Effective November 1, 2023, refer to <u>CMS</u> <u>Manual 100-02, Chapter</u> <u>16-General Exclusions</u> <u>from Coverage</u> for services included in this policy.



Name of Blue Advantage Policy: Bispectral Index Monitoring During General Anesthesia

Policy #: 262

Latest Review Date: September 2023

Category: Medical

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;
- 2. Not experimental or investigational*;
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat bispectral index monitoring during general anesthesia to monitor the effects of anesthetics and sedatives on the brain as a non-covered benefit and as investigational.

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Sedation has historically been assessed indirectly, usually by using vital signs or subjective sedation scales. However, due to limitations of these subjective assessment tools, over sedation and under sedation remain a major challenge. 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.

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.

KEY POINTS:

The most recent literature search was performed through September 14, 2023.

Summary of Evidence

The evidence for bispectral index monitoring during general anesthesia to monitor the effects of anesthetics and sedatives on the brain includes both randomized and nonrandomized clinical trials, as well as prospective follow-up studies. The relevant outcomes are change in disease status, treatment-related morbidity and mortality. There is a paucity of data in the controlled trials and a lack of standardized approach to bispectral index monitoring. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

Not applicable.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Bispectral index (BIS) monitor, general anesthesia, BIS EEG VISTA MONITOR SYSTEM

APPROVED BY GOVERNING BODIES:

Medtronic, Bispectral Index (BISTM) monitoring system Aspect Medical Systems, BIS EEG VISTA MONITOR SYSTEM AND BISX

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

01999 Unlisted anesthesia procedure(s)

REFERENCES:

- 1. Bigham C, Bigham S, Jones C. Does the bispectral index monitor have a role in intensive care? JICS 2012 Oct;13(4):314-319
- 2. Bennett C, Voss LJ, Barnard JP, Sleigh JW. Practical use of the raw electroencephalogram waveform during general anesthesia: the art and science. Anesth Analg. 2009 Aug; 109(2):539-50.
- 3. Bispectral index for improving anesthetic delivery and postoperative recovery (review) 2007. The Cochrane Collaboration

- 4. Chollet-Xemard C, Combes X, et al. Bispectral index monitoring is useless during cardiac arrest patients' resuscitation. Resuscitation 2009; 80(2): 213-216.
- 5. DeDeyne, C.S. (2001) The acute care of traumatic brain injury. Current Opinion in Anaesthesiology 14(5) 475-481.
- 6. Ekman A, et al. Reduction in the incidence of awareness using BIS monitoring, Acta Anaesthesiology Scand, January 2004; 48(1): 20-26.
- 7. Ely, EW, Truman, B., Shintani, A. Thomason, JWW, Wheeler, A.P., Gordon, S. et al (2003) Monitoring sedation status over time in ICU patients; the reliability and validity of the Richmond Agitation Sedation Scale (RASS) JAMA 289:2983-2991.
- 8. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
- 9. Johansen JW, et al. Development and clinical application of electroencephalographic bispectrum monitoring, Anesthesiology, November 2000, Vol. 93, No. 5.
- 10. Kreuer S, et al. (2005) Narcotrend or Bispectral Index Monitoring During Desflurane-Remifentanil Anesthesia: A Comparison with a Standard Practice Protocol. Anesthesia & Analgesia. Volume 101 Issue 2 p 427-434.
- 11. Li XJ, Kang Y and Zhang C. [A study of bispectral index monitoring in assessing the depth of sedation of patients under mechanical ventilation]. Zhongguo Wei Zhong Bing Ji Jiu Yi Xue 2009; 21(6): 361-363.
- 12. Lindholm ML, Brudin L and Sandin RH. Bispectral index monitoring: Appreciated but does not affect drug dosing and hyp0notic levels. Acta Anaesthesiol Scand 2008; 52(1): 88-94.
- 13. Liu SS. Effects of bispectral index monitoring on ambulatory anesthesia, Anesthesiology, August 2004, Vol. 101, No. 2.
- 14. Miller: Miller's Anesthesia, 6th edition. Bispectral Electroencephalographic Monitoring.
- 15. 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.
- 16. O'Connor MF, et al. BIS monitoring to prevent awareness during general anesthesia, Anesthesiology, March 2001; 94(3): 520-522.
- 17. Pavlin JD, et al. Effects of bispectral index monitoring on recovery from surgical anesthesia in 1580 inpatients from an academic medical center, Anesthesiology, March 2005, Vol. 102, No. 3.
- 18. Practice parameters: Practice advisory for intraoperative awareness and brain function monitoring, www.asahq.org/publicationsandservices/practiceparam.htm#brain.
- 19. Sebel, P.S., Lang, E., Rampil, I.J., et al (1997) A Multicenter study of bispectral electroencephalogram analysis for monitoring anesthetic effect. Anesthesia and Analgesia, 84: 891-899.
- 20. Sebel PS, et al. The incidence of awareness during anesthesia: A multicenter United States study, Anesthesia Analg 2004; Vol., 99, p. 833-839.
- 21. 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:

Adopted for Blue Advantage, January 2006

Available for comment February 16-April 2, 2006

Medical Policy Group, January 2008

Medical Policy Group, January 2010

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

Medical Policy Group, October 2019

Medical Policy Group, August 2021

Medical Policy Group, October 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, September 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, November 2023: Archived effective 11/1/2023.

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 plans contracts.