 - Histocompatibility Testing - Not Yet Available
 - 190.2 - Diagnostic Pap Smears - Not Yet Available
 - 190.3 - Cytogenetic Studies - Not Yet Available
 - 190.4 - Electron Microscope - Not Yet Available
 - 190.5 - Sweat Test - Not Yet Available
 - 190.6 - Hair Analysis - Not Yet Available
 - 190.7 - Human Tumor Stem Cell Drug Sensitivity Assays - Not Yet Available
 - 190.8 - Lymphocyte Mitogen Response Assays - Not Yet Available
 - 190.9 - Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS) - Not Yet Available
 - 190.10 - Laboratory Tests - CRD Patients - Not Yet Available
 - 190.11 - Home Prothrombin Time INR Monitoring for Anticoagulation Management - Not Yet Available
- 200 - Pharmacology
- 210 - Prevention
 - 210.1 - Prostate Cancer Screening Tests
 - Covered
 - A - General
 - B - Screening Digital Rectal Examinations
 - C - Screening Prostate Specific Antigen Tests
 - 210.2 - Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer
 - 210.3 - Colorectal Cancer Screening Tests**
- 220 - Radiology - Not Yet Available
 - 220.1 - Computerized Tomography - Not Yet Available
 - 220.2 - Magnetic Resonance Imaging - Not Yet Available
 - 220.3 - Magnetic Resonance Angiography - Not Yet Available
 - 220.4 - Mammograms - Not Yet Available
 - 220.5 - Ultrasound Diagnostic Procedures - Not Yet Available

- 220.6 - Positron Emission Tomography (PET) Scans - Not Yet Available
- 220.7 - Xenon Scan - Not Yet Available
- 220.8 - Nuclear Radiology Procedure - Not Yet Available
- 220.9 - Digital Subtraction Angiography - Not Yet Available
- 220.10 - Portable Hand-Held X-Ray Instrument - Not Yet Available
- 220.11 - Thermography - Not Yet Available
- 220.12 - Single Photon Emission Computed Tomograph (SPECT) - Not Yet Available
- 220.13 - Percutaneous Image-Guided Breast Biopsy - Not Yet Available
- 230 - Renal and Genitourinary System - ESRD Services - Not Yet Available
 - 230.1 - Treatment of Kidney Stones - Not Yet Available
 - 230.2 - Uroflowmetric Evaluations - Not Yet Available
 - 230.3 - Sterilization - Not Yet Available
 - 230.4 - Diagnosis and Treatment of Impotence - Not Yet Available
 - 230.5 - Gravlee Jet Washer - Not Yet Available
 - 230.6 - Vabra Aspirator - Not Yet Available
 - 230.7 - Water Purification and Softening Systems Used in Conjunction With Home Dialysis - Not Yet Available
 - 230.8 - Non-Implantable Pelvic Flood Electrical Stimulator - Not Yet Available
 - 230.9 - Cryosurgery of Prostate - Not Yet Available
 - 230.10 - Incontinence Control Devices - Not Yet Available
 - 230.11 - Diagnostic Pap Smears - Not Yet Available
 - 230.12 - Dimethyl Sulfoxide (DMSO) - Not Yet Available
 - 230.13 - Peridex CAPD Filter Set - Not Yet Available
 - 230.14 - Ultrafiltration Monitor - Not Yet Available
 - 230.15 - Electrical Continence Aid - Not Yet Available
 - 230.16 - Bladder Stimulators (Pacemakers) - Not Yet Available
 - 230.17 - Urinary Drainage Bags - Not Yet Available
 - 230.18 - Sacral Nerve Stimulation for Urinary Incontinence - Not Yet Available
 - 230.19 - Levocarnitine for Use in the Treatment of Carnitine Deficiency in ESRD Patients - Not Yet Available
- 240 - Respiratory System
 - 240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)
 - 240.2 - Home Use of Oxygen
 - A - General
 - B - Medical Documentation
 - C - Laboratory Evidence
 - D - Health Conditions
 - E - Portable Oxygen Systems

F - Respiratory Therapists

- 240.3 - Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions
 - Not Covered
- 240.4 - Continuous Positive Airway Pressure (CPAP)
- 240.5 - Intrapulmonary Percussive Ventilator (IPV)
 - Not Covered
- 240.6 - Transvenous (Catheter) Pulmonary Embolectomy
 - Not Covered
- 240.7 - Postural Drainage Procedures and Pulmonary Exercises
- 250 - Skin
 - 250.1 - Treatment of Psoriasis
 - 250.2 - Hemorheograph
 - 250.3 - Intravenous Immune Globulin for the Treatment of Autoimmune Mucutaneous Blistering Diseases
 - 250.4 - Treatment of Actinic Keratosis
- 260 - Transplantation - Solid Organ Transplants - Not Yet Available
 - 260.1 - Adult Liver Transplantation - Not Yet Available
 - 260.2 - Pediatric Liver Transplantation - Not Yet Available
 - 260.3 - Pancreas Transplants - Not Yet Available
 - 260.4 - Reserved
 - 260.5 - Intestinal and Multi-Visceral Transplantation - Not Yet Available
 - 260.6 - Dental Examination Prior to Kidney Transplantation - Not Yet Available
 - 260.7 - Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) - Not Yet Available
 - 260.8 - Reserved
 - 260.9 - Heart Transplants - Not Yet Available
- 270 - Wound Treatment - Not Yet Available
 - 270.1 - Electrostimulation in the Treatment of Wounds-Not Covered - Not Yet Available
 - 270.1.1 - Electrical Stimulation for the Treatment of Wounds - Not Yet Available
 - 270.2 - Noncontact Normothermic Wound Therapy (NNWT) - Not Yet Available
 - 270.3 - Platelet-Derived Wound Healing Formula - Not Yet Available
 - 270.4 - Treatment of Decubitus Ulcers - Not Yet Available
 - 270.5 - Porcine Skin and Gradient Pressure Dressings - Not Yet Available
- 280 - Medical and Surgical Supplies - Not Yet Available
 - 280.1 - Durable Medical Equipment Reference List - Not Yet Available
 - 280.2 - White Cane for Use by a Blind Person - Not Yet Available

- 280.3 - Specially Sized Wheelchairs - Not Yet Available
- 280.4 - Seat Lift - Not Yet Available
- 280.5 - Safety Roller - Not Yet Available
- 280.6 - Pneumatic Compression Devices - Not Yet Available
- 280.7 - Hospital Beds - Not Yet Available
- 280.8 - Air-Fluidized Bed - Not Yet Available
- 280.9 - Power Operated Vehicles That May Be Used as Wheelchairs - Not Yet Available
- 280.10 - Prosthetic Shoe - Not Yet Available
- 280.11 - Corset Used as Hernia Support - Not Yet Available
- 280.12 - Sykes Hernia Control - Not Yet Available
- 280.13 - Transcutaneous Electrical Nerve Stimulators (TENS) - Not Yet Available
- 280.14 - Infusion Pumps - Not Yet Available
- 290 - Nursing Services - Not Yet Available
 - 290.1 - Home Health Visits to a Blind Diabetic - Not Yet Available
 - 290.2 - Home Health Nurses' Visits to Patients Requiring Heparin Injections - Not Yet Available
- 300 - Diagnostic Tests Not Otherwise Classified - Not Yet Available
 - 300.1 - Obsolete or Unreliable Diagnostic Tests - Not Yet Available
- 310 - Clinical Trials
 - 310.1 - Routine Costs in Clinical Trails

210.3 – Colorectal Cancer Screening Tests **(Rev. 5, 12-19-03)**

Section 4104 of the Balanced Budget Act of 1997 provides for coverage of screening colorectal cancer procedures under Medicare Part B. Medicare currently covers: (1) annual fecal occult blood tests (FOBTs); (2) flexible sigmoidoscopy over 4 years; (3) screening colonoscopy for persons at average risk for colorectal cancer every 10 years, or for persons at high risk for colorectal cancer every 2 years; (4) barium enema every 4 years as an alternative to flexible sigmoidoscopy, or every 2 years as an alternative to colonoscopy for persons at high risk for colorectal cancer; and, (5) other procedures the Secretary finds appropriate based on consultation with appropriate experts and organizations.

Coverage of the above screening examinations was implemented in regulations through a final rule that was published on October 31, 1997 (62 FR 59079), and was effective January 1, 1998. At that time, based on consultation with appropriate experts and organizations, the definition of the term “FOBT” was defined in 42 CFR §410.37(a)(2) of the regulation to mean a “guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools.”

In the 2003 Physician Fee Schedule Final Rule (67 FR 79966) effective March 1, 2003, CMS amended the FOBT screening test regulation definition at 42 CFR §410.37(a)(2) to provide that it could include either: (1) a guaiac-based FOBT, or, (2) other tests determined by the Secretary through a national coverage determination.

A. Covered Indications

Fecal Occult Blood Tests (FOBT) (effective for services performed on or after January 1, 2004)

1. History

FOBTs are generally divided into two types: immunoassay and guaiac types. Immunoassay (or immunochemical) fecal occult blood tests (iFOBT) use “antibodies directed against human globin epitopes. While most iFOBTs use spatulas to collect stool samples, some use a brush to collect toilet water surrounding the stool. Most iFOBTs require laboratory processing.

Guaiac fecal occult blood tests (gFOBT) use a peroxidase reaction to indicate presence of the heme portion of hemoglobin. “Guaiac turns blue after oxidation by oxidants or peroxidases in the presence of an oxygen donor such as hydrogen peroxide. Most FOBTs use sticks to collect stool samples and may be developed in a physician’s office or a laboratory. In 1998, Medicare began reimbursement for guaiac FOBTs, but not immunoassay type tests for colorectal cancer screening. Since the fundamental process is similar for other iFOBTs, CMS evaluated colorectal cancer screening using immunoassay FOBTs in general.

2. Expanded Coverage

*Medicare covers one screening FOBT per annum for the early detection of colorectal cancer. This means that Medicare will cover one guaiac-based (gFOBT) **or** one immunoassay-based (iFOBT) at a frequency of every 12 months; i.e., at least 11 months have passed following the month in which the last covered screening FOBT was performed, for beneficiaries aged 50 years and older. The beneficiary completes the existing gFOBT by taking samples from two different sites of three consecutive stools; the beneficiary completes the iFOBT by taking the appropriate number of stool samples according to the specific manufacturer’s instructions. This screening requires a written order from the beneficiary’s attending physician. (“Attending physician means a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Social Security Act) who is fully knowledgeable about the beneficiary’s medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary’s specific medical problem.)*

B. Noncovered Indications

All other indications for colorectal cancer screening not otherwise specified above remain noncovered.

(This NCD last reviewed December 2003.)