

7.02.01 Monitored Anesthesia Care	
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Section: 2.0 Medicine	Page: Page 1 of 24

Policy Statement

- I. The use of monitored anesthesia care (MAC) 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:
 - A. Increased risk for complications due to severe comorbidity (American Society of Anesthesiologists [ASA] class III, IV, or V [Table PG1])
 - B. Morbid obesity (body mass index [BMI] greater than 40 kg/m²)
 - C. Documented clinically significant obstructive sleep apnea; See Policy Guidelines
 - D. Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
 - E. Spasticity or movement disorder complicating the procedure
 - F. History of (or anticipated) intolerance to standard sedatives, such as:
 - 1. Chronic opioid use
 - 2. Chronic benzodiazepine use
 - G. Individuals with active medical problems related to drug or alcohol abuse
 - H. Individuals younger than 18 years or 70 years or older
 - I. Individuals who are pregnant
 - J. Individuals with increased risk for airway obstruction due to anatomic variation, such as:
 - 1. History of stridor
 - 2. Dysmorphic facial features
 - 3. Oral abnormalities (e.g., macroglossia)
 - 4. Neck abnormalities (e.g., neck mass)
 - 5. Jaw abnormalities (e.g., micrognathia)
 - K. Acutely agitated, uncooperative individuals
 - L. Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section)

- II. The use of monitored anesthesia care is considered **investigational** for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in individuals at average risk related to use of anesthesia and sedation.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Note: For dental anesthesia procedures see [Blue Shield Medical Policy: Dental Anesthesia](#).

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

Table PG1. ASA’s Physical Status Classification System

Class	Definition
ASA I	A normal, healthy individual
ASA II	An individual with mild systemic disease
ASA III	An individual with severe systemic disease

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

ASA: American Society of Anesthesiologists.

Monitored Anesthesia Care

Monitored anesthesia care (MAC) can be provided by qualified anesthesia personnel with training and experience in:

- Patient assessment
- Continuous evaluation and monitoring of patient physiologic functions
- Diagnosis and treatment (both pharmacologic and nonpharmacologic) of any and all deviations in physiologic function.

Procedural and Patient Risks

Examples of prolonged endoscopy procedures that may require deep sedation include the following:

- Endoscopy in patients with adhesions after abdominal surgery
- Endoscopic retrograde cholangiopancreatography
- Stent placement in the upper gastrointestinal 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 individual extend the neck, open the mouth, and extend the tongue while in a seated position. Individuals are scored from classes I through IV (Table PG2).

Table PG2. Mallampati Scoring System

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.

Clinically Significant Obstructive Sleep Apnea (OSA)

Clinically significant OSA for adults includes either of the following:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour
- An AHI, RDI, or REI of at least 5 events per hour in a patient with excessive daytime sleepiness (as determined by standard sleep questionnaires such as the Epworth Sleepiness Scale >10 or the Berlin Questionnaire with a score of at least 2 in Category 2) or hypertension

Clinically significant OSA for children includes either of the following:

- An AHI or RDI of greater than or equal to 5 events per hour
- An AHI or RDI greater than or equal to 1.5 events per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity

Coding

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)

These six Category I codes are for percutaneous image-guided spine and spinal cord anesthesia procedures. They were created to add clarity and granularity to the anesthesia services provided. CPT 01935 and 01936 are being deleted. 01937 and 01938 are for aspiration or drainage of the spine/spinal cord by region, 01939 and 01940 are for destruction on the spine/spinal cord by region, 01941 and 01942 are for intravertebral or neuromodulation procedures on the spine/spinal cord by region:

- **01937:** Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic
- **01938:** Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral
- **01939:** Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic
- **01940:** Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral
- **01941:** Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic
- **01942:** Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral

Description

Adequate sedation and analgesia are important parts of many diagnostic and therapeutic procedures. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient's condition and the procedure being performed. 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 a patient's airway becomes compromised.

Related Policies

- Manipulation Under Anesthesia

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 1989, propofol (Diprivan[®]; AstraZeneca) was 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 MAC sedation, combined sedation, and regional anesthesia; the label also states that Diprivan is indicated for the sedation of adults in the intensive care unit who have been intubated or mechanically ventilated. Moreover, Diprivan is also approved for the induction of general anesthesia in patients 3 years of age and older and maintenance of general anesthesia in patients 2 months of age and older.

Many other FDA approved medications for pain relief, anxiolysis, and sedation may be used in outpatient sedation.

Rationale

Background

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 American Society of Anesthesiologists (ASA) defined MAC,^{1,2} 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

In 2004 (amended in 2019), the ASA defined 4 levels of sedation and analgesia, as shown in Table 1.

Table 1. 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 ^a to verbal or tactile stimulation	Purposeful response ^a 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

^a Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Adapted from American Society of Anesthesiologists (2019).³

ASA: American Society of Anesthesiologists.

Because sedation is a continuum, it is not always possible to predict how a 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 or analgesia (conscious sedation) should be able to rescue patients who enter a state of deep sedation or analgesia, while those administering deep sedation or analgesia should be able to rescue patients who enter a state of general anesthesia.

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.^{2,1} By this standard, the personnel must be, in addition to the proceduralist, 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 (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.⁴

Risk Factors Associated with Anesthesia Outcomes

The ASA has recommended that any location providing MAC has the capability of cardiopulmonary resuscitation and monitoring equipment.⁵ Whippey et al (2013) published a case-control study of risk factors for unanticipated hospitalization following an outpatient procedure.⁶ 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). Fleisher et al (2004) 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).⁷ 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.⁸ 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 2003, the American College of Obstetricians and Gynecologists recommended that use of intermittent or continuous fetal monitoring during surgery be individualized.⁹

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.¹⁰ Physiologic changes in pregnancy may warrant MAC when airway protection becomes necessary, due to additional difficulties noted with emergent intubation in pregnant patients and the urgency to restore full oxygenation to the maternal and fetal patients.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant,

studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.”

Many recommendations for the indications for monitored anesthesia care (MAC) derive from narrative reviews and expert opinion.

Monitored Anesthesia Care

Monitored Anesthesia Care With Endoscopy

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 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

A review of the literature assessing sedation for gastrointestinal (GI) tract endoscopy, conducted by Cohen et al (2007), was published through the American Gastroenterological Association Institute (AGAI), portions of which are relevant for this evidence review.¹¹ 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. 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. Reviewers also noted endoscopic procedures that may require an anesthesia specialist include endoscopic retrograde cholangiopancreatography (ERCP), 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.

McCarty et al (2021) completed a comparative systematic review and meta-analysis of safety and sedation-associated adverse events among 1899 patients undergoing ERCP who had deep sedation with MAC (n=1284) versus general endotracheal anesthesia (n=615).¹² Five studies were included (1 RCT [Smith et al, see below], 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 that 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.

Randomized Controlled Trials

Three RCTs comparing MAC to general anesthesia have been conducted for individuals with ERCP. Trial characteristics are shown in Table 2. Results are shown in Table 3. Notable study limitations are shown in Tables 4 and 5. Even though the American Society of Anesthesiologists states that MAC "does not describe the continuum of depth of sedation, rather it describes a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure,"³ the RCTs appear to test the level of sedation rather than the anesthesia service. The MAC arms described in the RCTs below are conflated with moderate sedation or propofol-based sedation.

Smith et al (2019) reported results of a single-center RCT (n=200) comparing general endotracheal anesthesia (GEA) to propofol-based monitored anesthesia care (MAC) without endotracheal intubation in adults undergoing ERCP at high risk for sedation-related adverse events (SRAEs).¹³ Participants were eligible if they had STOP-BANG score ≥ 3 , abdominal ascites, body mass index ≥ 35 , chronic lung disease, American Society of Anesthesiologists (ASA) class >3 , Mallampati class 4 airway, or moderate to heavy alcohol use. Participants were sedated by an anesthesia team with experience in sedation for endoscopic procedures. The primary outcome was a composite

measure of incident SRAEs: hypoxemia, use of airway maneuvers, hypotension requiring vasopressors, sedation-related procedure interruption, cardiac arrhythmia, and respiratory failure. The incidence of composite SRAEs was significantly higher in the MAC group (51/99, 52%) versus the GEA group (10/101, 10%; $p<.01$) driven primarily by increased incidence of hypoxemia and need for airway maneuvers. There were no statistically significant differences measures of procedure duration, success, recovery, or in-room time.¹³

Alzanbagi, et al (2022) reported results of a single-center RCT comparing General Anesthesia (GA) with cisatracurium and propofol to propofol-based MAC in adults at average risk (ASA class <3) for SRAEs undergoing ERCP.¹⁴ Anesthesia was administered by a team with extensive experience in endoscopic sedation in a tertiary referral center. The primary outcome was a composite measure of SRAEs including hypotension, arrhythmia, hypoxia, hypercapnia, apnea, and procedural interruption or termination. The incidence of SRAEs was significantly higher in the MAC group (34/96 [35%]) compared with GA (10/107 [9%], $p<.01$), primarily driven by hypoxia. Procedure time, recovery time, cannulation time and success were not statistically significantly different between the groups. Patient satisfaction was higher with GA.¹⁴

Wu et al (2023) reported results of a single center, 3-arm RCT comparing propofol-based MAC to GA with a neuromuscular blocking agent and to GA muscle relaxant-free in adults at average risk (ASA class <3) for pulmonary and cardiac adverse events undergoing ERCP.¹⁵ The anesthesia team was not described. The primary outcome was the overall intraprocedural cardiopulmonary adverse events. The primary outcome occurred more frequently in the MAC group compared to either of the GA groups (MAC: 38% vs Group GA with neuroblocking: 19 vs Group GA muscle relaxant-free: 18%; $p<.01$) driven primarily by pulmonary events. The MAC and GA muscle relaxant-free groups had shorter total procedure time compared to the GA with neuroblocking group (MAC: 67±14 min vs GA muscle relaxant-free: 84±16 min vs GA with neuroblocking: 70±13 min; $p<.01$). Patient satisfaction was measured using an unspecified survey with a scale of 0 to 10 (0=not at all satisfied, 10=most satisfied). Patient satisfaction score was not statistically significantly different between groups.¹⁵

Table 2. Characteristics of RCTs of Monitored Anesthesia Care

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Smith (2019); NCT02850887 ¹³ .	US	1	2016 to 2017	Adults undergoing ERCP at high risk for sedation-related adverse events Mean age, 61 y 37% women	MAC (n=99)	GEA (n=101)
Alzanbagi (2022); NCT04099693 ¹⁴ .	Saudi Arabia	1	2019 to 2022	Adults undergoing ERCP at average risk for sedation- related adverse events Mean age, 50 y 53% women	MAC (n=97)	GA (n=107)
Wu (2023); NCT04087668 ¹⁵ .	China	1	2019	Adults undergoing ERCP at average risk for sedation- related adverse events Mean age, 55y 47% women	MAC (n=120)	GA with neuroblocking (n=120) GA muscle relaxant-free (n=120)

ERCP: endoscopic retrograde cholangiopancreatography; GA: General anesthesia; GEA: General endotracheal anesthesia; MAC: monitored anesthesia care; RCT: randomized controlled trial.

Table 3. Summary of Results of RCTs of Monitored Anesthesia Care

Study	Sedation Related Adverse Events	Conversion to General Anesthesia	Procedure Time	Patient Satisfaction
Smith (2019); NCT02850887¹³	n(%)	n(%)	Mean (SD) in minutes	
MAC	51/99 (52%)	10%	25 (20)	NR
GEA	10/101 (10%)	NA	25 (20)	
Treatment effect (95% CI); p-value	p<.01	NA	p=.91	
Alzanbagi (2022); NCT04099693¹⁴	n(%)		Mean (SD) in minutes	Measured on a 10 point visual analog scale
				Mean (SD)
MAC	34/96 (35%)	NR	31 (18)	9.0 (1)
GA	10/107 (9%)		38 (35)	9.6 (1)
Treatment effect (95% CI); p-value	p<.01		p=.27	p<.01
Wu (2023); NCT04087668¹⁵	Intraoperative pulmonary and cardiac adverse events in n(%)	n(%)	Mean (SD) in minutes	Patient satisfaction survey, unspecified
MAC	45/120 (38%)	7/120 (6%)	67 (14)	Only available in a figure
GA with neuroblocking	23/120 (19%)	NA	84 (16)	
GA muscle relaxant-free	21/120 (18%)	NA	70 (13)	
Treatment effect (95% CI); p-value	p<.01		p<.01	Only reported as NS

ERCP: endoscopic retrograde cholangiopancreatography; GEA: General endotracheal anesthesia; MAC: monitored anesthesia care; RCT: randomized controlled trial. CI: confidence interval; Diff: difference; HR: hazard ratio; NS: not statistically significant; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

The purpose of the study limitations tables (see Tables 4 and 5) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 4. Study Relevance Limitations of RCTs of Monitored Anesthesia Care

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Smith (2019); NCT02850887¹³	4. Race/ethnicity of participants not described	3. Unclear whether type of anesthesia personnel present during procedure varied across arms; appears to have varied level of sedation	3. Unclear whether type of anesthesia personnel present during procedure varied across arms; appears to have varied level of sedation	6. Unclear what size difference is clinically significant	
Alzanbagi (2022); NCT04099693¹⁴	4. Race/ethnicity of participants	3. Unclear whether type of anesthesia	3. Unclear whether type of anesthesia	6. Unclear what size difference is	

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
	not described; study conducted in Saudi Arabia	personnel present during procedure varied across arms; appears to have varied level of sedation	personnel present during procedure varied across arms; appears to have varied level of sedation	clinically significant	
Wu (2023); NCT04087668 ¹⁵ ,	4. Race/ethnicity of participants not described; study conducted in China	3. Unclear whether type of anesthesia personnel present during procedure varied across arms; appears to have varied level of sedation	3. Unclear whether type of anesthesia personnel present during procedure varied across arms; appears to have varied level of sedation	4. Unclear which patient satisfaction survey was performed 6. Unclear what size difference is clinically significant	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations of RCTs of Monitored Anesthesia Care

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Smith (2019); NCT02850887 ¹³ ,		1, 2, 3: Blinding was not possible but outcomes were objective			3. Powered to detect a 15% absolute reduction; no justification for this difference	
Alzanbagi (2022); NCT04099693 ¹⁴ ,		1, 2, 3: Blinding was not possible; some outcomes were objective			3. Powered to detect a 15% absolute reduction; no justification for this difference	
Wu (2023); NCT04087668 ¹⁵ ,		1, 2, 3: Blinding was not possible; some outcomes were objective			3. Powered to detect a 15% absolute reduction; no justification for this difference	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Prospective and Retrospective Studies

Enestvedt et al (2013) 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.¹⁶ These findings supported the use of ASA physical status class as a predictor of periendoscopic adverse events and as a tool for risk stratification.

Agostoni et al (2011) evaluated a prospective database of 17,999 GI endoscopies performed under MAC from 2001 to 2009.¹⁷ 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.

In a prospective cohort study of 470 ERCP patients receiving MAC, Berzin et al (2011) reported that adverse respiratory events were strongly associated with higher BMI using multivariate regression models (OR, 1.08; $p < .001$).¹⁸ 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; $p < .001$).

Coté et al (2010) reported on another prospective observational study of 766 patients undergoing advanced endoscopic procedures (e.g., ERCP, endoscopic ultrasound, small-bowel enteroscopy) who received propofol.¹⁹ 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.

Section Summary: Monitored Anesthesia Care With Endoscopy

The evidence comparing different anesthetic methods is not robust, consisting primarily of nonrandomized comparisons, observational studies, and systematic reviews of these studies. The American Society of Anesthesiologists states that MAC "does not describe the continuum of depth of sedation, rather it describes a specific anesthesia service performed by a qualified anesthesia provider." However, all RCTs purporting to test MAC appear to instead be testing level of sedation

Three RCTs with sample sizes ranging from 200 to 360, comparing propofol-based 'MAC' to general anesthesia in individuals undergoing endoscopic retrograde cholangiopancreatography reported higher rates of sedation-related adverse events with 'MAC'.

Monitored Anesthesia Care With Bronchoscopy

Clinical Context and Therapy Purpose

The purpose of MAC in patients with a planned bronchoscopy 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 following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with planned bronchoscopy 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 bronchoscopy: sedation or analgesia without MAC.

Outcomes

The general outcomes of interest are 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

No RCTs or nonrandomized comparative studies evaluating MAC and nonanesthesiologist-administered sedation for bronchoscopy were identified. One RCT addressed sedation in bronchoscopy but did not specifically address MAC. This trial, by Silvestri et al (2009), compared 2 doses of the sedative agent fospropofol in patients undergoing diagnostic bronchoscopy; sedatives were administered by pulmonologists without anesthesia supervision.²⁰ Patients (N=252) were randomized to induction doses of fospropofol 2 mg/kg or 6.5 mg/kg, followed by additional doses per protocol. All patients received a preprocedural dose of fentanyl. The primary endpoint was sedation success using the Modified Observer's Assessment of Alertness/Sedation. The higher dose group had greater sedation success (88.7% vs. 27.5%, respectively; $p < .001$). Treatment success also favored the higher dose group (91.3% vs. 41.25%, respectively; $p < .001$). Adverse events were higher for the higher dose group (e.g., the number of patients requiring any type of airway assistance; 33 [21.5%] vs. 14 [13.6%], respectively). The trial did not compare alternative sedation approaches; that comparison would be necessary to evaluate the clinical value of the fospropofol sedation strategy for bronchoscopy procedures.

Section Summary: Monitored Anesthesia Care With Bronchoscopy

There is a lack of published evidence on MAC in bronchoscopy procedures; no RCTs, nonrandomized comparative studies, or large case series were identified.

Monitored Anesthesia Care with Interventional Pain Management**Clinical Context and Therapy Purpose**

The purpose of MAC in patients with a planned interventional pain management procedure 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 following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with a planned interventional pain management procedure 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 interventional pain management procedures: sedation or analgesia without MAC.

Outcomes

The general outcomes of interest are 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Bernards et al (2008) published a literature review on neurologic complications of regional anesthesia in anesthetized or heavily sedated patients.²¹ Some experts have postulated that the inability of a sedated patient to express atypical symptoms during a regional block may lead to an increased risk of injury. No comparative studies have been done, and limited information is available from registries. In 2008, the American Society of Regional Anesthesia and Pain Medicine acknowledged the scarce and conflicting literature on the topic and recommended carefully weighing the risks and benefits of performing those procedures while the patient is heavily sedated or anesthetized.²²

Section Summary: Monitored Anesthesia Care With Interventional Pain Management

There is a lack of published evidence on MAC in interventional pain management procedures; no RCTs, nonrandomized comparative studies, or large case series were identified.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Anesthesiologists

In 2019, the American Society of Anesthesiologists (ASA) updated its 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."²³

"Rescue" was defined as correcting "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."

In 2021, the ASA updated its statement on anesthetic care during interventional pain procedures.²⁴

"Interventional pain procedures generally only require local anesthesia; however, patients may elect to also receive supplemental sedation. For most patients who require supplemental sedation, the physician performing the interventional pain procedure(s) can prescribe minimal sedation/analgesia (anxiolysis) or moderate (conscious) sedation as part of the procedure. For a limited number of patients, an anesthesia care team may be required..."

Significant patient anxiety and/or medical comorbidities may be an indication for moderate (conscious) sedation or anesthesia care team 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 moderate sedation or anesthesia care team services. Examples of such procedures include but are not limited to sympathetic blocks (celiac plexus, paravertebral and hypogastric), chemical or radiofrequency ablation, percutaneous discectomy, vertebral augmentation procedures; trial spinal cord stimulator lead placement, permanent spinal cord stimulator generator, and lead implantation, and intrathecal pump implantation.

In 2019, the ASA updated its statement on respiratory monitoring during endoscopic procedures.²⁵ The statement advised that "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."

American Society for Gastrointestinal Endoscopy

In 2018, guidelines on sedation during gastrointestinal endoscopy were released by the American Society for Gastrointestinal Endoscopy (ASGE).²⁶ The guidelines stated that anesthesia provider assistance during gastrointestinal endoscopy 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), and increased risk for airway obstruction because of anatomic variant. 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 2015, the ASGE published quality indicators for all gastrointestinal endoscopic procedures.²⁷ Specific to this evidence review, 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 2013, the ASGE published guidelines for endoscopic modification for geriatric patients.²⁸ Specific to this evidence review, ASGE recommended "standard monitoring procedures in the elderly during moderate sedation with heightened awareness of this population's increased response to sedatives." In 2014, the ASGE issued guidelines on the safety of the endoscopy unit, which made several recommendations on procedural sedation.²⁹:

"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 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.³⁰ 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date (status)
<i>Ongoing</i>			
NCT04107038	A Randomized Controlled Trial Comparing Monitored Anesthesia Care Versus General Anesthesia With Transesophageal Echocardiography for Transcatheter Aortic Valve Replacement	170	Jun 2024
<i>Unpublished</i>			
NCT02046590	A Randomized Controlled Trial (RCT) of Efficacy and Safety of Sedation Compared to General Anesthesia for Endoscopic Retrograde Cholangio-pancreatography	120	Feb 2023 (terminated; slow enrollment)

NCT: national clinical trial.

References

1. American Society of Anesthesiologists (ASA). Position on monitored anesthesia care (Amended October 17, 2018). 2018; <https://www.asahq.org/standards-and-guidelines/position-on-monitored-anesthesia-care>. Accessed September 15, 2023.
2. American Society of Anesthesiologists (ASA). Distinguishing monitored Anesthesia care (MAC) from moderate sedation/analgesia (Last Amended October 17, 2018). 2018; <https://www.asahq.org/standards-and-practice-parameters/statement-on-distinguishing-monitored-anesthesia-care-from-moderate-sedation-analgesia>. Accessed September 15, 2023.
3. American Society of Anesthesiologists (ASA). Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (Last Amended on October 23, 2019). 2019; <https://www.asahq.org/standards-and-practice-parameters/statement-on-continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia>. Accessed September 15, 2023.
4. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology*. Apr 2002; 96(4): 1004-17. PMID 11964611
5. American Society of Anesthesiologists (ASA). Guidelines for ambulatory anesthesia and surgery (Reaffirmed October 2018). 2018; American Society of Anesthesiologists (ASA). Guidelines for ambulatory anesthesia and surgery. <https://www.asahq.org/standards-and-guidelines/guidelines-for-ambulatory-anesthesia-and-surgery>. Accessed September 15, 2023.
6. Whippey A, Kostandoff G, Paul J, et al. Predictors of unanticipated admission following ambulatory surgery: a retrospective case-control study. *Can J Anaesth*. Jul 2013; 60(7): 675-83. PMID 23606232
7. Fleisher LA, Pasternak LR, Herbert R, et al. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. *Arch Surg*. Jan 2004; 139(1): 67-72. PMID 14718279
8. Mazze RI, Kallen B. Reproductive outcome after anesthesia and operation during pregnancy: a registry study of 5405 cases. *Am J Obstet Gynecol*. Nov 1989; 161(5): 1178-85. PMID 2589435
9. ACOG Committee on Obstetric Practice. ACOG Committee Opinion Number 284, August 2003: Nonobstetric surgery in pregnancy. *Obstet Gynecol*. Aug 2003; 102(2): 431. PMID 12907126
10. Higuchi H, Adachi Y, Arimura S, et al. Early pregnancy does not reduce the C(50) of propofol for loss of consciousness. *Anesth Analg*. Dec 2001; 93(6): 1565-9, table of contents. PMID 11726445
11. Cohen LB, Delegge MH, Aisenberg J, et al. AGA Institute review of endoscopic sedation. *Gastroenterology*. Aug 2007; 133(2): 675-701. PMID 17681185
12. McCarty TR, Hathorn KE, Creighton DW, et al. Safety and sedation-associated adverse event reporting among patients undergoing endoscopic cholangiopancreatography: a comparative systematic review and meta-analysis. *Surg Endosc*. Dec 2021; 35(12): 6977-6989. PMID 33966121
13. Smith ZL, Mullady DK, Lang GD, et al. A randomized controlled trial evaluating general endotracheal anesthesia versus monitored anesthesia care and the incidence of sedation-related adverse events during ERCP in high-risk patients. *Gastrointest Endosc*. Apr 2019; 89(4): 855-862. PMID 30217726
14. Alzanbagi AB, Jilani TL, Qureshi LA, et al. Randomized trial comparing general anesthesia with anesthesiologist-administered deep sedation for ERCP in average-risk patients. *Gastrointest Endosc*. Dec 2022; 96(6): 983-990.e2. PMID 35690151
15. Wu J, Li N, Zhang J, et al. Safety and efficacy of remifentanyl-propofol combination on "muscle relaxant-free" general anesthesia for therapeutic endoscopic retrograde

- cholangiopancreatography: a randomized controlled trial. *Am J Transl Res.* 2023; 15(8): 5292-5303. PMID 37692944
16. Enestvedt BK, Eisen GM, Holub J, et al. Is the American Society of Anesthesiologists classification useful in risk stratification for endoscopic procedures?. *Gastrointest Endosc.* Mar 2013; 77(3): 464-71. PMID 23410699
 17. Agostoni M, Fanti L, Gemma M, et al. Adverse events during monitored anesthesia care for GI endoscopy: an 8-year experience. *Gastrointest Endosc.* Aug 2011; 74(2): 266-75. PMID 21704990
 18. Berzin TM, Sanaka S, Barnett SR, et al. A prospective assessment of sedation-related adverse events and patient and endoscopist satisfaction in ERCP with anesthesiologist-administered sedation. *Gastrointest Endosc.* Apr 2011; 73(4): 710-7. PMID 21316669
 19. Cote GA, Hovis RM, Ansstas MA, et al. Incidence of sedation-related complications with propofol use during advanced endoscopic procedures. *Clin Gastroenterol Hepatol.* Feb 2010; 8(2): 137-42. PMID 19607937
 20. Silvestri GA, Vincent BD, Wahidi MM, et al. A phase 3, randomized, double-blind study to assess the efficacy and safety of fospropofol disodium injection for moderate sedation in patients undergoing flexible bronchoscopy. *Chest.* Jan 2009; 135(1): 41-47. PMID 18641105
 21. Bernards CM, Hadzic A, Suresh S, et al. Regional anesthesia in anesthetized or heavily sedated patients. *Reg Anesth Pain Med.* Sep-Oct 2008; 33(5): 449-60. PMID 18774514
 22. Neal JM, Bernards CM, Hadzic A, et al. ASRA Practice Advisory on Neurologic Complications in Regional Anesthesia and Pain Medicine. *Reg Anesth Pain Med.* Sep-Oct 2008; 33(5): 404-15. PMID 18774509
 23. American Society of Anesthesiologists (ASA). Statement on safe use of propofol (Amended October 2019). 2019; <https://www.asahq.org/standards-and-practice-parameters/statement-on-safe-use-of-propofol>. Accessed September 10, 2023.
 24. American Society of Anesthesiologists (ASA). Statement on anesthetic care during interventional pain procedures for adults. Amended October 13, 20. 2021; <https://www.asahq.org/standards-and-practice-parameters/statement-on-anesthetic-care-during-interventional-pain-procedures-for-adults>. Accessed September 13, 2023.
 25. American Society of Anesthesiologists (ASA). Statement on Respiratory Monitoring during Endoscopic Procedures (Amended October 2019). 2019; <https://www.asahq.org/standards-and-practice-parameters/statement-on-respiratory-monitoring-during-endoscopic-procedures>. Accessed September 14, 2023.
 26. Early DS, Lightdale JR, Vargo JJ, et al. Guidelines for sedation and anesthesia in GI endoscopy. *Gastrointest Endosc.* Feb 2018; 87(2): 327-337. PMID 29306520
 27. Rizk MK, Sawhney MS, Cohen J, et al. Quality indicators common to all GI endoscopic procedures. *Am J Gastroenterol.* Jan 2015; 110(1): 48-59. PMID 25448874
 28. Chandrasekhara V, Early DS, Acosta RD, et al. Modifications in endoscopic practice for the elderly. *Gastrointest Endosc.* Jul 2013; 78(1): 1-7. PMID 23664042
 29. Calderwood AH, Chapman FJ, Cohen J, et al. Guidelines for safety in the gastrointestinal endoscopy unit. *Gastrointest Endosc.* Mar 2014; 79(3): 363-72. PMID 24485393
 30. Vargo JJ, Cohen LB, Rex DK, et al. Position statement: nonanesthesiologist administration of propofol for GI endoscopy. *Gastrointest Endosc.* Dec 2009; 70(6): 1053-9. PMID 19962497

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - Anesthesiologist or proceduralist pre-operative assessment, including but not limited to ASA class, applicable comorbidities, high risk drug or alcohol use (both prescription and illegal), physical findings, pregnancy status or any other feature that might place the patient at high risk

- Procedure performed and pre-operative anticipated duration, including but not limited to if it was an anticipated complex or prolonged procedure
- Reason monitored anesthesia care is required

Post Service (in addition to the above, please include the following):

- Operative and anesthesia report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	00520	Anesthesia for closed chest procedures; (including bronchoscopy) not otherwise specified
	00635	Anesthesia for procedures in lumbar region; diagnostic or therapeutic lumbar puncture
	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
	01937	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic
	01938	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral
	01939	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic
	01940	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral
	01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic
	01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral
	01991	Anesthesia for diagnostic or therapeutic nerve blocks and injections (when block or injection is performed by a different physician or other qualified health care professional); other than the prone position

Type	Code	Description
	96373	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial
	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
	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)
HCPCS	G9654	Monitored anesthesia care (MAC)

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/28/2013	BCBSA Medical Policy adoption
01/30/2015	Coding Update
06/30/2015	Policy revision without position change Coding Update
09/30/2015	Policy revision without position change
01/01/2016	Coding Update
01/01/2017	Policy revision without position change Coding Update
01/01/2018	Policy revision without position change Coding Update
01/01/2019	Policy revision without position change
02/01/2020	Annual review. No change to policy statement. Literature review updated.
03/01/2020	Administrative Update. Policy statement and guidelines updated.
02/01/2021	Annual review. No change to policy statement. Literature review updated.
01/01/2022	Annual review. No change to policy statement. Policy guidelines and literature review updated. Coding update.
02/01/2022	Coding update
01/01/2023	Annual review. Policy statement, guidelines and literature review updated.
01/01/2024	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER
<p>Monitored Anesthesia Care 7.02.01</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. The use of monitored anesthesia care (MAC) 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: <ol style="list-style-type: none"> A. Increased risk for complications due to severe comorbidity (American Society of Anesthesiologists [ASA] class III, IV, or V [Table PGI]) B. Morbid obesity (body mass index [BMI] greater than 40 kg/m²) C. Documented clinically significant obstructive sleep apnea; See Policy Guidelines D. Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment) E. Spasticity or movement disorder complicating the procedure F. History of (or anticipated) intolerance to standard sedatives, such as: <ol style="list-style-type: none"> 1. Chronic opioid use 2. Chronic benzodiazepine use G. Individuals with active medical problems related to drug or alcohol abuse H. Individuals younger than 18 years or 70 years or older I. Individuals who are pregnant J. Individuals with increased risk for airway obstruction due to anatomic variation, such as: <ol style="list-style-type: none"> 1. History of stridor 2. Dysmorphic facial features 3. Oral abnormalities (e.g., macroglossia) 4. Neck abnormalities (e.g., neck mass) 5. Jaw abnormalities (e.g., micrognathia) K. Acutely agitated, uncooperative individuals 	<p>Monitored Anesthesia Care 7.02.01</p> <p>Policy Statement:</p> <ol style="list-style-type: none"> I. The use of monitored anesthesia care (MAC) 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: <ol style="list-style-type: none"> A. Increased risk for complications due to severe comorbidity (American Society of Anesthesiologists [ASA] class III, IV, or V [Table PGI]) B. Morbid obesity (body mass index [BMI] greater than 40 kg/m²) C. Documented clinically significant obstructive sleep apnea; See Policy Guidelines D. Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment) E. Spasticity or movement disorder complicating the procedure F. History of (or anticipated) intolerance to standard sedatives, such as: <ol style="list-style-type: none"> 1. Chronic opioid use 2. Chronic benzodiazepine use G. Individuals with active medical problems related to drug or alcohol abuse H. Individuals younger than 18 years or 70 years or older I. Individuals who are pregnant J. Individuals with increased risk for airway obstruction due to anatomic variation, such as: <ol style="list-style-type: none"> 1. History of stridor 2. Dysmorphic facial features 3. Oral abnormalities (e.g., macroglossia) 4. Neck abnormalities (e.g., neck mass) 5. Jaw abnormalities (e.g., micrognathia) K. Acutely agitated, uncooperative individuals

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<p>L. Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section)</p> <p>Table PG1. ASA's Physical Status Classification System</p> <table border="1"> <thead> <tr> <th>Class</th> <th>Definition</th> </tr> </thead> <tbody> <tr> <td>ASA I</td> <td>A normal, healthy individual</td> </tr> <tr> <td>ASA II</td> <td>An individual with mild systemic disease</td> </tr> <tr> <td>ASA III</td> <td>An individual with severe systemic disease</td> </tr> <tr> <td>ASA IV</td> <td>An individual with severe systemic disease that is a constant threat to life</td> </tr> <tr> <td>ASA V</td> <td>A moribund individual who is not expected to survive without the operation</td> </tr> <tr> <td>ASA VI</td> <td>A declared brain-dead individual whose organs are being harvested</td> </tr> </tbody> </table> <p>ASA: American Society of Anesthesiologists.</p> <p>II. The use of monitored anesthesia care is considered investigational for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in individuals at average risk related to use of anesthesia and sedation.</p> <p>Note: For dental anesthesia procedures see Blue Shield Medical Policy: Dental Anesthesia.</p>	Class	Definition	ASA I	A normal, healthy individual	ASA II	An individual with mild systemic disease	ASA III	An individual with severe systemic disease	ASA IV	An individual with severe systemic disease that is a constant threat to life	ASA V	A moribund individual who is not expected to survive without the operation	ASA VI	A declared brain-dead individual whose organs are being harvested	<p>L. Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section)</p> <p>II. The use of monitored anesthesia care is considered investigational for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in individuals at average risk related to use of anesthesia and sedation.</p>
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