Name of Policy:  
Monitored Anesthesia Care (MAC)

Policy #: 470       Latest Review Date: February 2014
Category: Anesthesia       Policy Grade: A

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:**
Adequate sedation and analgesia are important parts of many diagnostic and therapeutic procedures. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient’s condition 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.

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 monitored anesthesia care (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 preprocedure visit, intraprocedural care and postprocedure 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.

Monitored anesthesia care may include varying levels of sedation, analgesia, and anxiolysis as necessary. The provider of monitored anesthesia care 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 four 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, monitored anesthesia care (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 present continuously to monitor the patient and provide anesthesia care. MAC may include varying levels of sedation, analgesia, and anxiolyis, including but not limited to moderate sedation. 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. Monitored anesthesia care includes all aspects of anesthesia care – a pre-procedure visit, intra-procedure care and post-procedure anesthesia management. During MAC, the anesthesia personnel provides or medically directs a number of specific services such as administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary.

Sedation and anesthesia services that are provided in outpatient settings should be provided 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, anxiolyis 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 used increasingly 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. It 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. The American Society of Anesthesiologists 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.

This policy only addresses anesthesia services for diagnostic or therapeutic procedures performed in the outpatient setting.

**Policy:**

**For dates of service prior to July 1, 2012, see policy #265—Use of Anesthesia Services for Routine Gastrointestinal Endoscopy**

**Effective for dates of services on or after July 1, 2012:**

These claims **must** include physical status modifiers *P1-P4.

Use of monitored anesthesia care meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for procedures, **including, but not limited to gastrointestinal endoscopy, bronchoscopy, interventional pain procedures**, when there is documentation by the proceduralist and/or anesthesiologist in the patient’s medical record that specific risk factors or significant medical conditions are present. Those risk factors or significant medical conditions include any of 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., > 70 years of age;
• Patients age 18 and under;
• Patients who are pregnant;
• 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, dysrhythmias, CHF, COPD
• *Class IV ASA patients (severe systemic disease that limits activity and is a constant threat to life), e.g.,
  o Myocardial infarction within last 6 months
  o Stroke within last 6 months
  o Unstable angina
  o Severe CHF
  o Severe COPD
  o Hepatic failure
  o Renal failure
  o Uncontrolled epilepsy

**Monitored anesthesia care meets** Blue Cross and Blue Shield of Alabama’s medical criteria for use with interventional pain procedures at the cervical or thoracic level (unless CPT indicates otherwise), involving the intercostal nerve, sphenopalatine ganglion, stellate ganglion, superior hypogastric plexus, celiac plexus, paravertebral facet (zygapophyseal) joint, and/or injection of a neurolytic agent.

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.

**Anesthesia Consultation**
The anesthesia consultation is considered part of the global procedure when performed on the day of or days before the procedure and does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage unless:

The anesthesiologist performs the consultation, but monitored anesthesia care is not performed and the consultation meets medical criteria for coverage. (See Policy #129 Consultations vs Referrals)

*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 does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage in patients at average risk related to use of anesthesia and sedation for:

- Gastrointestinal endoscopic procedures,
- Bronchoscopic procedures, or
- **Interventional pain procedures (including diagnostic, screening or trial blocks).

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 member’s 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.

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 (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 through January 22, 2014:

Location of the Procedure
The American Society of Anesthesiologists has recommended that any location providing monitored anesthesia care have the capability of cardiopulmonary resuscitation and monitoring equipment. In 2004, Fleisher et al 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 seven 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. In 2013, Whippey et al published a case-control study of risk factors for unanticipated hospitalization following an outpatient procedure. The authors retrospectively identified 20,657 outpatient procedures and randomly selected 200 patients with an unanticipated hospitalization. These case patients were compared with 200 randomly selected control patients without an unanticipated hospitalization. Predictors of unanticipated hospitalization included procedures lasting longer than one hour, high ASA physical status classification, older age, and higher BMI.

Use of Monitored Anesthesia Care in Endoscopy
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.

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.

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 III through 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.

Enestvedt et al retrospectively reviewed 1,318,495 patients who underwent 1,590,648 endoscopic procedures and found the risk for serious adverse events with endoscopy increased with higher ASA physical status classification, especially Class 3 to 5. These findings support
the use of ASA physical status class as a predictor of periendoscopic adverse events and as a useful tool for risk stratification.

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 recent Cochrane review by Singh et al. in 2008 summarized the results of 20 randomized clinical trials (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 with traditional sedatives for patients undergoing colonoscopy. The secondary objective was to synthesize the studies comparing propofol administration by anesthesiologists with 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 seven trials were published in only abstract format, including the largest trial from 2000 (n=7286 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, remifentanil or alfentanil). One trial published in 2003 included only a narcotic (remifentanil), 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 with 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 (seven 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 (ten 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 (nine studies; 736 patients) or complication rates. There was also no difference in pain control with
non-patient controlled sedation (five studies; 396 patients) between propofol and the control arm (OR=0.90; 95% CI, 0.58, 1.39).

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The Cochrane review found only one RCT, reported in abstract format, for the secondary objective, comparison of propofol administration by anesthesiologists (Group A) that by endoscopists (Group B). This RCT has subsequently been published by Poincloux et al. Ninety adult patients (from a university center in France) undergoing colonoscopy were randomized into the above two 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 the receipt of 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 III and IV 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 endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasound and small-bowel enteroscopy who received propofol. These procedures are notable for the duration and complexity of these procedures compared to diagnostic EGD. The primary outcome measure was airway modifications (AMs) with a comparison of defining characteristics of the group requiring at least one 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, male sex, and ASA class III 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 continue to meet the definition of monitored anesthesia care.

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 state 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, direct comparison groups is not available, nor are death rates for endoscopic procedures under monitored anesthesia care. However, the incidence of published adverse events appears to be low.

Agostoni et al evaluated a prospective database of 17,999 GI endoscopies performed under MAC during the period of October 2001 to December 2009. The authors identified six variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year OR=1.02 [95% 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 et al reported adverse respiratory events were strongly associated with higher BMI using multivariate regression models. (OR=1.08; p=0.0001). 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).

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 with 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 with 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, because 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 et al published an RCT comparing two doses of the sedative agent fospropofol in patients undergoing diagnostic bronchoscopy. The study was performed by pulmonologists without anesthesia supervision. Patients (n=252) were randomized to receive either 2mg/kg or 6.5mg/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 and updated these guidelines in 2013. 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. Sedation should be limited to a depth which permits verbal contact at all times. The preferred sedation agent is a benzodiazepine, intravenous midazolam.

Interventional Pain Management Procedures
In 2008, Bernards et al 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 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, the American Society of Anesthesiologist 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.

The October 2010, American Society of Anesthesia’s amended Statement on Anesthetic Care during Interventional Pain Procedures for Adults states:

It is the opinion of the Committee that the majority of minor pain procedures, under most routine circumstances, do not require anesthesia care other than local anesthesia. Such procedures include epidural steroid injections, epidural blood patch, trigger point injections, sacroiliac joint
injections, bursal injections, occipital nerve block, and facet injections. The use of general anesthesia for routine pain procedures is warranted only in unusual circumstances. The Committee recognizes that conditions may exist that make skilled anesthesia care necessary for procedures not normally requiring such care. Major co-morbidities and mental or psychological impediments to cooperation are examples of conditions dictating anesthesia care for even minor pain procedures in unusual patients. The use of sedation and anesthesia must be balanced with the potential risk of harm from doing pain procedures in a sedated patient, especially those undergoing cervical spine procedures.

Procedures that are prolonged and/or painful often require intravenous sedation and may warrant use of monitored anesthesia care (MAC). These include sympathetic blocks (stellate ganglion, celiac plexus, and lumbar paravertebral), radiofrequency ablation (R/F), discography, percutaneous discectomy, and trial spinal cord stimulator lead placement. Major nerve/plexus blocks are done less often in the chronic pain clinic but the Committee believes that these blocks may warrant the use of intravenous sedation and at times, MAC (e.g. brachial plexus block, sciatic nerve block, particularly continuous catheter techniques).

Other Procedures
Any procedure which may be complicated by patient characteristics noted in the policy statement may be appropriate for monitored anesthesia care.

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 1970’s and 1980’s, 5405 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 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 monitored anesthesia care when airway protection may become 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 monitored anesthesia care can be considered medically necessary for procedures performed during pregnancy.

Summary
MAC 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 supporting 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) and overall satisfaction scores. Pain control and incidence of respiratory depression appear to be similar. The use of monitored anesthesia care may be considered medically necessary in specific cases of high risk as indicated in the policy statement.

Technology Assessments, 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 esophagastroduodenoscopy [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 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.
**Key Words:**
Conscious sedation, moderate sedation, deep sedation, propofol, Diprivan®, monitored
Anesthesia care, MAC

**Approved by Governing Bodies:**
Multiple agents are FDA approved for conscious/moderate sedation

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Coding:**
CPT Codes:
- 00520 Anesthesia for closed chest procedures; (including bronchoscopy) not otherwise specified
- 00740 Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum
- 00810 Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum
- 01991 Anesthesia for diagnostic or therapeutic nerve blocks and injections (when block or injection is performed by a different provider); other than the prone position
- 01992 prone position

Modifiers:
- 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

**References:**

**Policy History:**
Medical Policy Panel, January 2011
Medical Policy Group, February 2011 (2)
Medical Policy Group, October 2011 (2)
Medical Policy Administration Committee, November 2011
Available for comment November 11, 2011 through March 1, 2012
Medical Policy Group, March 2012 (2): Update policy re: use of MAC for patients ages 18 and less and use with interventional pain procedures at the cervical or thoracic level (unless CPT indicates otherwise), involving the intercostal nerve, sphenopalatine ganglion, stellate ganglion, superior hypogastric plexus, celiac plexus, paravertebral facet (zygapophyseal) joint, and/or injection of a neurolytic agent, coverage for anesthesia consultations, Key Points, Approved by Governing Agencies, References
Medical Policy Administration Committee, April 2012
Medical Policy Administration Committee, May 2012
Medical Policy Panel, February 2014
Medical Policy Group, February 2014 (3): 2014 Updates to Key Points & References; Policy Statement updated to include bullet “patients who are pregnant” under risk factors or significant medical conditions noted in coverage criteria – no change in effective date

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.