COMPUTED TOMOGRAPHY (CT) SCAN OR IMAGING AS A SCREENING TECHNIQUE
RAD604.006
POSTED DATE: 6/11/2003
EFFECTIVE DATE: 8/15/2003

COVERAGE:

Electron-Beam Computed Tomography (EBCT), with or without contrast media, is considered NOT medically necessary when:

1. Imaging the heart and/or brain, as it is considered experimental or investigational for:
   - detection of obstruction in coronary or cerebral arteries (including calcification) as a screening examination for asymptomatic patients,
   - assessment of coronary artery bypass graft patency,
   - measurement of cardiac perfusion and quantification of right and left ventricular muscle mass, chamber volumes, and systolic and diastolic function (such as cardiac output and ejection fraction), and
   - Evaluation of intra-cardiac and congenital cardiac lesions.

2. Imaging the heart and/or brain, as there is no proven value for:
   - detection of the risk of obstruction in coronary or cerebral arteries (including calcification) as a screening examination for asymptomatic patients, and
   - Replacement of traditional tests (i.e., stress test[s], coronary angiography), if the patient has documented, typical symptoms of coronary artery disease.

   NOTE: For special statements from the American Heart Association, refer to the Rationale section of this policy.

3. Viewing other areas within the body for abnormalities as there is no proven value, such as -
   - aorta,
   - breasts,
   - chest wall,
   - esophagus,
   - gallbladder,
   - kidneys,
   - liver,
   - upper abdomen,
   - Thoracic and most of the lumbar spine.

4. Screening patients in the early detection of the following indications, as there is no proven value -

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• aneurysms,
• cysts,
• emphysema,
• enlarged lymph nodes,
• gallstones,
• hiatal hernia,
• kidney stones,
• liver disease,
• osteoporosis,
• Suspicious masses in other organs.

Viewing or screening patients for the detection of polyps or adenomas using Virtual Colonoscopy (VC) (minimally invasive EBCT scan or magnetic resonance colonography) is considered experimental or investigational.

NOTE: This policy does not address wireless camera endoscopy procedures (also known as the pill-sized endoscopy camera) of the small intestine. Refer to the Medical Policy, Information on Endoscopic, Arthroscopic, Laparoscopic, Thoracoscopic Surgery, and SUR701.014.

Spiral (Helical) Computed Tomography (Spiral CT, Helical CT) with or without contrast media, when imaging the heart, is considered experimental or investigational for:

1. detection of the risk of obstruction in coronary or cerebral arteries (including calcification) as a screening examination for asymptomatic patients, and

2. replacement of traditional tests (i.e., stress test[s], coronary angiography), if the patient has documented, typical symptoms of coronary artery disease.

SPECIAL CONSIDERATION FOR EVALUATION OF THE PANCREAS USING SPIRAL (Helical) CT (DYNAMIC CONTRAST-ENHANCED CT SCAN) or USING EBCT (Ultrafast):

• Spiral CT with contrast used during a routine evaluation of pancreatitis is considered medically necessary to distinguish between interstitial pancreatitis and necrotizing pancreatitis as a special consideration.

• Viewing or screening the pancreas (using EBCT) for any other abnormalities or lesions, with or without contrast, is considered NOT medically necessary.
SPECIAL CONSIDERATION FOR SCREENING OF LUNG CANCER SPIRAL (Helical) CT (DYNAMIC CONTRAST-ENHANCED CT SCAN) or USING EB (Ultrafast) CT:

- Spiral (Helical) CT with contrast OR EBCT (Ultrafast) as a screening technique for lung cancer is considered experimental or investigational.

DESCRIPTION:

Currently, **Computed Tomography (CT)** Scan or Imaging screening techniques include:

- **Electron-Beam Computed Tomography (EBCT) Scan/Imaging,**
- **Spiral (Helical) Computed Tomography (Spiral CT, Helical CT),** and
- **Virtual Colonoscopy (VC).**

**EBCT** utilizes advanced high-speed digital technology with rapid scan times to "freeze" moving organs (stop-action pictures of the heart between heartbeats) and to reduce or eliminate distortion/blurring usually created by motion. The scan needs only one-tenth of a second to make an x-ray image of the heart compared to between one and ten seconds for a conventional scan. This rapid scanning is made possible by an electron beam/gun rather than the mechanical movement of an x-ray tube as required by conventional computed tomography scanners. It can be utilized with or without an intravenous (IV) injection of radiographic contrast medium. It is reported that the scan can detect the quantity of calcium throughout the body.

When used to reveal whether a patient has calcium in their coronary arteries, EBCT becomes an indicator that plaque may be building up, narrowing the arteries, and reducing the blood flow (even before symptoms such as chest pain appear). The four main claims of EBCT for imaging of coronary artery disease are:

1. detection of coronary artery wall calcification, cardiac output, and cardiac wall thickness as a screening test for coronary artery disease,
2. evaluation of coronary artery bypass graft patency,
3. measurement of myocardial perfusion and quantification of right and left ventricular muscle mass, chamber volumes, and systolic and diastolic function, and
4. evaluation of intra cardiac and congenital cardiac lesions.

In non-exercise dependent scanning:
• patients wear loose clothing or a gown,
• recline on a radiographic table,
• have three electrocardiogram electrodes placed on their chest, and
• hold their breath several times while scanning is done.

EBCT **MAY BE** known by several different names, such as:

• Computed Tomography (CT),
• Ultrafast CT (UFCT) or Fast CT,
• Spiral CT*,
• Helical CT*,
• Heart Scan,
• Total or Full Body Scan,
• Health-View Test or Heart-View Cardiac Screening,
• Rapid Heart Imaging,
• Coronary Artery Scanning,
• Cine computed x-ray tomography,
• Rapid acquisition x-ray computed tomography,
• High-speed computed x-ray tomography,
• Dynamic Contrast Enhanced CT, and
• Dynamic Spatial Reconstructor.

(EBCT has been confused with Spiral CT* or Helical CT*. While both EBCT and Spiral CT may be valued as an alternative to conventional CT scanning due to their faster processing. It is their speed of image acquisition and method of acquisition that permits unique imaging of moving organs, such as the heart or colon. Thus, there is a difference between the two forms of CT scanning, as well as confusion by interchanging their names.)

**Spiral (Helical) Computed Tomography (Spiral CT, Helical CT):**

**Spiral CT or Helical CT** also creates images at greater speeds by rotating a standard x-ray tube around the patient such that data are gathered in a continuous spiral or helix rather than individual slices.

**Virtual Colonoscopy (VC):**

**VC,** also known as Virtual CT-colonoscopy (VCTC), Magnetic Resonance Colonography (MRC), Computed Tomography Colonoscopy (CTC), is an emerging, minimally invasive, new technique. VC uses data generated from CT or MR imaging to create two- or three-dimensional (2-D or 3-D) scans of the colon. VC is actually a post-processing or off-line method, which allows for reconstruction of the inner bowel surface structures from the most commonly used Helical CT datasets. VC has been investigated as an alternative to conventional endoscopic...
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Colonoscopy, specifically as an alternative screening technique for colon cancer.

The patient follows a regimen of cleansing the bowel, similar to the traditional colonoscopy regimen. There is no sedation and the exam is less time-consuming. An air enema, which may be uncomfortable to the patient, is administered, followed by the EBCT scanning or MRC. The scan takes about 30 seconds with the patient lying on their back and then once more lying face down. Sophisticated software combines the data to produce the 2-D or 3-D image of the colon.

According to some clinical studies, the scans are detailed enough to reveal cell changes, such as polyps (tiny precancerous and cancerous growths) or adenomas (benign growths), of the intestinal mucosa as small as 6 millimeters in diameter. If abnormalities are present, the patient will have a follow-up traditional colonoscopy examination.

RATIONALE:

The use of EBCT for the diagnosing or screening of coronary artery disease or other body areas/conditions has not been proven outside the investigational setting. While Spiral CT has been used for the same purpose, there are minimal data regarding this application and there are inadequate data to determine whether calcium scores derived from Spiral CT imaging are equivalent to those from EBCT imaging. Limitations in the data for EBCT would also apply to Spiral CT scanning.

CORONARY ARTERY DISEASE:

Over 3,500 symptomatic and asymptomatic patients with coronary artery disease or at risk of coronary artery disease were studied. The results were inconclusive when compared to conventional, noninvasive diagnostic evaluation.

SPECIAL COMMENT FROM AMERICAN HEART ASSOCIATION (1996):
"Even though EBCT radiation dose is minimal, indiscriminate use or mass screening is not condoned..., There are insufficient data to determine whether the relation between coronary calcium and coronary heart disease risk warrants the use of calcium screening in low-risk, asymptomatic subjects. The widespread proliferation of screening programs for coronary calcium as a single, isolated diagnostic modality in such persons should be discouraged. The manifest relation between calcification and atherosclerosis suggests that EBCT may have a role in establishing susceptibility (as opposed to merely quantitating risk) for coronary disease. The role of EBCT as a screening tool in asymptomatic patients with conventional risk factors is not yet clearly defined. It can be anticipated, however, that identifying the presence of premorbid coronary artery disease would influence the aggressiveness with which risk factor modification is..."
approached."

**SPECIAL COMMENT FROM AMERICAN HEART ASSOCIATION (1999):**
"Several studies have shown a marked variability in repeated measures of coronary calcium by EBCT. Therefore, the use of serial EBCT scans in individual patients for identification and serial assessment of the progression or regression of calcium remains problematic."

**SPECIAL COMMENT FROM AMERICAN HEART ASSOCIATION (2000):**
"The increased predictive value of EBCT of coronary arteries relative to traditional risk factor assessment is not yet completely defined. EBCT is not a substitute for cardiac catheterization. EBCT measurement of coronary calcium is of no known value in patients who have already had a heart attack or undergone coronary bypass surgery or coronary angioplasty."

**COLON CANCER:**

Validation of VC as an alternative screening test for colon cancer requires prospective studies focusing on its diagnostic performance compared to the gold standard, such as either sigmoidoscopy or colonoscopy in both low-, average-, and high-risk patient populations.

There are a few technical and practical problems surfacing from the clinical studies of patients undergoing a VC or a traditional colonoscopy. There is an inability of VC to:

- provide texture/color, which results in problems in identifying flat lesions (perceptual errors);
- adjust in the presence of retained or adherent fecal matter that may result in a false positive diagnosis (meticulous bowel preparation is required as in a conventional colonoscopy); and/or
- compensate for collapsed segments of bowel resulting in the inability of evaluating the colon during image reconstruction (inadequate colon distention).

A blinded clinical study of 46 patients revealed the specificity of 3-D CTC detecting adenomas one centimeter or larger at 89%. This translates to 41 of the 46 patients requiring a follow-up conventional colonoscopy with its own pre-exam bowel preparation. One study, published in 2001, reported that patients preferred the conventional colonoscopy to a VC followed by a conventional colonoscopy. These 83 patients reported more pain, more discomfort, and less respect after the VC than conventional colonoscopy. Virtual endoscopy is evolving and is a promising tool for colorectal cancer screening.

**PANCREATIC DISEASE:**

The American College of Gastroenterology stated in their Practice Guidelines in Acute Pancreatitis, "Dynamic contrast-enhanced CT scan should be performed among patients who have severe pancreatitis on the
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basis of a high APACHE-II (Ranson's Criteria of Severity at Admission) score and/or evidence of organ failure. Dynamic contrast-enhanced CT scan (using intravenous contrast) is the best available test to distinguish interstitial from necrotizing pancreatitis."

LUNG CANCER:

Validation of a screening technique requires evidence regarding the detection rate in asymptomatic patients, but also that the screening technique results in improved health outcomes. Surgery for non-small cell cancer is considered the treatment of choice. Thus, improved outcomes related to screening may include discovery of cancer at an earlier stage such that a greater percentage of cases are considered surgically resectable. A number of trials of CT screening for lung cancer have been published. The studies published so far have focused on the use of spiral CT scanning as opposed to EBCT scanning. These trials have examined the detection rate of lung cancer by spiral CT as compared to chest x-rays, and have determined the average stage of tumors detected by chest x-ray screening and by spiral CT scanning. The results established that spiral CT is more sensitive for detection of lung cancer as compared to chest x-rays. However, no trials have examined mortality or morbidity from lung cancer in patients screened by spiral CT, compared to no screening or screening with chest x-ray. Randomized trials examining the effect of spiral CT scanning on lung cancer mortality and morbidity are necessary to determine the true impact of this technology on health outcomes. Such trials are under discussion by the National Institute of Health. At the present time, neither the American Cancer Society, the National Institute of Health, or the American Society of Clinical Oncology explicitly endorse the use of CT scans for screening of lung cancer.

PRICING:

There is no specific CPT code for EBCT scanning of the heart.

There is no specific CPT code for VC.

REFERENCES:

- "Imaging With Photons." 1991 Scientific American Medicine (CD

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DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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