The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required; the physician performing the diagnostic or therapeutic procedure must submit supporting documentation to Utilization Management. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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 Protocol 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. (1) 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 four levels of sedation/analgesia as follows (2):

- **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 ASA’s 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.

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 et al 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 has been proposed that contribute to this increased use of anesthesia services including patient and physician preferences, clinical need, regulatory requirements, and financial considerations. (6)

**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 sedation of intubated, mechanically ventilated patients (adults only). It is also approved for induction of general anesthesia in patients three years of age and older and maintenance of general anesthesia in patients two months of age and older.

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

**Related Protocol**

Manipulation under Anesthesia

**Policy (Formerly Corporate Medical Guideline)**

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)

*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 Guideline**

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. (7) 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 I - 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are
considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


33. Local Coverage Determination (LCD): Pain Management (L28529), Revision Effective Date for services performed on or after 10/25/2013.