



**BlueCross BlueShield
of Alabama**

Name of Policy:

Bispectral Index Monitoring During General Anesthesia

Policy #: 262

Category: Other

Latest Review Date: January 2010

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:

In the past, anesthesiologists have been unable to monitor the effects of anesthetics on the brain in terms of “depth” or “adequacy” of anesthesia. Until recently, sedation has been assessed indirectly, usually by using vital signs or subjective sedation scales. However, due to limitations of these subjective assessment tools, oversedation and under sedation remain a major challenge. It is believed that general anesthetics block the consciousness by depressing the central nervous system. Since the electroencephalogram (EEG) measures electrical activity of the brain, it is expected that some component of the EEG should relate to adequacy of anesthesia. The bispectral index (BIS) is the hypnotic component of a continuous EEG parameter and ranges from an awake, no drug effect value of 95 to 100 to no detectable EEG activity with a value of zero.

BIS monitors are non-invasive devices that reflect a signal-processed EEG. They provide an index of the degree of sedation in patients receiving mechanical ventilation and sedative agents after surgery, trauma, or medical illness.

The BIS monitor system consists of a sensor, a digital signal converter, and the monitor. The sensor picks up the electrical signals from the cerebral cortex and passes them to the digital signal converter. The digitized signals then travel to the device’s pre-processor, which filters out the stray high-frequency signals or “artifacts” resulting from patient movement or electrocautery equipment. It then subjects the filtered EEG data to a sophisticated algorithm to determine the bispectral index, a numerical level between 0-100. The BIS readings mean the following: 0 = no EEG activity; 40-60 = deep sedation; 70-80 = moderate sedation; 80-90 = light sedation; 100 = fully awake.

It has been proposed that the Bispectral Index (BIS) may be used to titrate volatile anesthetics more precisely to individual requirements. This would avoid exposure to unnecessarily high concentrations of anesthetics while minimizing the likelihood of awareness during anesthesia. These benefits may then correlate with faster emergence, shorter recovery times in the post-anesthesia care unit, and decreased adverse effects of anesthesia.

Aspect Medical Systems introduced the Bispectral Index (BIS) monitor in 1996. Also, in 1996, the U.S. Food and Drug Administration (FDA) approved the commercially available version as a monitor of anesthetic effect on the brain.

Policy:

Bispectral index monitoring during general anesthesia to monitor the effects of anesthetics and sedatives on the brain **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

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:

There are many articles published in the peer-reviewed literature on the use of BIS during surgery, with conflicting results. We have summarized four of the most recent articles. The first article is a meta-analysis of 11 RCT's from 1997-2003. The next two articles showed beneficial results and the fourth articles did not.

Liu (2004) published the results of a meta-analysis that looked at 11 RCT's enrolling 1,380 patients. All the trials compared BIS monitoring to standard clinical practice without BIS monitoring in ambulatory surgery with short-acting agents. The results showed BIS monitoring reduced anesthetic use by 19%, reduced the risk of post-operative nausea and vomiting (32% vs. 38%), and reduced the duration of time in the PACU (45.2% vs. 49.1 minutes). BIS monitoring did not affect ability to bypass the PACU (32% vs. 29%) and did not reduce the duration of time in the ASU (159 vs. 165 minutes).

Ekman et al (2004) published results of a prospective study done to evaluate if cerebral monitoring using BIS to guide the conduction could reduce the incidence of explicit recall (ER). A prospective cohort of 4,945 surgical patients requiring muscle relaxants and/or intubation were monitored with BIS and subsequently interviewed for BIS three times. BIS values of 40-60 were recommended. These results were compared with a historical group of 7,826 similar cases in a previous study without cerebral monitoring. The results showed two patients in the BIS-monitored group (0.04%) had ER as compared with 0.18% in the control group ($p<0.038$). The two BIS-monitored patients with ER were aware during intubation when the BIS values were high (>60) for 4 minutes and > 10 minutes, respectively. However, periods with high BIS = 4 minutes were also seen in other patients with no ER. Episodes with high BIS (≥ 4 minutes) were found in 19% of the monitored patients during induction and in 8% of cases during maintenance. They concluded that BIS monitoring during general anesthesia requiring intubation and/or muscle relaxants was associated with a reduced incidence of awareness as compared with historical controls.

Myles et al (2004) published the results of a prospective, randomized, double-blind trial that looked at whether BIS-guided anesthesia reduced the incidence of awareness during surgery in adults. 2,463 adult patients at high risk of awareness were randomly allocated into two groups: 1225 in BIS group and 1238 in routine care group. The results showed 2 reports of awareness in the BIS group and 11 reports in the routine care group. BIS-guided anesthesia reduced the risk of awareness by 82%.

Pavlin et al (2005) reported on a study done to determine whether monitoring BIS would affect recovery parameters in patients undergoing inpatient surgery. 1,580 patients at an academic medical center were divided into 2 groups: 749 in BIS group and 831 in control group. The distribution of surgical procedures and the type of anesthesia used were similar in both groups. The mean BIS in the monitored group was 47. There were no differences in recovery parameters between the BIS-monitored group and the control group when all patients were considered

without regard to anesthetic type or duration. PACU times were 94 ± 1.6 minutes for the BIS group and 92 ± 1.3 minutes for the control group. The authors concluded that the use of BIS monitoring had no impact on recovery parameters.

At the annual meeting of the American Society of Anesthesiologists in Atlanta in October 2005, the House of Delegates voted to approve the final report of the ASA's task force on Intraoperative Awareness. This report did not recommend the standard use of brain function monitoring devices to minimize the risk of intraoperative awareness. They stated that doctors should use multiple modalities, including clinical techniques and conventional monitoring systems. They said that brain function monitoring should be used on a "case-by-case" basis.

Weaver et al (2007) conducted a prospective, observational study to assess the correlation of bispectral index (BIS) to 2 clinical sedation scales. There were 75 patients enrolled in a 6-month period using the Observer's Assessment of Alertness/Sedation and the Continuum of Depth of Sedation scales. The conclusion by the authors determined that moderate correlation between BIS and the 2 clinical sedation scales. The correlation is not strong enough to be used reliably in a clinical setting. The mean minimum BIS scores were not significantly different for those with sedation complication versus those without complications.

January 2010 Update

A recent literature search identified a few studies that were reviewed regarding BIS monitoring. Lindhom et al published the results of a study that investigated how increasing experience from BIS in clinical practice affect the hypnotic level, drug consumption, as well as subjective opinion on this monitoring. Eight CRNA's with previous experience from BIS monitored cases anesthetized 80 cases with concealed BIS, followed by 80 cases with available BIS. Additional training was given to the CRNA's and then another 160 patients were randomized to open or blindly records BIS. The fraction of time with BIS levels of 40-60 did not deteriorate in cases with concealed monitoring and no further improvement was found in subsequent cases with available data from the BIS monitoring, not even after additional training and encouragement to adhere to the 40-60 interval. The authors concluded that although BIS became considerably appreciated, growing experience and repeated education had no impact on drug dosing and BIS levels.

Li et al investigated the use of BIS monitoring in patients under mechanical ventilation for monitoring the depth of sedation. In this prospective randomized controlled trial, 83 patients in the intensive care unit were assigned to receive the sedation based on BIS monitor (42 cases) or the sedation based on the subjective SAS (41 cases). The parameters of respiration, circulation, and the depth of sedation (BIS, SAS, Ramsay) were recorded. Differences were compared and the correlation index and significance were calculated. A statistically significant difference was found between the two groups in respiratory rate, fraction of inspiratory oxygen, and pulse saturation of oxygen before and after sedation. Statistical significance was not found in the parameters of respiration and circulation between the two groups. It was concluded that BIS monitoring is feasible for assessing the depth of sedation in mechanically ventilated patients.

Chollet-Xemard et al examined the use of out-of-hospital BIS monitoring during advanced cardiac life support (ACLS) might provide an indication of cerebral resuscitation. The focus of

this prospective observational study was to establish whether BIS values during ACLS might predict return to spontaneous circulation and whether BIS values on hospital admission might predict survival. 92 patients with cardiac arrest were included in the study that received basic life support from a fire fighter squad followed by ACLS upon arrival at the emergency room. BIS values, electromyographic activity, and signal quality index were recorded throughout resuscitation and out of hospital management. Seven of the patients recovered spontaneous cardiac activity by the time the medical team arrived on scene. 62 patients died on the scene and 30 patients returned to spontaneous cardiac activity and were admitted to the hospital of which 27 died. There was no significant difference in BIS values on admission between the group of patients who died and the group who survived. As a result, the BIS monitoring did not predict return to spontaneous cardiac activity, nor survival after admission to intensive care. Its use to monitor cerebral function during ACLS is therefore pointless.

The above studies provided additional uses of BIS and based upon the conclusions do not change the coverage statement of the policy.

Key Words:

Bispectral index (BIS) monitor, general anesthesia

Approved by Governing Bodies:

Not applicable

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 requirements: Not applicable

Current Coding:

CPT codes: **01999** Unlisted anesthesia procedure(s)

References:

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8. Myles PS, et al. *Bispectral index monitoring to prevent awareness during anesthesia: The B-aware randomised controlled trial*, Lancet, May 2004; 363(9423): 1757-1763.
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11. *Practice parameters: Practice advisory for intraoperative awareness and brain function monitoring*, <http://www.asahq.org/publicationsandservices/practiceparam.htm#brain>
12. Sebel PS, et al. *The incidence of awareness during anesthesia: A multicenter United States study*, Anesthesia Analg 2004; Vol., 99, p. 833-839.
13. Weaver CS, Hauter WH, et al. *An assessment of the association of bispectral index with 2 clinical sedation scales for monitoring depth of procedural sedation*. American Journal of Emergency Medicine 2007; 25: 918-924.

Policy History:

Medical Policy Group, January 2006 (2)

Medical Policy Administration Committee, February 2006

Available for comment February 16-April 3, 2006

Medical Policy Group, January 2008 (1)

Medical Policy Group, January 2010 (1)

Medical Policy Group, September 2012 (3): Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.

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.