Name of Policy: Computer-Assisted Endoscopic Sinus Surgery

Policy #: 101
Category: Surgical

Latest Review Date: March 2009
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Image guided surgery uses preoperative diagnostic tests such as MRIs or CAT scans to map out the anatomical structures in the operative field.

Prior to the surgery, a CAT scan and/or MRI will be performed. These scans can be translated into precise axial, coronal, and transverse images by using advanced computer technology. Patients wear a special headset during the scans and/or during the operation. The headset ensures that the navigation device is aligned precisely with the orientation of the patient. Several surgical instruments, such as probes and suctions, have sensors attached to them so that their location can be precisely tracked.

This method gives an image showing the tip of the integrated instrument and its relationship to the surrounding anatomy. This technology may be electromagnetically or optically guided by light-emitting diodes. Although real-time surgical changes are not seen, the position of the linked surgical instruments can be localized within several millimeters of their actual positions.

**Policy:**
**Effective for dates of service on or after February 7, 2006:**
**Computer-assisted volumetric navigation** during sinus surgery *meets* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to assist the surgeon in providing localization of anatomical structures in the following situations:

1. Revision sinus surgery.
2. Distorted sinus anatomy of development, postoperative, or traumatic origin.
3. Extensive sino-nasal polyposis.
4. Pathology involving the frontal, posterior ethmoid and sphenoid sinuses.
5. Disease abutting the skull base, orbit, optic nerve or carotid artery.
6. CSF rhinorrhea or conditions where there is a skull base defect.

**Computer-assisted volumetric navigation** during sinus surgery *does not meet* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used routinely in the absence of the medical conditions listed above.

**Effective for dates of service February 26, 2003 through February 6, 2006:**
**Computer-assisted volumetric navigation** during sinus surgery *meets* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used to assist the surgeon in providing localization of anatomical structures in the following situations:

1. Complex revision of previous sinus surgery.
2. Moderate to severe distorted sinus anatomy rendering endoscopic evaluation alone inadequate.
3. Extensive sino-nasal polyposis.
4. Moderate to severe pathology involving the frontal, posterior ethmoid and sphenoid sinuses.
5. Complex disease abutting the skull base, orbit, optic nerve or carotid artery.
6. CSF rhinorrhea or conditions where there is a skull base defect.
7. Benign and/or malignant sino-nasal neoplasm.

**Computer-assisted volumetric navigation** during sinus surgery **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used routinely in the absence of the medical conditions listed above.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
Nearly 50 million Americans suffer from occasional or frequent sinus infections. Most of these individuals will respond to medical management. Some patients will develop chronic sinus infections, which will not respond to medical therapy. Straight forward initial or revision sinus surgery does not require computer-aided (image-guided) assistance.

Revision cases, where the patients have had previous, often multiple sinus surgeries with clinically significant alterations of anatomy present the greatest challenge to surgeons. The image guidance system helps to localize precisely where the pathology is, and its proximity to other structures like the eye or brain.

Fried, et al studied 63 patients who underwent endoscopic sinus surgery using an electromagnetic intraoperative image system. The study group had a 1% major complication rate compared to an 11% complication rate in the control group. The repeat surgery rate within three months was not statistically significant, with the control group reporting 4.8% compared to the study group at 1.6%.

Neumann, et al studied 107 patients using the Insta Trak® system for transnasal endoscopic procedures. The Insta Trak® system had an estimated accuracy of less than 3 mm in 106 cases (97.2%). Intraoperative complications were very low at 1.8%.

This procedure is especially helpful for revision sinus surgery cases, in which there is related scar tissue formation, difficult anatomy or extensive pathology. This technology provides additional patient safety while allowing more extensive dissection of the diseased tissues.

The American Academy of Otolaryngology-Head and Neck Surgery reviewed this technology and issued a policy statement in November 2002 ([http://www.entlink.net/practice/rules/image-guiding.cfm](http://www.entlink.net/practice/rules/image-guiding.cfm)). This statement endorses the intraoperative use of computer-aided surgery in...
appropriately selected cases to assist the surgeon in accurate localization of anatomical structures.

It is estimated that 10-15% of the endoscopic sinus surgery cases might benefit from the use of intraoperative computer image guidance. The routine use of image guidance for all sinus surgery has not been validated in the medical literature. This technology is most beneficial when used for complex cases involving extensive sinus disease, areas that are difficult to locate, or situations wherein other structures such as the brain, eye, or other skullbase features are at risk.

March 2009 Update
There is no new information identified that would alter the coverage statement of this policy.

**Key Words:**

**Approved by Governing Bodies:**
The image-guided surgery systems are evolving at a rapid pace. The devices used for these procedures should have final FDA approval for the procedure to be considered for medical necessity.

Listed below are a few of the devices, which have final FDA approval:

2. LandmarX ENT Image Guided Surgery System.
3. Insta Trak® with Solaris operating System by Visualization Technology, Inc.
4. Cbyon Suite
5. Allegro Work Station with Viewing Wand
6. Brain Lab
7. Stryker

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity
Pre-certification/Pre-determination requirements: Not applicable
Current Coding:
HCPCS codes:
Effective for dates of service on or after January 1, 2011:
61782 Stereotactic computer-assisted (navigational) procedure; cranial, extradural (list separately in addition to code for primary procedure)

Previous Coding:
Effective for dates of service prior to January 1, 2011:
61795 Stereotactic computer assisted volumetric (navigational) procedure, intracranial, extracranial, or spinal (Code deleted effective January 1, 2011)

References:

Policy History:
Medical Policy Group, June 1999
Medical Policy Group, February 2003 (3)
Medical Review Committee, February 2003
Available for comment April 1-May 16, 2003
Medical Policy Group, February 2006 (3)
Medical Policy Administration Committee, February 2006
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.