Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures

Policy Number: 0008
Effective Date: August 1, 2015
Reviewed Date: May 2024
Next Review: May 2025
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BACKGROUND

CLINICAL BACKGROUND *(extracted from KP MTAT 2010)*

Usual Care for Sedation During Colonoscopy and Routine Upper Endoscopy Procedures
Traditional sedation for routine colonoscopy and upper endoscopy procedures, including esophagogastroduodenoscopy (EGD), has involved a benzodiazepine with or without an opioid. These agents have known antidotes and are usually administered by a registered nurse (RN) under the supervision of an endoscopist.

Administration of Propofol (Source: verbatim from Singh et al., 2008; Vargo et al., 2009)
In recent years propofol (2, 6-di-isopropylphenol) has increasingly been utilized as an alternative method of sedation in endoscopy suites. Propofol was initially introduced in 1989 and has since then been widely used in critical care units and emergency departments for providing sedation. Although propofol is associated with a more rapid onset of action, its use for sedation during endoscopy by non-anesthesiologists in many parts of the world (particularly North America) has been limited by concerns of potential side-effects. This agent has also been administered by anesthesiologists and certified registered nurse anesthetists (CRNAs) within KP SCAL for endoscopy procedures. Emergency medicine physicians also appear to be privileged for at least select medical centers for GI procedures. Unlike other standard sedation agents, propofol does not have an antidote/reversal agent.

There are several key terms and definitions related to methods for the administration of propofol. Several terms and definitions were summarized recently in a position statement from the American Gastroenterological Association (AGA) (Vargo et al., 2009):

Monitored Anesthesia Care (MAC): Monitored anesthesia care (MAC) is the service provided by an anesthesia specialist to the patient undergoing a diagnostic or therapeutic procedure. In many instances, although not all, MAC results in deep sedation, and the normal airway protective reflexes may be lost. MAC can include general anesthesia with endotracheal intubation.

Standard Sedation: Standard sedation refers to the administration of intravenous drugs, usually a benzodiazepine and an opioid, under the supervision of an endoscopist. A level of moderate sedation is usually targeted.

Nonanesthesiologist-administered propofol (NAAP) Administration of propofol under the direction of a physician who has not be trained as an anesthesiologist. Propofol may be used either alone or in combination with 1 or more additional agents. A level of moderate-to-deep sedation is targeted with NAAP.

Nurse-administered propofol sedation (NAPS) Describes the administration of propofol as a single agent under the direction of a physician who has not been trained as an anesthesiologist. A level of deep sedation is targeted with NAPS.

Balanced propofol sedation (BPS) (Source: Vargo et al., 2009) Administration of the combination of a benzodiazepine, and opioid, and propofol under the direction of a physician who is not an

anesthesiologist. The opioid and benzodiazepine are each given as a single dose, which is followed by small incremental doses of propofol administered to achieve a target level of moderate sedation.

Another potential method for administering propofol involves computer assistance.

Computer Assisted Propofol Administration (CAPS) The SEDASYS (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) system is a computer-assisted personalized sedation that integrates a suite of patient monitors (pulse oximetry, capnometry, EKG, noninvasive blood pressure (NIBP), and patient responsiveness) with oxygen and computer-controlled propofol delivery. Details on the published evidence on computer-assisted personalized sedation (CAPS) can be found in a SCPMG Technology Assessment and Guidelines Unit (TAG) assessment from February 2009.

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an NCD or LCD, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures" for medical necessity determinations. Use the criteria below.

Monitored anesthesia care (MAC) is considered medically necessary during gastrointestinal endoscopic procedures when there is documentation by the operating physician and/or the anesthesiologist that demonstrates any of the following higher risk situations exist:

A. Prolonged or therapeutic endoscopic procedure requiring deep sedation; OR
B. A history of or anticipated intolerance to standard sedatives; OR
C. Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists ASA class III physical status or greater; OR
D. Age 30 years or younger; OR
E. Pregnancy; OR
F. History of/or active drug or alcohol abuse; OR
G. Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); OR
H. Anxiety, defined as a history of excessive nervousness or worry that is difficult to control, causes significant distress and impairment or ICD-10 diagnosis of nervousness or anxiety/anxiety disorder; OR
I. Post-traumatic stress disorder (PTSD); OR
J. History of sexual abuse; OR
K. Hearing impairment; OR
L. Spasticity or movement disorder complicating procedure; OR
M. Increased risk for airway obstruction due to anatomic variant including ANY of the following:
    a. Documented history of previous problems with anesthesia or sedation; OR
    b. History of stridor or severe sleep apnea requiring oxygen and BIPAP; OR
    c. Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy 21; OR
    d. Presence of oral abnormalities including but not limited to a small oral opening (less than 3 cm in an adult), high arched palate, macroglossia, tonsillar hypertrophy, or a non-visible uvula (not visible when tongue is protruded with patient in sitting position, e.g., Mallampati class greater than II), as documented by anesthesia; OR

e. Neck abnormalities including but not limited to short neck, obesity involving the neck and facial structures, limited neck extension, decreased hyoid-mental distance (less than 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis as documented by anesthesia; OR
f. Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by anesthesia.

GENERAL CLINICAL INFORMATION

1. Prolonged or therapeutic endoscopic procedures requiring deep sedation include:
    a. Endoscopic ultrasound (EUS)
    b. Double balloon enteroscopy (push endoscopy)
    c. Transanal endoscopic microsurgery (TEM)
    d. Endoscopic retrograde cholangio-pancreatography (ECRP)
2. History of or anticipated intolerance to standard sedatives includes:
    a. Patient has allergy to opiates or benzodiazepines
    b. Patient on chronic narcotics and/or benzodiazepines (e.g., using these medications consistently most days in a week, long term)
    c. Patient has an unstable neuropsychiatric disorder which would prevent cooperation
3. ASA class III physical status definition: A patient with severe systemic disease. Adult examples include, but are not limited to:
    a. Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
4. History of/or active drug abuse:
    a. Heavy Marijuana use: Daily use
    b. Alcohol abuse:
        i. National Institute on Alcohol Abuse and Alcoholism (NIAAA) definition for heavy alcohol use: For men, consuming more than 4 drinks on any day or more than 14 drinks per week. For women, consuming more than 3 drinks on any day or more than 7 drinks per week.

Special Group Considerations

These criteria apply to OR/WA Commercial members.

These criteria apply to Medicare.

RATIONALE

EVIDENCE BASIS

A 2010 Kaiser Permanente review of monitored anesthesia care for gastrointestinal disorders reported findings from systematic reviews, meta-analyses, randomized controlled trials, and published internal data (KP MTAT 2010). Their findings included the following:

“There is good evidence of improved patient satisfaction and reductions in discharge and recovery times with propofol used alone or in combination with other agents compared to standard sedation for colonoscopy exams. There is fair evidence from a KP SCAL-based comparative study of improved cecal intubation rates with propofol used as a single agent for sedation during colonoscopy. The evidence is of insufficient quantity or quality to draw definitive conclusions on differences in polyp detection. There is less comparative data on EGD procedures, but some evidence of improved recovery and patient satisfaction with propofol sedation. The evidence is of insufficient quantity and/or quality to draw definitive conclusions on comparative risk of serious adverse events, including death, neurologic injury, endotracheal intubations, bleeding, and colonic perforations during these procedures. There does not

appear to be a significant difference in the risk of cardiopulmonary and respiratory events with propofol compared to standard sedation and no evidence of greater risk for serious adverse events for either colonoscopy or EGD procedures in lower risk patients (ASA I or II).

Following the review of one systematic review and two comparative observational studies, the evidence is of insufficient quantity and quality to draw definitive conclusions on the safety of anesthesiologist- versus non anesthesiologist-directed or administered propofol sedation in GI endoscopy. Controlled prospective studies with standardized protocols, patient selection, and reporting are needed.

Serious Adverse Events: The best available comparative evidence from the United States is a large observational registry study that suggests comparable rates of serious adverse events for anesthesiologist-directed propofol under monitored anesthesia care and gastroenterologist-administered propofol during colonoscopy procedures (0.16% and 0.14%) but a significantly increase risk of serious adverse events with gastroenterologist-administered propofol for upper endoscopy procedures, including EGDs (0.16% vs 0.5%). However, it is likely that these events differentially occurred in higher risk patients (ASAI III) who were also included in the study. Overall Cardiopulmonary Adverse Events. There is evidence from the same study of a significant increased risk of overall cardiopulmonary events with endoscopic-administered propofol in ASA I or II patients undergoing colonoscopy and upper endoscopy. The majority of the cardiopulmonary events are most likely to be of minor clinical consequence, but the challenge remains to identify which cardiopulmonary events are more likely to result in serious adverse events and what risk factors are specific to upper versus lower endoscopy procedures.

The evidence is of insufficient quantity and quality to draw conclusions on the safety of RN-administered propofol as compared to standard sedation for colonoscopy and EGD in ASA I and II patients. Based on a review of several systematic reviews and randomized controlled trials, there is no evidence of a significant increase in risk of adverse events with propofol compared to standard sedation and the risks appear to be comparable. However, these studies were not adequately sampled to detect or compare rates of serious adverse events. Comparative data from large and well-designed observational studies is needed. The existing series of RN-administered propofol are large and report low rates of adverse events."

A 2020 Kaiser Permanente evidence scan for more recent evidence on monitored anesthesia care for gastrointestinal disorders includes the following findings:

A 2018 systematic review (k=5 studies) of trials and observational studies compares patient safety and procedure quality outcomes following non-anesthesiologist-administered propofol vs. anesthesiologist-administered propofol in routine upper or lower gastrointestinal endoscopy and reports no significant differences in rates of airway intervention, hypotension, gastrointestinal bleeding between groups. Rates of bradycardia and cardiopulmonary events were substantially higher in patients who received non-anesthesiologist administered propofol, however. Studies included in this review primarily included patients meeting ASA class I or II criteria, and where patients meeting ASA class III-IV were included, proportions were not balanced between groups. (Daza et al., 2018)

A 2017 systematic review (k=27 studies; n=2,518 patients) evaluating sedation-related adverse events associated with the use of propofol vs. nonpropofol (i.e., midazolam, meperidine, pethidine, remifentanil, and/or fentanyl) for endoscopic procedures reports no significant differences in pooled odds ratios for rates of hypoxia, hypotension, or arrhythmia by sedation type. An analysis of studies of nonadvanced endoscopy procedures indicates that patients who received propofol were 39% less likely to develop any complications compared to those receiving non-propofol sedation (OR: 0.61; 95% CI: 0.38-0.99). No difference in the complication rate for advanced endoscopy procedures was found between sedation groups. A subgroup analysis comparing complication rates by sedation administration (non-gastroenterologist vs. gastroenterologist) showed no differences in rates of cardiopulmonary complications. (Wadhwa et. al, 2017) A 2019 meta-analysis comparing sedation with propofol to traditional sedatives with or without propofol during endoscopic procedures (k=23 trials; n=3,854) reports no statistical difference in rates of hypotension, oxygen desaturation, and post-procedure anesthetic recovery when propofol is used alone or in combination with benzodiazepines and/or opioids. This review reports greater patient satisfaction among patients who were sedated with benzodiazepines and/or

opioids compared to those sedated with propofol alone. This review did not include studies with participants groups with specific comorbidities, including obesity, cardiovascular disease, and pulmonary diseases. (Delgado et al., 2019)

CODES

CPT or HCPCS Code	Description
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum

ICD-10 Code	Description
	All diagnoses

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