Effective July 1, 2012
Refer to Policy #470-Monitored Anesthesia Care

BlueCross BlueShield of Alabama

Name of Policy:

Use of Anesthesia Services for Routine Gastrointestinal Endoscopy

Policy #: 265
Category: Other

Latest Review Date: May 2012
Policy Grade: **Active policy for dates of service prior to July 1, 2012 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:

Intravenous sedation and analgesia is routinely administered for gastrointestinal endoscopic examinations to help alleviate patient anxiety and discomfort. Provision of sedation and analgesia for endoscopy procedures is standard practice. In the United States, licensed registered nurse or physician assistant administration of intravenous opiate narcotic, usually meperidine (Demerol®), in combination with a benzodiazepine, usually midazolam (Versed®), under the direct supervision of a licensed physician endoscopist is the traditional method for achieving sedation.

Moderate (conscious) sedation is generally used for both diagnostic and uncomplicated therapeutic endoscopic procedures. Moderate sedation involves the administration of medication with or without analgesia to achieve a state of depressed consciousness while maintaining the patient's ability to respond to stimulation. It includes pre- and post-sedation evaluations, administration of sedation, and monitoring of the cardiorespiratory functions (heart rate, blood pressure, and oxygen level.) Moderate sedation is commonly performed using diazepines with or without narcotic agents. For routine endoscopic procedures and screenings among patients without risk factors or significant medical conditions, moderate sedation is considered a sufficient level of sedation.

Monitored anesthesia care (MAC) is directly provided by anesthesia personnel. MAC may include varying levels of sedation, analgesia, and anxiolysis. (If the patient loses consciousness and the ability to respond purposefully, the anesthesia care becomes general anesthesia.) Based on the American Society of Anesthesiologists' (ASA) standard for monitoring, MAC should be provided by qualified anesthesia personnel who must be present continuously to monitor the patient and provide anesthesia care. Monitored anesthesia care includes all aspects of anesthesia care – a pre-procedure visit, intra-procedure care and post-procedure anesthesia management. During MAC, the anesthesiology personnel provides or medically directs a number of specific services such as administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary.

Recently propofol (Diprivan®) has been used as an alternative method of sedation for patients undergoing endoscopy procedures. Propofol is a short-acting anesthetic agent. The advantages of propofol are its rapid induction of sedation, quicker patient recovery time, and anti-emetic effect. The use of propofol requires monitoring for respiratory and/or cardiac collapse by trained personnel. It has the potential to induce anesthesia and there is no antagonist to reverse its action.

Propofol (marketed as Diprivan® or as generic products) was first approved by the U.S. Food and Drug Administration (FDA) in the late 1980s. The current FDA-approved label for Diprivan states that it is indicated for initiation and maintenance of monitored anesthesia care (MAC) sedation, combined sedation and regional anesthesia, or intensive care unit (ICU)

sedation of intubated, mechanically ventilated patients (adults only). It is also approved for induction of general anesthesia in patients older than or equal to 3 years of age, and maintenance of general anesthesia in patients older than or equal to 2 months of age.

Policy:

Effective for dates of services on or after July 1, 2012, see policy #470—Monitored Anesthesia Care

Effective for dates of services prior to July 1, 2012:

The use of **anesthesia services** to provide sedation and analgesia for patients for **routine** gastrointestinal endoscopy procedures **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **except for the following**:

- Patients with potential for difficult intubation and/or ventilation with a mask, or at risk for airway obstruction, including but not limited to:
    - Patients with previous problems with anesthesia or sedation;
    - Patients with a history of stridor or tracheal stenosis
    - Patients with a diagnosis of clinically significant sleep apnea;
    - Morbidly obese patients;
    - Patients with dysmorphic facial features, such as Pierre-Robin syndrome, trisomy-21, or Turner's syndrome;
    - Patients with oral abnormalities, such as a small opening (<3 cm in an adult), macroglossia, tonsillar hypertrophy, or a nonvisible uvula;
    - Patients with neck abnormalities, such as limited neck extension, decreased hyoid mental distance (<3 cm in an adult), neck mass, oral or glottic tumors, previous head and neck surgery or radiation, unstable cervical spine, tracheal deviation due to mass or previous surgery, ankylosed cervical spine or advanced rheumatoid arthritis;
    - Patients with IX or X cranial nerve impairment;
    - Patients with spinal cord instability;
    - Patients with jaw abnormalities such as micrognathia, retrognathia, trismus, or significant malocclusion.
- Patients with allergies to sedation and analgesia agents;
- Alcohol or drug addicted patients or patients with increased tolerance to sedation and analgesic agents such as patients with a chronic pain syndrome;
- Patients with increased risk for aspiration, e.g., diabetics with autonomic neuropathy and gastroparesis, achalasia, ascites, swallowing disorders, or bulbar neurologic disorders;
- Patients with chronic degenerative neurologic diseases which may cause difficulty swallowing or pose a risk for muscle weakness and respiratory failure e.g., multiple sclerosis, myasthenia gravis, Parkinson's disease, ALS, etc.;
- Extremes of age, i.e., < 1 year of age or > 70 years of age;
- Combative or uncooperative patients;
- Patients with neurobehavioral delays when rapid onset of sedation is a safety concern;
- Uncooperative pediatric patients;
- Patients with history of severe, nausea and/or vomiting after administration of sedation with narcotics and/or benzodiazepines;

- Patients undergoing prolonged or complex diagnostic or therapeutic procedures such as ERCP;
- Class III ASA patients **when respiratory and/or cardiac complications are a concern**.

  Class III ASA is defined as: *severe systemic disease that limits activity, but is not incapacitating,* e.g., stable angina, H/O myocardial infarction, H/O stroke, insulin dependent diabetes, poorly controlled disorders, e.g., HTN,-asthma, psychiatric disorders, etc., dysrhythmias ,CHF, COPD
  - Class IV ASA patients *(severe systemic disease that limits activity and is a constant threat to life), e.g.,*
    - Myocardial infarction within last 6 months
    - Stroke within last 6 months
    - Unstable angina
    - Severe CHF
    - Severe COPD
    - Hepatic failure
    - Renal failure
    - Uncontrolled epilepsy*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:

Sedation-related risk factors, the depth of sedation, and the urgency of the endoscopic procedure all play important roles in determining whether the assistance of anesthesia personnel is needed. Sedation related risk factors include significant medical conditions such as extremes of age, severe pulmonary, neurological, cardiac, renal, or hepatic disease, abuse of drugs or alcohol, high tolerance to drugs due to chronic pain syndrome, uncooperative patients, or a potentially difficult airway for intubation or ventilation.

Sedation and analgesia comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation–analgesia, as developed by the American Society of Anesthesiologists (ASA); approved by the ASA House of Delegates October 13, 1999 and adopted by the ASA, are:

- *Minimal Sedation (Anxiolysis)* = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
- *Moderate Sedation/Analgesia (Conscious Sedation)* = a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to

maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

- *Deep Sedation/Analgesia* = a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- *General Anesthesia* = a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering *Moderate Sedation/Analgesia (Conscious Sedation)* should be able to rescue patients who enter a state of *Deep Sedation/Analgesia*, while those administering *Deep Sedation/Analgesia* should be able to rescue patients who enter a state of general anesthesia.

Monitoring of patient response to verbal commands should be routine during moderate sedation, except in patients who are unable to respond appropriately (e.g., young children, mentally impaired or uncooperative patients), or during procedures where movement could be detrimental. During deep sedation, patient responsiveness to a more profound stimulus should be sought, unless contraindicated, to ensure that the patient has not drifted into a state of general anesthesia. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

An anesthetic agent such as propofol can be useful in certain patients undergoing endoscopic procedures. However, clinically important benefits have not been consistently demonstrated in average risk patients undergoing standard upper and lower endoscopy. In a randomized study, 90 patients received a bolus administration of propofol or midazolam both before and during upper endoscopy. The propofol treatment arm was superior in terms of patient tolerance, maximum level of sedation achieved, and shorter recovery room times, although amnesia for the procedure and perceived patient discomfort were not different. The ability of the endoscopist or the facility to speed the recovery time so that more procedures can be accomplished in a given time is an economic issue. It does not bear on the medical necessity of deep sedation/analgesia for routine, low-to-average risk endoscopy procedures.

In a comparison of the combination of propofol and fentanyl with midazolam and meperidine in a nonrandomized group of 274 patient undergoing upper endoscopy and colonoscopy, the group receiving propofol and fentanyl had better patient comfort and deeper sedation without an increase in untoward side effets. There was not, however, a significant difference in the recovery times between the two groups. Sipe, et al., randomized 80 patients undergoing colonoscopy to combination midazolam/meperidine versus propofol. The propofol group had a greater depth of

sedation, modest improvement in satisfaction scores, and faster post procedure recovery times. However, a prior randomized study of sedation for colonoscopy in 57 patients did not find a benefit for propofol/fentanyl over diazepam/meperidine or midazolam/fentanyl in terms of sedation, analgesia, recovery rate, or incidence of side effects. Taken together, these studies have not shown a convincing benefit for propofol when used for standard upper and lower endoscopy. Further randomized controlled trials are needed. Therefore, the routine assistance of anesthesia personnel for average risk patients undergoing standard upper and lower endoscopic procedures in not warranted and is not considered medically necessary.

Two randomized controlled trials in 80 and 196 patients respectively, have shown that propofol has more clinically significant advantages when used for prolonged and therapeutic procedures such as ERCP.

Various individual factors such as age, developmental level, and previous experience determine how a child responds to painful procedures. Some children may require deeper sedation for procedures.

In March 2004, the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) issued the following Joint Statement on Recommendations on the Administration of Sedation for the Performance of Endoscopic Procedures:

- In general, diagnostic and uncomplicated therapeutic endoscopy and colonoscopy are successfully performed with moderate (conscious) sedation.
- Compared to standard doses of benzodiazepines and narcotics, propofol may provide faster onset and deeper sedation.
- More rapid cognitive and functional recovery can be expected with the use of propofol as a single agent.
- Clinically important benefits over standard sedatives have not been consistently demonstrated in average-risk patients undergoing standard routine upper and lower endoscopy. Further randomized clinical trials are needed in this setting.
- Propofol may have more clinically significant advantages when used for prolonged and therapeutic procedures, including, but not limited to, ERCP and EUS.
- There are data to support the use of propofol by adequately trained non-anesthesiologists. Large case series indicate that with adequate training physician-supervised nurse administration of propofol can be done safely and effectively. The regulations governing the administration of propofol by nursing personnel vary from state to state.
- Patients receiving propofol should receive care consistent with deep sedation. Personnel should be capable of rescuing the patient from general anesthesia and/or severe respiratory depression.

- A designated individual, other than the endoscopist, should be present to monitor the patient throughout the procedure and should be able to recognize and assist in the management of complications.
- The routine assistance of an anesthesiologist/anesthetist for average risk patients undergoing standard upper and lower endoscopic procedures is not warranted
- Physician-nurse teams administering propofol should possess the training and skills necessary to rescue patients from severe respiratory depression.
- Complex procedures and procedures in high-risk patients may justify the use of an anesthesiologist/anesthetist to provide conscious and/or deep sedation. In such cases this provider may bill separately for their professional services.
- The use of agents to achieve sedation for endoscopy must conform to the policies of the individual institution.
- Reimbursement for conscious sedation is included within the codes covering endoscopic procedures.
- Billing separately for conscious sedation has been targeted by the OIG as a possible fraud and abuse violation, and is not recommended.

Propofol has been administered by non-anesthesiologists in endoscopic procedures, including by a dedicated gastroenterologist, registered nurses, and patient-controlled systems. Although properly trained physicians can administer propofol, the regulations governing its administration by nursing personnel are variable on a state-by-state basis. The ASA Taskforce recommends that patients receiving propofol should receive care consistent with deep sedation and the personnel should be capable of rescuing the patient from general anesthesia.

In April 2004, the ASA and American Association of Nurse Anesthetists (AANA) issued a joint statement stating:

> "Whenever propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these general or surgical procedures. This restriction is concordant with specific language in the propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death".

In summary, the central issue is in which clinical situations is it medically necessary to have Anesthesia staff in attendance for routine low-to-average risk patients for endoscopic procedures. Deep sedation administered by anesthesia staff for routine, low-to-average risk patients for routine endoscopy is not medically necessary except in the situations outlined above. In the great majority of cases, sedation administered under supervision of licensed physician endoscopist has been and remains the standard practice and continues to be considered medically necessary.

February 2008 Update
No new information was located that would alter the coverage statement of this policy.

February 2010 Update
An extensive review of the literature related to sedation for gastrointestinal (GI) endoscopy was published through the American Gastroenterological Association (AGA) Institute in 2007. Portions of their review were relevant to this policy. The review recommended that use of an anesthesia professional should be strongly considered for American Society of Anesthesiologists (ASA) physical status IV and V patients. They noted that other possible indications for an anesthesia specialist include patients with pregnancy, morbid obesity, neurologic or neuromuscular disorders, a history of alcohol or substance abuse, and patients who are uncooperative or delirious. They also noted that endoscopic procedures that may require an anesthesia specialist include endoscopic retrograde cholangiopancreatography (ERCP), stent placement in the upper GI tract, and complex therapeutic procedures such as plication of the cardio-esophageal junction. This review was used in formulating the conclusions of this policy.

Given the interest in use of propofol, additional details are provided concerning its use in GI endoscopy.

A recent Cochrane review by Singh et al. in 2009 summarized the results of 20 randomized clinical trials comparing the use of propofol and traditional agents for use during colonoscopy. This review encompassed and enlarged on a prior review by McQuaid and Laine in 2008, which reviewed a broader set of studies of all randomized trials of any agents used for sedation for endoscopic procedures. The reviews come to largely similar conclusions, but certain comparisons were only performed in one or the other review.

The regimens used in the propofol and comparison groups in these studies varied. In the different clinical trials, propofol has been used alone, in combination with other agents, and in patient-controlled sedation systems. In a few of the studies, it was intended that propofol be used to induce deep sedation. The comparison groups received either benzodiazepines alone or a combination of a benzodiazepine and narcotic, and all patients in these comparison arms were sedated to a level of moderate sedation.

Although 20 randomized clinical trials were identified, studies examined different outcomes, so that for any given outcome, a smaller number of studies contributed to the findings. The outcomes noted in the Cochrane review were:

Recovery time
In 3 studies in which propofol was used as a single agent, the pooled difference in recovery time was 14.7 minutes shorter for the propofol arms. In 6 studies in which propofol was used in combination with other agents, patients sedated with propofol had a mean shorter recovery time of 17.9 minutes. In 4 studies in which propofol was used with patient-controlled sedation (PCS), average recovery time was 24.9 minutes shorter. Overall, after excluding studies that could not be pooled, studies with patient-controlled analgesia, and an outlier study, recovery time with propofol was 14.2 minutes shorter.

Discharge time
Combining 7 studies (n =542) that reported discharge time, the discharge time was shorter for propofol by an average of 20.9 minutes.

Procedure duration
When pooling all 9 studies that reported this outcome, there was no significant difference between propofol and the comparator (average difference of 0.9 minutes). An additional analysis pooling 7 studies that examined measures of procedure success (i.e., intubating the cecum) found no difference in the procedure completion rate.

Patient satisfaction
In 7 studies in which patient satisfaction was reported, a higher proportion of patients were satisfied with propofol (odds ratio [OR] for dissatisfaction 0.35, statistically significant). The odds ratio metric does not adequately reveal the absolute difference in satisfaction between propofol and the alternative used in the studies, but being dissatisfied was a generally low frequency event. The review by McQuaid and Laine report this outcome as an absolute difference in satisfaction, and they report an absolute difference of 10% in their meta-analysis of 2 studies.

Pain control
In pooling 9 studies that reported pain control, there was better pain control with traditional agents than with propofol (OR 1.71, statistically significant), but there was significant heterogeneity in the results. When the propofol studies were stratified by whether PCS was used or not, there was no difference between propofol and traditional agents without PCS, but propofol with PCS was inferior to traditional agents (OR 3.09, statistically significant).

Hypoxia, apnea, arrhythmias, hypotension
In all pooled analyses of these various outcomes, there was no difference between the propofol arms and the traditional agents.

In summary, the principal differences between propofol and the traditional agents used in these clinical trials are a shorter recovery period (a mean of 14.2 minutes) and overall satisfaction scores. Pain control and incidence of respiratory depression appear to be similar.

Guidelines and Position Statements
Recent guidelines regarding sedation during endoscopy were released by the American Society for Gastrointestinal Endoscopy (ASGE). These guidelines indicate "Adequate and safe sedation can be achieved in most patients undergoing routine esophagogastroduodenoscopy [EGD] and colonoscopy by using an intravenous benzodiazepine and opiod combination." These guidelines also include a discussion of use of propofol for routine endoscopy, and their overall conclusion is that "clinically important benefits in average-risk patients undergoing upper endoscopy and colonoscopy have not been consistently demonstrated with regard to patient satisfaction and safety. Therefore, the routine use of propofol in average-risk patients cannot be endorsed." In addition to addressing the efficacy and safety of propofol, the guidelines discuss the issue of who is qualified to give propofol. The ASGE endorses

gastroenterologist-directed propofol use when adequate training for its use has been achieved. Numerous case series studies were cited showing very low rates of clinical adverse events when propofol was administered by registered nurses under gastroenterologist supervision. The Cochrane review included 1 randomized clinical trial, reported in abstract form only, comparing administration of propofol by anesthesiologists compared to non-anesthesiologists. The review reports that the study showed no difference in procedure time or patient satisfaction in this small study of 94 patients.

Key Words:

Conscious sedation, moderate sedation, deep sedation, propofol, Diprivan®

Approved by Governing Bodies:

FDA ALERT [6/15/2007] - FDA is issuing this alert to inform healthcare professionals about several clusters of patients who have experienced chills, fever, and body aches shortly after receiving propofol for sedation or general anesthesia. FDA has tested multiple units of propofol vials and lots used in patients who have experienced these symptoms and to date, these tests have not identified any vials contaminated with bacteria or endotoxins.

FDA recommends that healthcare professionals who administer propofol for sedation or general anesthesia carefully follow the recommendations for handling and use found in the current product labeling.

In addition, please report to the MedWatch program patients who have received propofol for sedation or general anesthesia and subsequently experienced fever, chills, and body aches or other symptoms of an acute febrile reaction (see MedWatch reporting information at the bottom of this page). Patients who develop these symptoms shortly after receiving propofol should be evaluated for bacterial sepsis.

Benefit Application:

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

ITS: Home Policy provisions apply
BellSouth/AT&T contracts: No special consideration
FEP contracts: Anesthesia for surgical procedures is covered and colonoscopies are considered a surgical procedure; therefore, anesthesia for colonoscopies is covered.
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification requirements: Not applicable

Coding:

CPT Codes: **00740** Anesthesia for upper gastrointestinal endoscopic procedures,

endoscope introduced proximal to duodenum

00810 Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum

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Policy History:

Medical Policy Group, September 2005 **(2)**
Medical Policy Group, October 2005 **(2)**
Medical Policy Group, February 2006 **(2)**
Medical Review Committee, February 2006
PMD Advisory Committee, March 2006
Medical Policy Administration Committee, March 2006
PCN Advisory Committee, March 2006
Available for comment April 4-May 18, 2006
Medical Policy Group, February 2008 **(1)**
Medical Policy Group, February 2010 **(1)** Description and Key Points and References updated, no policy changes
Medical Policy Group, November 2011 **(2)** Refer to Policy #470
Medical Policy Administration Committee, November 2011
Available for comment November 11, 2011 through January 31, 2012
Medical Policy Group, May 2012 **(2)**
Policy Retired, July 2012: **Active policy for dates of service prior to April 30, 2009 but no longer scheduled for regular literature reviews and updates.**