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

Corporate Medical Policy

File Name: Monitored Anesthesia Care (MAC) during Gastrointestinal Endoscopy Bronchoscopy, or Interventional Pain Procedures in Outpatient Settings
File Code: UM.ANES.01
Origination: 07/2009
Last Review: 11/2017
Next Review: 11/2018
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Description/Summary

Monitored anesthesia care (MAC) refers to a set of physician services, not a particular level of sedation. The services include the ability to convert a patient to general anesthesia if needed and to intervene in the event that a patient’s airway becomes compromised. 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 clinical indications and risk factors that might necessitate the presence of dedicated anesthesia providers during procedures performed in a properly equipped and staffed outpatient setting.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I- CPT® Coding Table & Instructions

When a service may be considered medically necessary

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

When a service is considered not medically necessary

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 or strictures post-abdominal surgery or as a result of medical disease
• endoscopic retrograde cholangiopancreatography
• esophageal ultrasound
• history of removal of numerous large (>=10mm in diameter) polyps
• stent placement in the upper GI tract
• 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 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.

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).

Background

MAC is a spectrum of anesthesia services defined by the type of anesthesia personnel present during a procedure, not specifically by 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 preprocedure visit, intraprocedure 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.

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.

MAC refers to a particular type of physician service, and not to the level of anesthesia provided. MAC often involves the provision of sedatives and/or analgesics to induce moderate sedation but may also involve the use of sedatives, hypnotics, analgesics, and anesthetic drugs which are commonly used for the induction and maintenance of general anesthesia.

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.

Multiple diagnostic and therapeutic procedures performed in the outpatient setting, including endoscopy, colonoscopy, bronchoscopy, and interventional pain management procedures, rely on some degree of sedation for anxiolysis and pain control. Regardless of sedation depth, 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 frequently administered under the supervision of the proceduralist.

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.

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 used 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 adverse effects and safety when used by nonanesthesiologists. 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 nonanesthesiologists, stating that personnel must be prepared to respond to deep sedation and loss of airway protection should these complications inadvertently occur during sedation.

**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 and older.

There are multiple other FDA-approved medications for pain relief, anxiolysis, and sedation that may be used in outpatient sedation.

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.

**Rationale**

This policy is updated regularly with searches of the MEDLINE database. The most recent literature review was through September 14, 2017.

**SUMMARY OF EVIDENCE**

For individuals who have planned endoscopy and certain risk factors or significant medical conditions who receive MAC, the evidence includes systematic reviews, a randomized controlled trial (RCT), and observational studies. Relevant outcomes are overall survival, morbid events, hospitalizations, and treatment-related mortality and morbidity. A literature review for the American Gastroenterological Association Institute identified potential indications requiring an anesthesia specialist. However, the evidence from RCTs is sparse. The single RCT comparing propofol administration by anesthesiologists for purpose of anesthesia with propofol administered by nonanesthesiologists for sedation during colonoscopy reported that patients receiving propofol from anesthesiologists indicated greater willingness to undergo further colonoscopies under the same conditions. This trial did not show any differences in procedure time or patient satisfaction and reported a higher rate of hypoxia in patients treated by anesthesiologists with propofol. However, this trial may have been underpowered to detect differences in complication rates. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have planned bronchoscopy and certain risk factors or significant medical
conditions who receive MAC, the evidence includes no studies that directly address this issue. Relevant outcomes are overall survival, morbid events, hospitalizations, treatment-related mortality and morbidity. There is a lack of published evidence on MAC for bronchoscopy procedures; no RCTs, nonrandomized comparative studies, or large case series were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have planned interventional pain management procedures and certain risk factors or significant medical conditions who receive MAC, the evidence includes no studies that directly address this issue. Relevant outcomes are overall survival, morbid events, hospitalizations, treatment-related mortality and morbidity. There is a lack of published evidence on MAC for interventional pain management procedures; no RCTs, nonrandomized comparative studies, or large case series were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

National guidelines (eg, from the American Society of Anesthesiologists) support the use of MAC for patients undergoing outpatient procedures who have certain risk factors or significant medical conditions. Therefore, MAC is considered medically necessary in these situations.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Society of Anesthesiologists
In 2016, ASA updated its statement on anesthetic care during interventional pain procedures. ASA indicated that:

“Many patients can undergo interventional pain procedures without the need for supplemental sedation in addition to local anesthesia. For most patients who require supplemental sedation, the physician performing the interventional pain procedure(s) can provide moderate (conscious) sedation as part of the procedure. For a limited number of patients a second provider may be required to manage moderate or deep sedation or, in selected cases other anesthesia services....

Significant anxiety may be an indication for moderate (conscious) sedation or anesthesia services. In addition, procedures that require the patient to remain motionless for a prolonged period of time and/or remain in a painful position may require sedation or anesthesia services. Examples of such procedures include but are not limited to sympathetic blocks (celiac plexus, paravertebral and hypogastric), chemical or radiofrequency ablation, percutaneous discectomy, trial spinal cord stimulator lead placement, permanent spinal cord stimulator generator and lead implantation, and intrathecal pump implantation. Major nerve/plexus blocks are performed less often in the chronic pain clinic, but the Committee believes that these blocks may more commonly require moderate (conscious) sedation or anesthesia services (e.g., brachial plexus block, sciatic nerve block, and continuous catheter techniques).”

American Society for Gastrointestinal Endoscopy
Guidelines on sedation during gastrointestinal endoscopy were released in 2008 by the American Society for Gastrointestinal Endoscopy (ASGE). The guidelines stated that determining the level of sedation is dependent on both the degree of invasiveness of the procedure as well as patient characteristics such as age, health status, concurrent medications, anxiety, and pain tolerance. The guidelines made the following recommendations for the use of propofol during endoscopies:

- “A sedation team with appropriate education and training [including] at least 1 person … qualified in advanced life support skills….
- Trained personnel [for] uninterrupted monitoring of patient’s clinical and physiologic parameters….
- Physiologic monitoring must include pulse oximetry, electrocardiography, and intermittent blood pressure measurement. Monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function. Capnography should be considered because it may decrease the risks during deep sedation…
- Personnel should have the ability to rescue a patient who becomes unresponsive or unable to protect his or her airway or who loses spontaneous respiratory or cardiovascular function.
- Age-appropriate equipment for airway management and resuscitation must be immediately available.
- A physician should be present throughout propofol sedation and remain immediately available until the patient meets discharge criteria.”

In 2013, ASGE published guidelines for endoscopic modification for geriatric patients. Specific to this Policy, ASGE recommended “standard monitoring procedures in the elderly during moderate sedation with heightened awareness of this population’s increased response to sedatives.”

In 2014, ASGE issued guidelines on the safety of the endoscopy unit that made several recommendations on procedural sedation:

“Staff Recommendations for intra-procedure care based on level of sedation

- No sedation - One assistant … other than the physician performing the procedure should be present to assist with the technical aspects of the procedure.
- Moderate sedation (also known as conscious sedation) - Sedation should be directed by a physician who is credentialed and privileged to do so and can be administered by an RN. During the period in which the patient is sedated, the RN must monitor the patient for vital sign changes, hypoxemia and comfort. The RN may assist with minor, interruptible tasks. In the event that more intense technical assistance is required, a second assistant (RN, LPN, or UAP [unlicensed assistive personnel]) should be available to join the care team for the technical aspects of the procedure.
- Deep sedation - Most institutions require that deep sedation be administered by an anesthesia professional such as an anesthesiologist, Certified Registered Nurse Anesthetist (CRNA), or Anesthesiologist Assistant who is credentialed and privileged to
do so. In this situation, the anesthesia provider should be responsible for administering sedation and monitoring the patient. A second staff person (RN, LPN, or UAP) is required to assist with technical aspects of the procedure.”

“Recommendations for Patient Monitoring

- All patients undergoing endoscopy should be monitored, the frequency of which depends on procedural and patient factors (e.g., type of sedation, duration and complexity of procedure, patient condition). At a minimum, monitoring should be performed before the procedure, after administration of sedatives, at regular intervals during the procedure, during initial recovery, and just before discharge.
- Units should have procedures in place to rescue patients who are sedated deeper than intended.
- When the target level is moderate sedation (also known as conscious sedation):
  - The individual assigned responsibility for patient monitoring may perform brief, interruptible tasks.
  - Minimal monitoring requirements include electronic assessment of blood pressure, respiratory rate, heart rate, and pulse oximetry combined with visual monitoring of the patient's level of consciousness and discomfort.
  - Currently, there are inadequate data to support the routine or required use of capnography during endoscopic procedures in adults when moderate sedation is the target.
- When deep sedation is targeted:
  - The individual responsible for patient monitoring must be dedicated solely to that task and may not perform any other function during the procedure.
  - The use of capnography in EUS [endoscopic ultrasound], ERCP [endoscopic retrograde cholangiopancreatography], and colonoscopy to assess the adequacy of ventilation may reduce the incidence of hypoxemia and apnea, but its impact on the frequency of other sedation-related adverse events such as bradycardia and hypotension is unknown. As such, capnography may be considered for the performance of endoscopy under deep sedation. However, there is no safety data to date to support the universal use of capnography in such cases.
  - Documentation of the clinical assessments and monitoring data during sedation and recovery is required.”

In 2015, ASGE published quality indicators for all GI endoscopic procedures. Specific to this
policy. ASGE stated: “Individuals administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those administering deep sedation should be able to rescue patients who enter a state of general anesthesia.”

In 2009, ASGE with the American Association for the Study of Liver Diseases, American College of Gastroenterology, and American Gastroenterological Association, jointly issued a position statement on nonanesthesiologist administration of propofol (NAAP) for gastrointestinal (GI) endoscopy. The societies found that NAAP was as safe and effective as anesthesiologist-administered propofol. They asserted that proper training and proper patient selection were necessary for the safe practice of NAAP sedation.

References


Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and
revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

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.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for services as outlined in Attachment I. 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.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

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 an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

07/2009  New Policy
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<tr>
<td>02/2011</td>
<td>Clarifications to “when services may be covered”. Policy guidelines combined into “when services may be covered” section.</td>
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<td>09/2012</td>
<td>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.</td>
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<td>06/2014</td>
<td>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.</td>
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<td>08/2015</td>
<td>No language update. Added CPT 00520 for clarification only, does not require PA. Added CPTs: 00635, 01935 &amp; 01936, 01991 &amp; 01992- requires PA.</td>
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<tr>
<td>08/2016</td>
<td>Updates language per updated BCBSA policy</td>
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<tr>
<td>11/2017</td>
<td>Updated description language, updated medical criteria, updated references, and minor formatting changes. Coding reviewed and no changes to current policy statement.</td>
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<td>01/2018</td>
<td>2018 Adaptive Maintenance Effective 01/01/2018: Deleted codes 00740 &amp; 00810 effective 01/01/2018. New codes will require PA 00731, 00732, 00811, 00812, 00813.</td>
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**Eligible Providers**

Qualified healthcare professionals practicing within the scope of their license(s)

**Approved by BCBSVT Medical Directors**

Gabrielle Bercy-Roberson, MD, MPH, MBA
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

**Attachment I**

CPT Coding Table & Instructions
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<th>Code</th>
<th>Description</th>
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The following code is considered Informational and is not reimbursable.

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