Anesthesia Services for Gastrointestinal (GI) Endoscopy Procedures

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DESCRIPTION

Note: This medical policy only addresses the identified anesthesia services during gastrointestinal endoscopic outpatient procedures.

Adequate sedation and analgesia are important parts of many diagnostic and therapeutic procedures. Anesthesia services include all services associated with the administration and monitoring of analgesia/anesthesia to an individual in order to produce partial or complete loss of sensation. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient's condition and the procedure being performed. Examples of various methods of anesthesia include moderate sedation, monitored anesthesia care, regional anesthesia, and general anesthesia.

Moderate (conscious) sedation is generally used for both diagnostic and uncomplicated therapeutic 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 cardiorespiratory functions. Moderate sedation is commonly performed using diazepines with or without narcotics. For routine endoscopic procedures and screenings among individuals without risk factors or significant medical conditions, moderate sedation is considered a sufficient level of sedation. The class of drugs used for conscious sedation are designed to provide for sedation, hypnosis-like compliance, relieve anxiety, muscle relaxation, and anticonvulsant activity. The "side effect" that medical professionals most like about these drugs is that they generally induce anterograde amnesia (prevent memory by blocking the acquisition and encoding of new information). In other words, medical professionals like these drugs because most people will not remember what happens to them while under their effect even though they are "awake." Not all drugs used for conscious sedation have amnesic effects.

Monitored Anesthesia Care

Monitored anesthesia care (MAC) is a set of anesthesia services defined by the type of anesthesia personnel present during a procedure, not specifically by the level of anesthesia needed. The services include the ability to convert a patient to general anesthesia (if needed) and to intervene in the event a patient's airway becomes compromised. Monitored anesthesia care (MAC) may include varying levels of sedation, anxiolysis, and analgesia. Based on the American Society of Anesthesiologists' (ASA) standard for monitoring, MAC is to be provided by qualified anesthesia personnel who provide or medically direct a number of specific services such as administration of sedatives, analgesics, hypnotics, anesthetic agents or other medications as necessary. Anesthesia care becomes general anesthesia if the patient loses consciousness and the ability to respond purposefully.

The American Society of Anesthesiologists (ASA) defined MAC, and the following is derived from the ASA's 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 for 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."

Sedation Depth
(2004, Amended in 2019), the American Society of Anesthesiologists (ASA) defined four levels of sedation and analgesia, as shown below.

ASA's Definitions of General Anesthesia and Levels of Sedation and Analgesia

Terms	Minimal Sedation (Anxiolysis)	Moderate Sedation or Analgesia (Conscious Sedation)	Deep Sedation or Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Sedation for Diagnostic and Therapeutic Procedures
Multiple diagnostic and therapeutic procedures performed in the outpatient setting (e.g., endoscopy, colonoscopy, bronchoscopy, interventional pain management procedures) rely on some degree of sedation for anxiolysis and pain control. Regardless of sedation depth, sedation and anesthesia services 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 the 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, present continuously to monitor the patient and provide anesthesia care. For individuals 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 (e.g., fentanyl with midazolam) at doses individualized to obtain the desired sedative effect. Other combinations have also been used. While benzodiazepines and opioids can cause respiratory depression, effective reversal agents exist for both.

Propofol has increasingly been used to provide sedation for procedures. It is associated with a rapid onset of action and fast recovery from sedation. However, there are 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. The American Society of Anesthesiologists 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.

Risk Factors Associated with Anesthesia Outcomes

The ASA has recommended that any location providing MAC has the capability of cardiopulmonary resuscitation and monitoring equipment.

(2013) Whippey et al. published a case-control study of risk factors for unanticipated hospitalization following an outpatient procedure. They retrospectively identified 20,657 outpatient procedures and randomly selected 200 patients with an unanticipated hospitalization. These patients were compared with 200 randomly selected control patients without an unanticipated hospitalization. Predictors of unanticipated hospitalization included procedures lasting longer than 1-hour, high ASA physical status classification, older age, and higher body mass index (BMI).

(2004) Fleisher et al. performed a retrospective claims data review on 564,267 outpatient surgical procedures (360,780 at a hospital outpatient department, 175,288 at an ambulatory surgical center, 28,199 at a physician's office). The rates of all-cause death, emergency department visits, and inpatient admissions (within 7 days of the procedure) were compared. The highest rates were seen among patients in the hospital outpatient surgery department, suggesting that patients evaluated to be at the highest risk had their procedure in the location of lowest anesthesia risk. Multivariate analysis noted that increasing patient age, increasing procedural risk, and medical history of inpatient admissions were all independently predictive of adverse outcomes.

Pregnancy

Concerns about procedures and sedation during pregnancy are twofold: (1) there is a sensitivity of the fetus to the anesthetic and/or procedural hypotension; and (2) there are maternal factors that increase sensitivity to sedation and make intubation more difficult in an emergency situation. In a large (N=720,000) Swedish registry of pregnant patients

from the 1970s and 1980s, 5405 surgeries took place. Congenital malformations and stillbirths were not increased in the offspring of women having surgery. The incidence of low birth-weight infants was increased as a result of both prematurity and intrauterine growth retardation. Neonatal death was also increased in patients who had surgery. No specific types of anesthesia or surgery were associated with these outcomes. The contribution of the underlying condition that 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 a more sensitive indicator of placental perfusion and fetal oxygenation than observations of maternal hemodynamic stability alone. In 2021, the American College of Obstetricians and Gynecologists (ACOG) recommended the following:

- The following generalizations may be helpful to guide decision making:
    - No currently used anesthetic agents have been shown to have any teratogenic effects in humans when using standard concentrations at any gestational age.
    - There is no evidence that in utero human exposure to anesthetic or sedative drugs has any effect on the developing fetal brain; and there are no animal data to support an effect with limited exposures less than 3 hours in duration.
- The following recommendations represent the consensus of the committee:
    - A pregnant woman should never be denied medically necessary surgery or have that surgery delayed regardless of trimester because this can adversely affect the pregnant woman and her fetus.
    - Elective surgery should be postponed until after delivery.
    - Given the potential for preterm delivery with some nonobstetric procedures during pregnancy, corticosteroid administration for fetal benefit should be considered for patients with fetuses at viable premature gestational ages, and patients should be monitored in the perioperative period for signs or symptoms of preterm labor.
    - Pregnant women undergoing nonobstetric surgery should be screened for venous thromboembolism risk and should have the appropriate perioperative prophylaxis administered.

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 MAC when airway protection becomes necessary, due to additional difficulties noted with emergent intubation in pregnant individuals and the urgency to restore full oxygenation to the maternal and fetal patients.

Clinical Context and Therapy Purpose

The purpose of MAC in patients with a planned endoscopy and certain risk factors or significant medical conditions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of MAC improve the net health outcome in individuals with planned endoscopy and certain risk factors or significant medical conditions?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with planned endoscopy and certain risk factors or significant medical conditions.

Interventions
The therapy being considered is MAC.

Comparators
The following therapy is currently being used to manage patients with planned endoscopy: sedation or analgesia without MAC.

Outcomes
The general outcomes of interest are overall survival (OS), morbid events (e.g., vomiting, nausea), hospitalizations, treatment-related mortality, and treatment-related morbidity. This mild level of sedation wears off within minutes after the sedative is discontinued, so short-term follow-up is of interest.

Monitored Anesthesia Care with Endoscopy
Systematic Reviews
(2021) McCarty et al. completed a comparative systematic review and meta-analysis of safety and sedation-associated adverse events among 1,899 patients undergoing endoscopic cholangiopancreatography who had deep sedation with MAC (n=1284) versus general endotracheal anesthesia (n=615). Five studies were included (1 RCT, 2 prospective studies, and 2 retrospective studies). Outcomes included procedure success, all-cause and anesthesia-associated adverse events, and post-procedure recovery time. Results revealed that total anesthesia-associated adverse events were not different between the groups (odds ratio [OR], 1.33; 95% confidence interval [CI], 0.27 to 6.49). When evaluating anesthesia-associated events by type, MAC resulted in fewer episodes of clinically significant hypotension (OR, 0.32; 95% CI, 0.12 to 0.87), increased hypoxemic events (OR, 5.61; 95% CI, 1.54 to 20.37), and no difference in cardiac arrhythmias (OR, 0.48; 95% CI, 0.13 to 1.78). Additionally, the groups were similar with regard to all-cause total adverse events (OR, 1.16; 95% CI, 0.29 to 4.70) and time to recovery from anesthesia; however, mean procedure time was reduced with MAC. The procedure success rate was similar between the groups (OR, 1.16; 95% CI, 0.51 to 2.64). The authors noted there was significant heterogeneity among included studies (e.g., differences in patient population with regard to age, gender, body mass index (BMI), and ASA status; indications for endoscopic cholangiopancreatography) and concluded MAC

may be a safe alternative in endoscopic cholangiopancreatography; however, MAC may not be appropriate in all patients due to its increased risk of hypoxemia.

Prospective and Retrospective Studies
(2013) 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 ASA III to V. These findings supported the use of ASA physical status class as a predictor of periendoscopic adverse events and as a tool for risk stratification.

(2011) Agostoni et al. evaluated a prospective database of 17,999 GI endoscopies performed under MAC from 2001 to 2009. The authors identified 6 variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year OR, 1.02; 95% CI, 0.01 to 1.02), BMI (1-point OR, 1.03; 95% CI, 0.02 to 1.05), ASA score (ASA III-IV vs. ASA I-II; OR, 1.69; 95% CI, 1.44 to 1.99), Mallampati score (ASA III-IV vs. ASA I-II; OR, 1.33; 95% CI, 1.04 to 1.70), emergency nature of the procedure (OR, 1.48; 95% CI, 1.13 to 1.94), and length of the procedure (OR, 2.00; 95% CI, 1.78 to 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.

(2011) Berzin et al. completed a prospective cohort study of 470 endoscopic retrograde cholangiopancreatography patients receiving MAC, reported that adverse respiratory events were strongly associated with higher BMI using multivariate regression models (OR, 1.08; $p<.001$). Patients with obesity experienced respiratory events almost twice as often as patients who were not obese ($p=.03$). Higher ASA class was not associated with adverse respiratory events under MAC (OR, 1.2; $p=.25$) but was associated with cardiovascular events (OR, 2.88; $p<.001$).

(2010) Coté et al. reported on another prospective observational study of 766 patients undergoing advanced endoscopic procedures (e.g., endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, small bowel enteroscopy) who received propofol. These procedures are notable for their duration and complexity compared with diagnostic esophagogastroduodenoscopy. The primary outcome measure was airway modifications, with a comparison of defining characteristics of the group requiring at least 1 airway modifications (e.g., chin lift, 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 airway modification. Patients received anesthesia from a certified registered nurse anesthetist and generally had a level of deep sedation.

(2007) Cohen et al. completed a review of the literature assessing sedation for gastrointestinal (GI) tract endoscopy which was published through the American Gastroenterological Association Institute (AGAI), portions of which are relevant for this evidence review. The AGAI review recommended that the use of an anesthesia

professional should be strongly considered for the American Society of Anesthesiologists (ASA) physical status ASA III, IV, and V patients. The reviewers 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. The reviewers also noted endoscopic procedures that may require an anesthesia specialist include endoscopic retrograde cholangiopancreatography, stent placement in the upper GI tract, and complex therapeutic procedures (e.g., plication of the cardioesophageal junction). The AGAI review was used to formulate the initial conclusions on MAC in endoscopy.

Propofol in Endoscopy

Given the interest in the use of propofol, additional details are provided on its use in GI endoscopy.

Propofol in Endoscopy: Systematic Reviews

(2008) Singh et al. completed a Cochrane review by summarized the results of RCTs comparing the use of propofol with traditional agents for sedation during colonoscopy. The Cochrane review did not address MAC. Outcomes of interest included the technical performance of colonoscopy, patient satisfaction, and complication rates. Twenty-two studies met reviewers' inclusion criteria. Eight studies evaluated propofol as a single agent; 7 trials were published in abstract-only format, including the largest trial from 2000 (N=7,286 patients), which reported on different rates of colonic perforation. Only 1 trial (published in 2006) was double-blind. The agents administered in the control arms included benzodiazepines alone (diazepam, midazolam) or a combination of a benzodiazepine and a narcotic (pethidine, fentanyl, remifentanil, or alfentanil). Doses of 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 studies had a potential of moderate-to-high risk of bias; moreover, combining data for some of the outcomes for meta-analysis was problematic. Recovery time (reported in 11 studies; 776 patients) was shorter with propofol than with the control arm (weighted mean difference, -14.2 minutes; 95% CI, -17.6 to -10.8 minutes), with no significant heterogeneity (p=.41). Discharge time (7 studies; 542 patients) was also reported as shorter with propofol (weighted mean difference, -20.9 minutes; 95% CI, -30.9 to 10.8 minutes); however, there was significant heterogeneity among studies (p<.001). There was higher patient satisfaction (10 studies, 819 patients) with the use of propofol (OR for dissatisfaction, 0.35; 95% CI, 0.23 to 0.53). There was no difference in procedure time (9 studies; 736 patients) or complication rates. There was also no difference in pain control with non-patient-controlled sedation (5 studies; 396 patients) between propofol and the control arm (OR, 0.90; 95% CI, 0.58 to 1.39). The reviewers found only a single RCT (2011), reported in abstract format, for the secondary objective, comparison of propofol administration between anesthesiologists and endoscopists.

Propofol in Endoscopy: Randomized Controlled Trials

(2015) Shen et al. completed a RCT published by evaluated the safety, complication rates, and patient and examiner satisfaction with 2 different sedation regimens in patients

aged 60 to 80 years undergoing outpatient diagnostic gastroscopy. The trial included 720 patients randomized to etomidate-remifentanil (n=360) or propofol-remifentanil (n=360). Five subjects in the etomidate-remifentanil group were excluded from the analysis. Patients in the propofol-remifentanil group demonstrated decreases in their systolic and diastolic blood pressures and heart rates during and after the gastroscopy compared with baseline ($p<.05$). For subjects in the propofol-remifentanil group, average systolic blood pressure dropped from 125 mm Hg preprocedural to 95 mm Hg during the gastroscopy; average diastolic blood pressure dropped from 67 to 52 mm Hg; and average heart rate dropped from 75 to 70 bpm (data extrapolated from graphs). The authors stated that "the decrease of these cardiopulmonary function parameters led to adverse effects in older patients," but the adverse events are not specified. Compared with those in the etomidate-remifentanil group, patients in the propofol-remifentanil group were more likely to have hypoxemia (21.39% vs. 12.68%; $p=.002$), injection pain (22.5% vs. 0.85%; $p<.001$), and body quiver (43.06% vs. 19.15%; $p<.001$). Those in the etomidate-remifentanil group were more likely to have myoclonus (4.51% vs. 0.83%; $p=.002$). There were no significant differences between groups for duration time, recovery time, and time to leave the recovery room.

(2014) Treeprasertsuk et al. completed a small-block RCT, allocated 48 patients undergoing double-balloon enteroscopy to sedation with propofol or meperidine plus midazolam. Twenty-eight patients were randomized to meperidine plus midazolam, 1 of whom was excluded from the study due to hemodynamic instability preprocedure. Twenty-eight patients were randomized to propofol, but 5 were excluded due to hemodynamic instability; 2 more were later excluded for refusing treatment. Among included patients, recovery times and patient satisfaction scores did not differ significantly between groups. However, the trial's small size and high rates of dropout after randomization might have limited the ability to detect significant between-group differences.

(2011) Poincloux et al. completed a single RCT included in the Cochrane review previously described, randomized 90 adults (from a university center in France) undergoing colonoscopy to propofol administration by anesthesiologists (group A) or endoscopists (group B). The goal of propofol administration among anesthesiologists was anesthesia; the goal of propofol administration among endoscopists was sedation. There was no difference in procedure time (16.7 minutes for group A vs. 17.7 minutes for group B) or patient satisfaction (average visual analog scale score, 90.8 vs. 89). Subjects in group A indicated greater willingness to undergo further colonoscopies under the same conditions (95% vs. 79%; $p=.02$). A higher proportion of patients administered propofol by an anesthesiologist experienced hypoxia, but no patient required an intervention.

Propofol in Endoscopy: Observational Studies

Representative observational studies assessing outcomes when propofol was administered by anesthesiologists or by nonanesthesiologists or large studies evaluating propofol administration by nonanesthesiologists are described next.

(2015) De Paulo et al. published a comparative observational study of 2,000 outpatients undergoing GI endoscopy at a tertiary care hospital. A total of 1,000 patients underwent MAC with propofol and 1,000 had nonanesthesiologist administration of propofol (NAAP) administered by endoscopists. To comply with local regulations, an anesthesiologist was in the room when propofol was administered by endoscopists. Compared with the MAC group, the NAAP group had a greater proportion of patients who received fentanyl in addition to propofol (50.5% vs. 61.1%, p<.05), and fewer patients who underwent deep sedation (66.1% vs. 44.7%, p<.05). The proportion of patients experiencing hypoxemia did not differ significantly between groups, but when hypoxemia occurred, it lasted significantly longer in the NAAP group (mean, 7.26 seconds) than in the MAC group (mean, 4.22 seconds). The rate of bag-mask ventilation (3 [0.3%] in the NAAP group vs. 6 [0.6%] in the MAC group) did not differ significantly between groups. Only 4 (0.4%) patients in the NAAP group and 3 (0.3%) in the MAC group expressed dissatisfaction (e.g., stated they would not repeat the procedure in the same manner).

(2014) Sieg et al. reported on outcomes from a prospective, multicenter study of endoscopist-directed sedation with propofol in 53 German outpatient gastroenterology practices. The study included 24,441 subjects who underwent 13,793 colonoscopies, 6,467 esophagogastroduodenoscopies, and 4,181 combination procedures. Propofol monosedation was used in 52% of the patients, while 48% received a combination of midazolam and propofol. Major adverse events occurred in 4 (0.016%) patients, including 3 requirements for mask ventilation and 1 laryngospasm. Minor adverse events included hypoxemia in 93 (0.381%) patients, intestinal bleeding in 12 (0.049%) patients, bradycardia in 7 (0.029%) patients, and persistent hypotension requiring intravenous fluids in 5 (0.02%) patients. Propofol monosedation was associated with a higher probability of hypoxemia (0.50%) compared with propofol-midazolam sedation (0.5% vs. 0.25%; p<.000). Patient questionnaires were available for 15,690 subjects. Of those, patients sedated with propofol had higher scores on a scale from 1 (very bad) to 9 (very good) describing how they felt compared with the previous day than those sedated with propofol-midazolam (mean, 7.225 vs. 7.216, p<.02).

Summary of Evidence

The evidence comparing different anesthetic methods is not robust, consisting primarily of nonrandomized comparisons and observational studies. A RCT comparing propofol administration by anesthesiologists with that by nonanesthesiologists for sedation during colonoscopy did not show any differences in procedure time or patient satisfaction, and it 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. Reviewers did not find evidence of increased complications. However, the current evidence base does not rule out increased complication rates with propofol, because there were low complication rates in general, thus making it difficult to discern between-group differences in the absence of large RCTs.

Professional Guidelines and Position Statements

American Society of Anesthesiologists

(2019) The ASA provided a statement on *respiratory monitoring during endoscopic procedures.* The statement advised the following:

- "Monitoring for exhaled carbon dioxide should be conducted during endoscopic procedures in which sedation is provided with propofol alone or in combination with opioids and/or benzodiazepines, and especially during these procedures on the upper gastrointestinal tract. Careful attention to airway management must be provided during complex upper endoscopic procedures and procedures performed in the prone position where ventilatory monitoring, airway maintenance, and resuscitation may be especially difficult." (*Accessed February 2022*)

(2019) The ASA provided 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."
    - "Rescue" was defined as - "Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level. It is not appropriate to continue the procedure at an unintended level of sedation.
- The physician responsible for the use of sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.
- The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.
- The practitioner administering propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications.
- The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.
- During the administration of propofol, patients should be monitored without interruption to assess level of consciousness, and to identify early signs of hypotension, bradycardia, apnea, airway obstruction and/or oxygen desaturation. Ventilation, oxygen saturation, heart rate and blood pressure should be monitored

at regular and frequent intervals. Monitoring for the presence of exhaled carbon dioxide should be utilized unless invalidated by the nature of the patient, procedure or equipment because movement of the chest will not dependably identify airway obstruction or apnea.

- Age-appropriate equipment must be immediately available for the maintenance of a patent airway, oxygen enrichment and artificial ventilation in addition to circulatory resuscitation.

(*Accessed February 2022*)

American Society for Gastrointestinal Endoscopy (ASGE)

(2018) The ASGE standards of practice committee provided a Guideline for Sedation and Anesthesia in GI Endoscopy which stated:

Anesthesia provider assistance should be considered in the following situations:

- Prolonged or therapeutic endoscopic procedures requiring deep sedation
- Anticipated intolerance to standard sedatives
- Increased risk for adverse event because of severe comorbidity (ASA class IV or V)
- Increased risk for airway obstruction because of anatomic variant

Several factors that may determine whether the assistance of anesthesia providers is needed include patient specific risk factors for sedation, the planned depth of sedation, and the urgency and type of endoscopic procedure performed. Patient risk factors include:

- Significant medical conditions such as extremes of age
- Severe pulmonary, cardiac, renal, or hepatic disease
- Pregnancy
- The abuse of drugs or alcohol
- Uncooperative patients
- A potentially difficult airway for positive-pressure ventilation
- Individuals with anatomy that is associated with more difficult intubation.

Recommendations

- We recommend that all patients undergoing endoscopic procedures be evaluated to assess their risk of sedation related to pre-existing medical conditions.
- We recommend that the combination of an opioid and benzodiazepine is a safe and effective regimen for achieving minimal to moderate sedation for upper endoscopy and colonoscopy in patients without risk factors for sedation-related adverse events.
- We suggest using an appropriate adjunctive agent (eg, diphenhydramine, promethazine, or droperidol) in combination with conventional sedative drugs in select clinical circumstances.
- We recommend that providers undergo specific training in the administration of endoscopic sedation and possess the skills necessary for the diagnosis and

management of sedation-related adverse events, including rescue from a level of sedation deeper than that intended.

- We recommend the routine monitoring of blood pressure, oxygen saturation, and heart rate in addition to clinical observation for changes in cardiopulmonary status during all endoscopic procedures using sedation. Supplemental oxygen administration should be considered for moderate sedation and should be administered during deep sedation. Supplemental oxygen should be administered if hypoxemia is anticipated or develops.
- We suggest that capnography monitoring be considered for patients undergoing endoscopy targeting deep sedation.
- We recommend anesthesia provider–administered sedation be considered for complex endoscopic procedures or patients with multiple medical comorbidities or at risk for airway compromise.
- We suggest that endoscopists use propofol-based sedation (endoscopist-directed or anesthesia-provider administered) when it is expected to improve patient safety, comfort, procedural efficiency, and/or successful procedure completion.

(*Accessed February 2022*)

(2014) The ASGE issued guidelines on the *safety of the endoscopy unit*, which made several recommendations on procedural sedation:

- "Staff Recommendations for intra-procedure care based on level of sedation:
  - No sedation – One assistant (RN, LPN, or UAP) 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.

(*Accessed February 2022*)

(2013) The ASGE published guidelines *for endoscopic modification for geriatric patients*. Specific to this evidence review, ASGE recommended the following:

- "… in younger adults, midazolam and/or narcotics are generally used. Fentanyl may have an advantage over meperidine in the elderly because of its faster onset of action and shorter half-life, thereby allowing faster recovery from sedation. Propofol has a narrower margin of safety in elderly patients, but has been shown to be safe when used in elderly patients with continuous monitoring. Minimizing the use of sedation or no sedation is an option for reducing anesthesia-related adverse events during endoscopic procedures."
- We recommend standard monitoring procedures in the elderly during moderate sedation with heightened awareness of this population's increased response to sedatives.

- We suggest that practitioners exercise additional caution when performing colonoscopy in elderly patients because this procedure may confer a higher risk of adverse events.
  (*Accessed February 2022*)

Joint Guidelines
(2009) The ASGE-along with the American Association for the Study of Liver Diseases, American College of Gastroenterology, and American Gastroenterological Association issued a joint position statement on nonanesthesiologist administration of propofol (NAAP) for gastrointestinal 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. (*Accessed February 2022*)

PRIOR APPROVAL

Not applicable.

POLICY

Notes: This medical policy only addresses the identified anesthesia services during gastrointestinal endoscopic outpatient procedures.

Medically Necessary
Monitored anesthesia care (MAC) or general anesthesia may be considered **medically necessary** during *gastrointestinal (GI)* endoscopic procedures when at least **one of the following indications are met**:

- $\geq$ 70 years old; **or**
- $\leq$ 17 years old; **or**
- Acutely agitated or an uncooperative individual to include but not limited **to one of the following**:
  - Delirium; **or**
  - Organic brain disease; **or**
  - Senile dementia; **or**
- Active medical complications related to alcohol or drug abuse (including intoxication); **or**
- Body Mass Index (BMI) $\geq$ 40; **or**
- History of or anticipated intolerance to standard sedatives (i.e., chronic narcotic use, chronic benzodiazepine therapy); **or**
- History of previous problems with anesthesia or sedation; **or**
- Inability to follow simple commands (cognitive dysfunction or developmental disorder, psychological, or neuropsychiatric diagnosis); **or**
- Increased risk for airway obstruction in **one of the following** anatomic variants:

- Dysmorphic facial features; to include but not limited to one of the following:
  - Pierre-Robin syndrome; **or**
  - Trisomy-21 **or**
- Jaw abnormalities to include but not limited **to one the following**:
  - Micrognathia; **or**
  - Prior orthognathic surgery limiting mouth opening; **or**
  - Retrognathia; **or**
  - Significant malocclusion; **or**
  - Trismus; **or**
- Neck abnormalities to include but not limited to **one of the following**:
  - Advanced rheumatoid arthritis; **or**
  - Cervical spine disease, trauma, or fusion; **or**
  - Decreased hyomental distance (< 3 cm); **or**
  - Limited neck extension; **or**
  - Neck mass; **or**
  - Obesity involving the neck and facial structures; **or**
  - Short neck; **or**
  - Tracheal deviation; **or**
- Oral abnormalities including but not limited to **one of the following**:
  - Edentulous patients; **or**
  - High arched palate; **or**
  - Macroglossia; **or**
  - Non-visible uvula [e.g., Mallampati class greater than II]; **or**
  - Small oral opening (< 3 cm); **or**
  - Tonsillar hypertrophy; **or**
- Sleep apnea; **or**
- Stridor; **or**

- Increased risk of complications due to a *severe* comorbidity (*American Society of Anesthesiologists [ASA] class III physical status or greater*. *See additional information below in the Policy Guidelines*.); **or**
- Pregnancy; **or**
- Prolonged or therapeutic endoscopic procedure requiring deep sedation to include but not limited to patients with **one of the following**:
  - Adhesions after abdominal surgery; **or**
  - Complex therapeutic procedures such as plication of the cardioesophageal junction; **or**
  - Stent placement in the upper gastrointestinal (GI) tract; **or**

  Note: Combination upper and lower endoscopy completed simultaneously would not be considered a prolonged procedure.
- Spasticity or movement disorder complicating the procedure.

Not Medically Necessary
Monitored anesthesia care (MAC) or general anesthesia are considered **not medically necessary** during gastrointestinal (GI) endoscopic procedures to include but not limited to the following:

- For the routine assistance of an anesthesiologist or a certified registered nurse anesthetist (CRNA) for average-risk adult patients undergoing standard upper and/or lower gastrointestinal endoscopic procedures
- When the above criteria have not been met

Policy Guidelines
Note: Moderate (conscious) sedation will continue to be reimbursed as an inherent part of the procedure when administered to average-risk adult individuals undergoing general, diagnostic, uncomplicated, therapeutic endoscopy, and colonoscopy.

Abbreviations:

- ASA: American Society of Anesthesiologists
- BMI: body mass index
- CHF: congestive heart failure
- COPD: chronic obstructive pulmonary disease.

American Society of Anesthesiology (ASA) Physical Status Classification:

Class	Definition
ASA III	A patient with severe systemic disease
ASA IV	A patient with severe systemic disease that is a constant threat to life
ASA V	A moribund patient who is not expected to survive without the operation
ASA VI	A declared brain-dead patient whose organs are being harvested

Note see the hyperlink above for ASA defined examples.

Mallampati Scoring System
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. Individuals are scored from classes I through IV.

Class	Definition
I	The tonsils, uvula and soft palate are fully visible
II	The hard and soft palate, uvula and upper portion of the tonsils are visible
III	The hard and soft palate and the uvula base are visible

IV	Only the hard palate is visible

Individuals with class III or IV Mallampati scores are considered to be at higher risk of intubation difficulty. While the Mallampati score does not determine a need for MAC, 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.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 00731 Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified
- 00732 Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP)
- 00811 Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified
- 00812 Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy
- 00813 Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum

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POLICY HISTORY

Date	Reason	Action
August 2022	Interim Review	Policy Revised
March 2022	Annual Review	Policy Revised

March 2021	Annual Review	Policy Revised
March 2020	Annual Review	Policy Revised
March 2019	Annual Review	Policy Renewed
March 2018	Annual Review	Policy Revised
March 2017	Annual Review	Policy Renewed
March 2016	Annual Review	Policy Revised
April 2015	Annual Review	Policy Renewed
May 2014	Annual Review	Policy Renewed
July 2013	Annual Review	Policy Renewed
August 2012	Annual Review	Policy Renewed
August 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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