

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.

Policy:

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, ~~or~~ 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

The purpose of Blue Cross and Blue Shield of Alabama’s medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

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 (11) 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 (5), 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 effects. There was not, however, a significant difference in the recovery times between the two groups (2). Sipe, et al. (18) 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. (7) 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 is 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. (10)

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.

Key Words:

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

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

BellSouth contracts: No special consideration

FEP contracts: Anesthesia for surgical procedures is covered and colonoscopies are considered a surgical procedure; therefore, anaesthesia for colonoscopies is covered.

Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification requirements: Not applicable

Pre-determination requirements: Pre-determinations will be performed as a courtesy review at the request of the physician and/or subscriber.

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Policy History:

- Medical Policy Group, September 2005 (2)
- Medical Policy Group, October 2005 (2)
- Available for comment, February 1, 2006-March ??????
- 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

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.