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Corporate Medical Policy

Monitored Anesthesia Care (MAC) during Gastrointestinal Endoscopy, Bronchoscopy, or Interventional Pain Procedures in Outpatient Settings

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Description

Adequate sedation and analgesia are important parts of diagnostic and therapeutic endoscopic procedures. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient's status and the procedure being performed. This policy addresses the potential role of dedicated anesthesia providers during procedures performed in a properly equipped and staffed outpatient setting.

Background

Monitored anesthesia care (MAC) refers to the anesthesia personnel present during a procedure and does not implicitly indicate the level of anesthesia needed. The American Society of Anesthesiologists (ASA) has defined MAC. The following is derived from ASA statements:

Monitored anesthesia care is a specific anesthesia service for a diagnostic or therapeutic procedure. Indications for monitored anesthesia care include the nature of the procedure, the patient's clinical condition and/or the potential need to convert to a general or regional anesthetic.

Monitored anesthesia care includes all aspects of anesthesia care—a pre-procedure visit, intra-procedure care and post-procedure anesthesia management. During monitored anesthesia care, the anesthesiologist provides or medically directs a number of specific services, including but not limited to:

- Diagnosis and treatment of clinical problems that occur during the procedure
- Support of vital functions
- Administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary for patient safety
- Psychological support and physical comfort
- Provision of other medical services as needed to complete the procedure safely.

MAC may include varying levels of sedation, analgesia, and anxiolysis as necessary. The provider of MAC must be prepared and qualified to convert to general anesthesia when necessary. If the patient loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation is required.

In 2004, the ASA defined 4 levels of sedation/ analgesia as follows:

Minimal sedation (anxiolysis): is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular function are unaffected.

Moderate sedation/analgesia (“conscious” sedation): is 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: is 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: is a drug-induced depression of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator 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.

According to the American Society of Anesthesiologists' (ASA) standard for monitoring, MAC should be provided by qualified anesthesia personnel, including physicians and nurse specialists. By this standard, the personnel must be in addition to the proceduralist and must be present continuously to monitor the patient and provide anesthesia care. For patients at high risk of an unsuccessful procedure under moderate sedation, this allows for the safe continuation of the procedure under deep sedation or general anesthesia by trained personnel.

Sedation and anesthesia services that are provided in outpatient settings should be administered by qualified and appropriately trained personnel. Moderate sedation is generally sufficient for many diagnostic and uncomplicated therapeutic procedures. Moderate sedation using benzodiazepines, with or without narcotics, is usually administered by, or under the supervision of the proceduralist.

Moderate sedation can be achieved using pharmacologic agents for sedation, anxiolysis, and analgesia. A frequently used combination is an opioid and benzodiazepine, for example, fentanyl with midazolam at doses individualized to obtain the desired sedative effect. Other combinations have also been utilized for this purpose. While both benzodiazepines and opioids can cause respiratory depression, effective reversal agents exist for both.

Propofol is an agent that has been increasingly used to provide sedation for procedures. Propofol is associated with a rapid onset of action and fast recovery from sedation. However, there have been concerns about potential side effects and safety when used by non-anesthesiologists. Propofol has the potential to induce general anesthesia, and there is no pharmacologic antagonist to reverse its action. When used as moderate sedation, Propofol may be administered by anesthesia personnel or under the direction of the proceduralist. ASA has offered practice guidelines for the provision of sedation by non-anesthesiologists, stating that personnel must be prepared to respond to deep sedation and loss of airway protection should these complications inadvertently occur during sedation.

The use of MAC has been increasing rapidly over the last decade and has been applied to patients with lower anesthetic risk. Liu and colleagues estimated the utilization of anesthesia services (in contrast to sedation typically provided by nurses) among low-risk patients (ASA P1-P2). (5) As a means of highlighting the discretionary nature of the services, the investigators studied changes in utilization over time between different geographic locations within the U.S. The proportion of gastrointestinal (GI) tract procedures performed with anesthesia services increased from approximately 14% in 2003 to more than 30% in 2009, with wide geographic variation in the use of these services. (5) A complex set of factors have been proposed that contribute to this increased use of anesthesia services including patient and physician preferences, clinical need, regulatory requirements, and financial considerations.

Regulatory Status

In October, 1989 Propofol "Diprivan®" (AstraZeneca) was first approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for the induction and maintenance of anesthesia. 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.

This policy only addresses anesthesia services for diagnostic or therapeutic procedures involving gastrointestinal (GI) endoscopy, bronchoscopy, and interventional pain procedures performed in the outpatient setting.

Policy

Use of monitored anesthesia care may be considered medically necessary for gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures, when there is documentation by the proceduralist and anesthesiologist that specific risk factors or significant medical conditions are present. Those risk factors or significant medical conditions include any of the following:

- Increased risk for complications due to severe comorbidity (ASA P3* or greater)
- Morbid obesity (BMI [body mass index] >40)
- Documented sleep apnea
- Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
- Spasticity or movement disorder complicating procedure
- History or anticipated intolerance to standard sedatives, such as:
 - Chronic opioid use
 - Chronic benzodiazepine use
- Patients with active medical problems related to drug or alcohol abuse
- Patients younger than 18 years or 70 years or older
- Patients who are pregnant
- Patients with increased risk for airway obstruction due to anatomic variation, such as:
 - History of stridor
 - Dysmorphic facial features
 - Oral abnormalities (e.g., macroglossia)
 - Neck abnormalities (e.g., neck mass)
 - Jaw abnormalities (e.g., micrognathia)
- Acutely agitated, uncooperative patients
- Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section).

* American Society of Anesthesiologists (ASA) physical status classification system for assessing a patient before surgery:

- P1 - A normal, healthy patient
- P2 - A patient with mild systemic disease
- P3 - A patient with severe systemic disease
- P4 - A patient with severe systemic disease that is a constant threat to life
- P5 - A moribund patient who is not expected to survive without the operation
- P6 - A declared brain-dead patient whose organs are being harvested

Use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in patients at average risk related to use of anesthesia and sedation.

Policy Guidelines

Monitored anesthesia care can be provided by qualified anesthesia personnel with training and experience in:

- Patient assessment
- Continuous evaluation and monitoring of patient physiological functions
- Diagnosis and treatment (both pharmacological and non-pharmacological) of any and all deviations in physiological function.

Examples of prolonged endoscopy procedures that may require deep sedation include adhesions post-abdominal surgery, endoscopic retrograde cholangiopancreatography, stent placement in the upper GI tract, and complex therapeutic procedures such as plication of the cardioesophageal junction

The Mallampati score is considered a predictor of difficult tracheal intubation and is routinely used in preoperative anesthesia evaluation. The score is obtained by having the patient extend the neck, open the mouth, and extend the tongue while in a seated position. Patients are scored from Class 1-4 as follows:

Class 1 - the tonsils, uvula and soft palate are fully visible

Class 2 - the hard and soft palate, uvula and upper portion of the tonsils are visible

Class 3 - the hard and soft palate and the uvula base are visible

Class 4 - only the hard palate is visible.

Patients with Class 3 or 4 Mallampati scores are considered to be at higher risk of intubation difficulty. While the Mallampati score does not determine a need for monitored anesthesia care, it may be considered in determining risk for airway obstruction. Other tests to predict difficult tracheal intubation include the upper lip bite test, the intubation difficulty scale, and the Cormack-Lehane grading system.

For reference, the add-on code for anesthesia for patient of extreme age is:

99100 - Anesthesia for patient of extreme age, younger than 1 year and older than 70 (List separately in addition to code for primary anesthesia procedure).

Rationale

Literature Review

This policy was created in 2009 and updated regularly with searches of the MEDLINE database. The most recent literature search was through January 22, 2014.

One updated systematic review on the use of Propofol for sedation during colonoscopy has been published by the Cochrane Collaboration. One randomized controlled trial (RCT) has examined the use of moderate sedation with monitored anesthesia care (MAC) against moderate sedation without monitored care; it has been published in abstract form only. Many of the RCTs and comparative studies have focused on comparisons of agents for moderate sedation. Many recommendations for the indications for MAC are derived from narrative reviews and expert opinion. The following is a summary of the key literature to date:

Location of the Procedure

The American Society of Anesthesiologists (ASA) has recommended that any location providing MAC have the capability of cardiopulmonary resuscitation and monitoring equipment. In 2004, Fleisher and colleagues performed a retrospective claims data review on 564,267 outpatient surgical procedures: 360,780 at an outpatient department of a hospital, 175,288 at an ambulatory surgical center and 28,199 at a physician's office. The rates of all-cause death, emergency department visits, and inpatient admissions within 7 days of the procedure were compared. The highest rates were seen among patients in the outpatient surgery department of the hospital, suggesting that patients evaluated to be at highest risk had their procedure in the location of lowest anesthesia risk. Multivariate analysis noted that increasing patient age, increasing procedural risk, and increasing past medical history of inpatient admissions were all independently predictive of adverse outcome.

Use of Monitored Anesthesia Care in Endoscopy

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 ASA physical status 3 through 5 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 cardioesophageal junction. This review was used in formulating the initial conclusions of this policy.

Comparison of Sedative Agents Used in Endoscopy

Given the interest in use of Propofol, additional details are provided concerning its use in GI endoscopy. A Cochrane systematic review by Singh and colleagues (updated in June 2011), summarized the results of RCTs 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 primary objective of the Cochrane review was to compare the relative effectiveness, patient acceptance, and safety of Propofol compared to traditional sedatives for patients undergoing colonoscopy. The secondary objective was to synthesize the studies comparing Propofol administration by anesthesiologists to that by non-anesthesiologists for sedation during colonoscopy. This review is an update of a previously published Cochrane systematic review in 2008. The literature search for the updated review was undertaken up to December 2010. The outcome measures of interest were technical performance of colonoscopy (recovery time, discharge time, procedure time), patient satisfaction, pain control, and complication rates (cardio-respiratory events, colonic perforations and hospital admission rate after procedure, and death).

Twenty-two studies met the inclusion criteria for the primary objective in this updated review. Eight (of 22) eligible RCTs evaluated Propofol as a single agent, and 7 trials were published in only abstract format, including the largest trial from 2000 (n=7,286 patients), which reported on different rates of colonic perforation. Only one trial published in 2006 was a double-blinded RCT, where all patients as well as all those involved in administering the medications and assessing the outcomes were not aware of the intervention in different arms of the trial. The agents administered in the control arms across these trials included benzodiazepines alone (diazepam, midazolam) or a combination of a benzodiazepine and a narcotic (pethidine, fentanyl, remifentanyl or alfentanil). One trial published in 2003 included only a narcotic (remifentanyl), and all patients in the control arm of this study remained awake throughout the procedure. The dosage of the agents used varied across trials. The intended level of sedation when stated was defined in most studies as that needed for patients tolerance of the procedure. Many of the studies had a potential of moderate to high risk of bias and combining data for some of the outcomes for meta-analysis was problematic. Most studies included only healthy outpatients.

Recovery time (reported in 11 studies; 776 patients) was shorter with Propofol compared to the control arm (weighted mean difference [WMD]: -14.2 minutes; 95% confidence interval [CI]: -17.6, -10.8), with no significant heterogeneity (p=0.41). Discharge time (7 studies; 542 patients) was also reported to be shorter with use of Propofol (WMD: -20.9 minutes; 95% CI: -30.9, 10.8); however, there was significant heterogeneity between studies (p<0.0001). There was higher patient satisfaction (10 studies, 819 patients) with use of Propofol (odds ratio [OR]: for dissatisfaction 0.35; 95% CI: 0.23, 0.53). There was no difference in procedure time (9 studies; 736 patients) or complication rates. There was also no difference in pain control with non-patient controlled sedation (5 studies; 396 patients) between Propofol and the control arm (OR: 0.90; 95% CI: 0.58, 1.39).

The Cochrane review found only one RCT, reported in abstract format, for the secondary objective, comparison of Propofol administration by anesthesiologists (Group A) to that by endoscopists (Group B). This RCT has subsequently been published by Poincloux and colleagues. Ninety adult patients (from a university center in France) undergoing colonoscopy were randomized into the above 2 groups. The goal of Propofol administration by anesthesiologists was anesthesia and that by

endoscopists was sedation. There was no difference in procedure time (16.7 minutes for Group A and 17.7 minutes for Group B) or patient satisfaction (average score on Visual Analog Scale, 90.8 vs. 89). A higher proportion of patients administered Propofol by an anesthesiologist experienced hypoxia, but no patient required an intervention.

There are numerous observational studies, and some of the representative publications are summarized here. Horiuchi et al. reported an observational study from Japan. Low-dose Propofol was administered by nurses supervised by the endoscopist during diagnostic endoscopy. In this study, 10,662 patients were observed following receiving an age-dependent standard dose protocol of Propofol, which was administered by bolus injection, with additional doses given when required for adequate sedation prior to esophagogastroduodenoscopy (EGD). The incidence of respiratory depression was the primary outcome for this study, and further measures of successful completion of the procedure and patient satisfaction were analyzed. Twenty-eight patients required transient supplemental oxygen supply, while none required mask or endotracheal intubation. All procedures were successful and 79.1% diagnostic EGDs were completed with a single bolus of Propofol. The authors conclude that low-dose nurse-administered Propofol sedation is safe when supervised by the endoscopist, and practical for diagnostic EGD. The study is limited by the lack of a comparison group. Patients with ASA classification 3 and 4 were excluded from the study, so these conclusions may not be generalized to that group.

Coté et al. reported another prospective observational study on 766 patients undergoing advanced endoscopic procedures such as ERCP, endoscopic ultrasound, and small-bowel enteroscopy who received Propofol. These procedures are notable for their duration and complexity compared to diagnostic EGD. The primary outcome measure was airway modifications (AM), with a comparison of defining characteristics of the group requiring at least 1 airway modification, such as chin lift or nasal airway, to those requiring no modification. No patients in the study required endotracheal intubation. Body mass index (BMI), male sex, and ASA class 3 or above were associated with a need for AM. Patients in this study received anesthesia from a certified registered nurse anesthetist (CRNA) and generally had a level of deep sedation, and thus their care continues to meet the definition of MAC.

Rex et al. reviewed case series of endoscopist-directed Propofol sedation published in MEDLINE, CINAHL and EMBASE over the period of 1966 to 2008, resulting in 646,080 procedures in 28 studies published between 2002 and 2008. Incidence of mask ventilations, endotracheal intubation, neurologic injuries, and death were collected from the published studies and calculated to reveal a death rate 0.62 per 100,000 cases. A direct comparison group was not included in this review. The authors note that this death rate compares favorably to published surveys of death rates of endoscopic procedures utilizing opioids and benzodiazepines of 11 per 100,000. They also compare this to published data on the general anesthesia overall death rate of 1-2 per 100,000. As mentioned, a direct comparison group is not available nor are death rates for endoscopic procedures under MAC. However, the incidence of published adverse events appears to be low.

Agostoni and colleagues evaluated a prospective database of 17,999 GI endoscopies performed under MAC during the period of October 2001 to December 2009. The

authors identified 6 variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year OR: 1.02 [95% confidence interval [CI]: 0.01-1.02]), BMI (1-point OR: 1.03 [95% CI: 0.02-1.05]), ASA score ("3-4" vs. "1-2" OR: 1.69 [95% CI: 1.44-1.99]), Mallampati score ("3-4" vs. "1-2" OR: 1.33 [95% CI: 1.04-1.70]), emergency nature of the procedure (OR: 1.48 [95% CI: 1.13-1.94]), length of the procedure (OR: 2.00 [95% CI: 1.78-2.24]). The authors noted the Mallampati score is used to assess potential difficulty in tracheal intubation, and it is unclear why this score was predictive of any complication.

In a prospective cohort study of 470 ERCP patients receiving MAC, Berzin and colleagues reported adverse respiratory events were strongly associated with higher body mass index using multivariate regression models. (OR: 1.08; $p=0.0006$). Patients with obesity experienced respiratory events almost twice as often as non-obese patients ($p=0.03$). Higher ASA class was not associated with adverse respiratory events under MAC (OR: 1.2; $p=0.25$) but was associated with cardiovascular events (OR: 2.88; $p<0.0001$).

Conclusions

The evidence base comparing different anesthetic methods is not robust, consisting primarily of non-randomized comparisons and observational studies. A single RCT comparing Propofol administration by anesthesiologists to that by non-anesthesiologists for sedation during colonoscopy did not show any differences in procedure time or patient satisfaction, and reported a higher rate of hypoxia in patients treated with Propofol. However, a Cochrane review of randomized studies concluded that recovery time, discharge time, and patient satisfaction were all improved with Propofol compared to alternative agents. This review did not find any evidence of increased complications. However, this evidence base does not rule out an increased complication rate with Propofol, since there is a low complication rate in general, thus making it difficult to discern differences in the absence of large RCTs.

Bronchoscopy

In 2009, Silvestri and colleagues published an RCT comparing 2 doses of the sedative agent fosPropofol in patients undergoing diagnostic bronchoscopy. The study was performed by pulmonologists without anesthesia supervision. Patients ($n=252$) were randomly assigned to receive either 2 mg/kg or 6.5 mg/kg induction doses of fosPropofol, followed by additional doses per protocol. All patients received a pre-procedural dose of fentanyl. The primary endpoint was sedation success using the Modified Observer's Assessment of Alertness/Sedation (MOAA/S). A secondary endpoint was treatment success, as measured by percentage of patients who did not require alternate sedation or ventilation. The higher dose group had greater sedation success (88.7% vs. 27.5%, respectively; $p<0.001$). Treatment success also favored the higher dose group (91.3% vs. 41.25%, respectively; $p<0.001$). Adverse events were higher for the higher dose group; for example, the number of patients requiring any type of airway assistance (33 vs. 14, or 21.5% vs. 13.6%, respectively). The trial does not compare alternate sedation approaches; that comparison is necessary to evaluate the clinical value of the fosPropofol sedation strategy for bronchoscopic procedures.

The British Thoracic Society published guidelines for flexible bronchoscopy in 2001. With respect to sedation, the guidelines state that sedation should be offered,

patients should be monitored during and immediately after the procedure and that at least two assistants, at least one a qualified nurse, should be in attendance. Resuscitation equipment should be readily available. The sedation agents are not specified. An update to these guidelines is expected in early 2013.

Interventional Pain Management Procedures

In 2008, Bernards and colleagues published a review of the literature around neurologic complications of regional anesthesia in anesthetized or heavily sedated patients. Some experts postulate that the inability of a sedated patient to express atypical symptoms during a regional block may lead to increased risk of injury. No comparative studies have been done, and limited information is available from registries. The American Society of Regional Anesthesia (ASRA) and Pain Medicine has acknowledged the scarce and conflicting literature on the topic and recommends carefully weighing the risks and benefits in considering performing those procedures while the patient is heavily sedated or anesthetized.

In 2005, ASA released a statement on anesthetic care during interventional pain procedures. While recognizing that conditions exist which may make skilled anesthesia care necessary, most minor pain procedures, under most routine circumstances, do not require anesthesia care other than local anesthesia.

Other Procedures

Any procedure which may be complicated by patient characteristics noted in the policy statement may be appropriate for MAC.

Pregnancy

Concerns regarding procedures and sedation during pregnancy are two-fold: sensitivity of the fetus to the agents and/or procedural hypotension and maternal factors that increase sensitivity to sedation and that make intubation more difficult in an emergency situation. In a large (n=720,000) Swedish registry of pregnant patients from the 1970s and 1980s, 5,405 operations took place. Congenital malformations and stillbirths were not increased in the offspring of women having an operation. Incidence of low birth weight infants was increased as a result of both prematurity and intrauterine growth retardation. Neonatal death was also increased in the patients who had an operation. No specific types of anesthesia or operation were associated with these outcomes. The contribution of the underlying condition which led to the need for surgery could not be separated from the effects of the surgery or sedation/anesthesia.

Fetal heart rate monitoring is considered to be a more sensitive indicator of placental perfusion and fetal oxygenation than observations of maternal hemodynamic stability alone. The American College of Obstetricians and Gynecologists (ACOG) has recommended that the use of intermittent or continuous fetal monitoring during surgery be individualized.

Physiologic changes in pregnancy may require changes in standard doses of anesthetic or sedative agents. However, Propofol does not generally require a change in loading dose for induction. Physiologic changes in pregnancy may warrant MAC when airway protection becomes necessary, due to additional difficulties noted with emergent intubation in pregnant patients and the urgency to restore full oxygenation to the

maternal and fetal patients. Thus MAC can be considered medically necessary for procedures performed during pregnancy.

Ongoing Clinical Trials

A search of online site Clinicaltrials.gov on January 23, 2014 did not identify any open studies evaluating predictive factors for risks of sedation-related adverse events.

Summary

Monitored anesthesia care is the use of anesthesia personnel during a procedure to provide various levels of sedation and analgesia (anesthesia) depending on the patient's condition and the procedure being performed. This policy addresses the potential role of dedicated anesthesia providers during diagnostic or therapeutic procedures involving gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures performed in the outpatient setting.

Comparative evidence that supports the use of monitored anesthesia care in specific procedures is limited. Patient characteristics, such as comorbidities, airway features, or the ability to cooperate with the proceduralist, are more indicative of the need for this service. Physician-directed moderate sedation is a safe and effective alternative to monitored anesthesia care for the majority of patients undergoing procedures in whom deep sedation or anesthesia is unnecessary, such as gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures. Propofol may be used both for general anesthesia and moderate sedation. The principal differences between Propofol and the traditional agents used in these clinical trials of moderate sedation are a shorter recovery period (a mean of 14.2 minutes), shorter discharge time, and higher overall satisfaction scores. Pain control and incidence of complication rates appear to be similar overall, but the available evidence does not rule out small differences in these outcomes. The use of monitored anesthesia care may be considered medically necessary in cases with specific risk factors or significant medical conditions as indicated in the policy statement.

Practice Guidelines and Position Statements

In 2004, and amended in 2009, the American Society of Anesthesiologists released a statement on the safe use of Propofol:

“The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer Propofol should be qualified to rescue patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.”

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 opioid 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 administer 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.

References

1. Blue Cross and Blue Shield Association (BCBSA). Medical Policy Reference Manual for Monitored Anesthesia Care. Policy # 7.02.01, reviewed February 2014.
2. American Society of Anesthesiologists (ASA). ASA position on monitored anesthesia care. Amended September 2, 2008. Available online at: <http://www.asahq.org/For-Members/Clinical-Information/-/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Monitored%20Anesthesia%20Care.ashx>. Last accessed January 27, 2012.
3. American Society of Anesthesiologists (ASA). Levels of sedation/analgesia. Amended October 29, 2009. Available online at: <http://www.asahq.org/For-Members/Clinical-Information/-/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Continuum%20of%20Depth%20of%20Sedation.ashx>. Last accessed January 27, 2012.
4. American Society of Anesthesiologists (ASA). Distinguishing monitored Anesthesia care ("MAC") from moderate sedation/analgesia. Amended October 21, 2009. Available online at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>. Last accessed January 27, 2012.
5. American Society of Anesthesiologists (ASA). Statement on qualifications of anesthesia provided in the office-based setting. Amended October 21, 2009. Available online at: <http://www.asahq.org/For-Members/Clinical-Information/-/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Qualifications%20of%20Anesthesia%20Providers%20in%20the%20Office.ashx>. Last accessed January 27, 2012.
6. Liu H, Waxman DA, Main R et al. Utilization of anesthesia services during outpatient endoscopies and colonoscopies and associated spending in 2003-2009. JAMA 2012; 307(11):1178-84.
7. Fleisher LA. Assessing the value of "discretionary" clinical care: the case of anesthesia services for endoscopy. JAMA 2012; 307(11):1200-1.
8. Mallampati SR, Gatt SP, Gugino LD et al. A clinical sign to predict difficult tracheal intubation: a prospective study. Can Anaesth Soc J 1985; 32(4):429-34.
9. American Society of Anesthesiologists. Statement on nonoperating room anesthetizing locations. Amended October 2008. Available online at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>. Last accessed February 6, 2012.
10. American Society of Anesthesiologists. Guidelines for ambulatory anesthesia and surgery. Amended October 2008. Available online at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>.

Members/Standards-Guidelines-and-Statements.aspx. Last accessed February 6, 2012.

11. Fleisher LA, Pasternak LR, Herbert R et al. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. *Arch Surg* 2004; 139(1):67-72.
12. Cohen LB, Delegge MH, Aisenberg J et al. AGA Institute review of endoscopic sedation. *Gastroenterology* 2007; 133(2):675-701.
13. Singh H PW, Cheang M, Choptain N, Inegbu E, Baron K, Taback SP. Propofol for sedation during colonoscopy. *Cochrane Database Syst Rev* 2008; (4):CD006268.
14. McQuaid KR, Laine L. A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures. *Gastrointest Endosc* 2008; 67(6):910-23.
15. Poincloux L, Laquiere A, Bazin JE et al. A randomized controlled trial of endoscopist vs. anaesthetist-administered sedation for colonoscopy. *Dig Liv Dis* 2011; 43(7):553-8.
16. Horiuchi A, Nakayama Y, Hidaka N et al. Low-dose Propofol sedation for diagnostic esophagogastroduodenoscopy: results in 10,662 adults. *Am J Gastroenterol* 2009; 104(7):1650-5.
17. Cote GA, Hovis RM, Ansstas MA et al. Incidence of sedation-related complications with Propofol use during advanced endoscopic procedures. *Clin Gastroenterol Hepatol* 2010; 8(2):137-42.
18. Rex DK, Deenadayalu VP, Eid E et al. Endoscopist-directed administration of Propofol: a worldwide safety experience. *Gastroenterology* 2009; 137(4):1229-37; quiz 518-9.
19. Agostoni M, Fanti L, Gemma M et al. Adverse events during monitored anesthesia care for GI endoscopy: an 8-year experience. *Gastrointest Endosc* 2011; 74(2):266-75.
20. Berzin TM, Sanaka S, Barnett SR et al. A prospective assessment of sedation-related adverse events and patient and endoscopist satisfaction in ERCP with anesthesiologist-administered sedation. *Gastrointest Endosc* 2011; 73(4):710-7.
21. Silvestri GA, Vincent BD, Wahidi MM et al. A phase 3, randomized, double-blind study to assess the efficacy and safety of fosPropofol disodium injection for moderate sedation in patients undergoing flexible bronchoscopy. *Chest* 2009; 135(1):41-7.
22. British Thoracic Society guidelines on diagnostic flexible bronchoscopy. *Thorax* 2001; 56 Suppl 1:i1-21.
23. British Thoracic Society Guidelines. Available online at: <http://www.brit-thoracic.org.uk/guidelines.aspx>. Last accessed January 2013.
24. Bernards CM, Hadzic A, Suresh S et al. Regional anesthesia in anesthetized or heavily sedated patients. *Reg Anesth Pain Med* 2008; 33(5):449-60.
25. Neal JM, Bernards CM, Hadzic A et al. ASRA Practice Advisory on Neurologic Complications in Regional Anesthesia and Pain Medicine. *Reg Anesth Pain Med* 2008; 33(5):404-15.
26. American Society of Anesthesiologists (ASA). Statement on anesthetic care during interventional pain procedures for adults. Amended October 20, 2010. Available online at: <http://www.asahq.org/For-Healthcare->

Professionals/-/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Anesthetic%20Care%20During%20Interventional%20Pain%20Procedures.ashx. Last accessed February 6, 2012.

27. Mazze RI, Kallen B. Reproductive outcome after anesthesia and operation during pregnancy: a registry study of 5405 cases. *Am J Obstet Gynecol* 1989; 161(5):1178-85.
28. ACOG Committee Opinion Number 284, August 2003: Nonobstetric surgery in pregnancy. *Obstet Gynecol* 2003; 102(2):431.
29. Higuchi H, Adachi Y, Arimura S et al. Early pregnancy does not reduce the C(50) of Propofol for loss of consciousness. *Anesth Analg* 2001; 93(6):1565-9.
30. McDonnell NJ PM, Clavisi OM et al.; ANZCA Trials Group. Difficult and failed intubation in obstetric anaesthesia: an observational study of airway management and complications associated with general anaesthesia for caesarean section. *Int J Obstet Anesth* 2008; 17(4):292-7.
31. American Society of Anesthesiologists (ASA). Statement of the safe use of Propofol. Amended October 2009. Available online at: <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>. Last accessed February 6, 2012.
32. Lichtenstein DR, Jagannath S, Baron TH et al. Sedation and anesthesia in GI endoscopy. *Gastrointest Endosc* 2008; 68(5):815-26.

Administrative and Contractual Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Requests for prior authorization should include at minimum documentation of the specific risk factors that require monitored anesthesia care as opposed to moderate sedation for the safe performance of the planned procedure.

Benefits for FEP members may vary. Please consult the FEP Service Plan Brochure.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through a self-funded (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's plan documents or contact the customer service department.

Eligible Providers

Anesthesiologist (MD or DO)
Certified Registered Nurse Anesthetist (CRNA)

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Policy Implementation/Update information

07/2009	New Policy
02/2011	Clarifications to “when services may be covered”. Policy guidelines combined into “when services may be covered” section.
09/2012	Minor Format/Font changes. Pg 1- Document Precedence section added. Pg. 3-Change patients of extreme age younger than 12 yrs, now states younger than 19 years. Pg 5-language added by Dr. Borden -“Propofol for pediatric patients”. Pg. 6- references added. Pg 7- Audit Information section added. Medical/Clinical Coder reviewed-RLJ.
06/2014	Effective 9/1/2014. Adoption of language from BCBSA policy #7.02.01. Clarification on ASA-P3 status. Clearer definition of conscious sedation versus monitored anesthesia.

Billing/Coding Information

Click the links below for attachments, coding tables & instructions.

[Attachment I- CPT Coding Table & Instructions](#)

Approved by BCBSVT Medical Policy Committee: Date Approved

Robert Wheeler MD
Chief Medical Officer

ATTACHMENT I CPT Coding Table & Instructions

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met and Prior Approval is obtained.			
CPT	00740	Anesthesia for upper intestinal endoscopic procedures, endoscope introduced proximal to duodenum	Prior Approval Required
CPT	00810	Anesthesia for lower gastrointestinal endoscopic procedures, endoscope introduced distal to duodenum	Prior Approval Required