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Corporate Medical Policy

Monitored Anesthesia Care (MAC) during Gastrointestinal Endoscopy

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Document Precedence

BCBSVT Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with all terms, conditions and limitations of the subscriber contract. Benefit determinations are based in all cases on the applicable contract language. To the extent that there may be any conflict between Medical Policy and contract language, the contract language takes precedence.

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.

Moderate (conscious) sedation is generally used for both diagnostic and uncomplicated therapeutic endoscopic procedures. Moderate sedation involves the administration of medication with or without analgesia to achieve a state of depressed consciousness while maintaining the patient's ability to respond to stimulation. It includes pre- and post-sedation evaluations, administration of sedation, and monitoring of the cardiorespiratory functions (heart rate, blood pressure, and oxygen level.) Moderate sedation is commonly performed using diazepines with or without narcotic agents. For routine endoscopic procedures and screenings among patients without risk factors or significant medical conditions, moderate sedation is considered a sufficient level of sedation.

Monitored anesthesia care (MAC) is directly provided by anesthesia personnel. MAC may include varying levels of sedation, analgesia, and anxiolysis. (If the patient loses consciousness and the ability to respond purposefully, the anesthesia care becomes general anesthesia.) Based on the American Society of Anesthesiologists' (ASA) standard for monitoring, MAC should be provided by qualified anesthesia personnel who must be present continuously to monitor the patient and provide anesthesia care.

Monitored anesthesia care includes all aspects of anesthesia care – a pre-procedure visit, intra-procedure care and post-procedure anesthesia management. During MAC, the anesthesiology personnel provides or medically directs a number of specific services such as administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary.

Propofol is an agent that has been used increasingly to provide monitored anesthesia care for endoscopic 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. In many practice situations, it is common for propofol to be administered by anesthesiologists, whereas moderate sedation using diazepines with or without narcotics is usually administered by or under the supervision of the endoscopist. Propofol (marketed as Diprivan® or as generic products) was first approved by the U.S. Food and Drug Administration (FDA) in the late 1980s. 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 endoscopic procedures.

Policy

Benefits are subject to all terms, limitations and conditions of the subscriber contract.

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

New England Health Plan requires a referral authorization for all outpatient surgery.

FEP members may have different benefits. For further information contact FEP Customer Service.

When service or procedure is covered

In accordance with national standards, conscious sedation is an included component of gastrointestinal endoscopic procedures. Use of monitored anesthesia care instead of conscious sedation may be considered medically necessary for gastrointestinal endoscopic procedures when there is documentation by the endoscopist and anesthesiologist that specific risk factors or significant medical conditions are present. Those risk factors or significant medical conditions are as follows:

- Increased risk for complications due to severe comorbidity (ASA P3* or greater);
- Morbid obesity (BMI > 30);
- Severe sleep apnea (oxygen and bi-pap required during sleep);

- 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 of extreme age, i.e., younger than age 19 or age 70 years or older;
- Patients who are pregnant;
- Patients with increased risk for airway obstruction due to anatomic variation, such as:
    - History of sleep apnea or stridor
    - Dysmorphic facial features
    - Oral abnormalities (e.g., macroglossia)
    - Neck abnormalities (e.g., neck mass)
    - Jaw abnormalities (e.g., micrognathia)
- Acutely agitated, uncooperative patients

When service or procedure may not be covered

Use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopic procedures in patients at average risk related to use of anesthesia and sedation that are undergoing gastrointestinal endoscopic procedures, including endoscopic procedures used in screening.

Information required

Clinical summary including at minimum the specific risk factors that require monitored anesthesia care as opposed to moderate sedation for the safe performance of the planned procedure.

Rationale

An extensive review of the literature related to sedation for gastrointestinal (GI) endoscopy was published through the American Gastroenterological Association (AGA) Institute in 2007. (1) 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 IV and 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.

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 2009 (2) summarized the results of 20 randomized clinical trials 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, (3) 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 regimens used in the propofol and comparison groups in these studies varied. In the different clinical trials, propofol has been used alone, in combination with other agents, and in patient-controlled sedation systems. In a few of the studies, it was intended that propofol be used to induce deep sedation. The comparison groups received either benzodiazepines alone or a combination of a benzodiazepine and narcotic, and all patients in these comparison arms were sedated to a level of moderate sedation.

Although 20 randomized clinical trials were identified, studies examined different outcomes, so that for any given outcome, a smaller number of studies contributed to the findings. The outcomes noted in the Cochrane review were:

Recovery time
In three studies in which propofol was used as a single agent, the pooled difference in recovery time was 14.7 minutes shorter for the propofol arms. In six studies in which propofol was used in combination with other agents, patients sedated with propofol had a mean shorter recovery time of 17.9 minutes. In four studies in which propofol was used with patient-controlled sedation (PCS), average recovery time was 24.9 minutes shorter. Overall, after excluding studies that could not be pooled, studies with patient-controlled analgesia, and an outlier study, recovery time with propofol was 14.2 minutes shorter.

Discharge time
Combining 7 studies (n =542) that reported discharge time, the discharge time was shorter for propofol by an average of 20.9 minutes.

Procedure duration
When pooling all 9 studies that reported this outcome, there was no significant difference between propofol and the comparator (average difference of 0.9 minutes). An additional analysis pooling 7 studies that examined measures of procedure success (i.e., intubating the cecum) found no difference in the procedure completion rate.

Patient satisfaction
In 7 studies in which patient satisfaction was reported, a higher proportion of patients were satisfied with propofol (odds ratio [OR] for dissatisfaction 0.35, statistically significant). The odds ratio metric does not adequately reveal the absolute difference in satisfaction between propofol and the alternative used in the studies, but being dissatisfied was a generally low frequency event. The review by McQuaid and Laine

report this outcome as an absolute difference in satisfaction, and they report an absolute difference of 10% in their meta-analysis of 2 studies.

Pain control
In pooling nine studies that reported pain control, there was better pain control with traditional agents than with propofol (OR 1.71, statistically significant), but there was significant heterogeneity in the results. When the propofol studies were stratified by whether PCS was used or not, there was no difference between propofol and traditional agents without PCS, but propofol with PCS was inferior to traditional agents (OR 3.09, statistically significant).

Hypoxia, apnea, arrhythmias, hypotension
In all pooled analyses of these various outcomes, there was no difference between the propofol arms and the traditional agents.

In summary, the principal differences between propofol and the traditional agents used in these clinical trials 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.

Propofol for Pediatric Patients
Propofol is a substituted phenol derivative, metabolized rapidly in the liver to water soluble compounds, which are excreted by the kidneys. After single-bolus injection, blood levels rapidly decrease due to redistribution and elimination. The initial distribution half life is 2-8 minutes, and its elimination half life varies from 1 to 3 hours. The time to peak effect is 90-100 seconds after a dose of 2.5 mg per kilogram. A dose of 2-3 mg per kilogram is needed for induction of General Anesthesia in children and an infusion of 50-150 microgram per kilogram per minute for maintenance, in combination with an opioid or Nitrous Oxide (4).

A review of anesthesia and sedation in pediatric gastrointestinal endoscopic procedures found that the use of IV sedation in children undergoing GI endoscopy may be considered safe (4). Propofol and remifentanil is recommended for sedation of children in a hospital setting in the presence of an anesthesiologist (5). Propofol is associated with a reduction of emergence agitation in children (6).When compared to midazolam for sedation; propofol provides equal or better control and more rapid recovery (7). In a study of fifty pediatric patients undergoing elective GI endoscopy, 52% of patients receiving inhalational anesthesia showed restlessness and agitation, compared to 8% in the propofol group (p=0.001) (8). Adverse events during monitored anesthesia are uncommon. A study of 17,999 procedures in a university hospital over 8 years showed that adverse events were more uncommon in children (2.6%) than adults (4.5%), and that only bradycardia (2.1%) and hypotension (0.44%) occurred in children (9).

Guidelines and Position Statements
Recent guidelines regarding sedation during endoscopy were released by the American Society for Gastrointestinal Endoscopy (ASGE). (10) 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 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. The Cochrane review included 1 randomized clinical trial, reported in abstract form only, comparing administration of propofol by anesthesiologists compared to non-anesthesiologists. The review reports that the study showed no difference in procedure time or patient satisfaction in this small study of 94 patients.

References:

1. Cohen LB, Delegge MH, Aisenberg J et al. AGA Institute review of endoscopic sedation. Gastroenterology 2007; 133(2):674-701.

2. Singh H, Poluha W, Cheung M et al. Propofol for sedation during colonoscopy. Cochrane Database Syst Rev 2008; (4):CD006268.

3. 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.

4. Abdul Q Dar, Zahoor A Shah, Anesthesia and sedation in pediatric gastrointestinal endoscopic procedures. A Review. World J Gastrointestinal Endosc 2010, July 16; 2(7):257-262

5. Abu-Shahwan I, Mack, D. Propofol and remifentanil for deep sedation in children undergoing gastrointestinal endoscopy. Paediatr Anaesth. 2007; 17:460-463.

6. Key KL, Rich C, DeCristofaro C, Collins S. Use of propofol and emergence agitation in children: a literature review. AANA J. 2010 Dec; 468-473.

7. O'Hare, RA, Mirakhur RK, Reid JE, Breslin DS, Hayes A. Recovery from, propofol anesthesia supplemented by remifentanil. Br J Anaesth2001; 86:361-365.

8. Kaddu R, Bhattacharya D, Metriyakool K, Thomas R, Tolia V. Gastrointestinal Endosc 2002 Jan; 55(1):27-32.

9. Agostoni M, Fanti L, Gemma M, Pasculli N, Beretta L, Testoni PA. Adverse Events during monitored anesthesia care for GI endoscopy: an 8-year experience. Gastrointestinal Endosc 2011 Aug74 (2):266-275.

10. Lichtenstein DR, Jagannath S, Baron TH et al.; Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy. Sedation and anesthesia in GI endoscopy. Gastrointestinal Endosc 2008; 68(5):815-26.

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.

Billing/Coding Information

See Attachment I.

Approved by BCBSVT Medical Policy Committee: Date Approved

Spencer Borden MD
Chair, Medical Policy Committee

Robert Wheeler MD
Chief Medical Officer

ATTACHMENT I
Coding Table & Instructions

Code Type	Number	Brief 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