Medical Policy

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Populations	Interventions	Comparators	Outcomes
Individuals: • With planned endoscopy and certain risk factors or significant medical conditions	Interventions of interest are: • Monitored anesthesia care	Comparators of interest are: • Sedation or analgesia without monitored anesthesia care	Relevant outcomes include: • Overall survival • Morbid events • Hospitalizations • Treatment-related mortality • Treatment-related morbidity
Individuals: • With a planned bronchoscopy and certain risk factors or significant medical conditions	Interventions of interest are: • Monitored anesthesia care	Comparators of interest are: • Sedation or analgesia without monitored anesthesia care	Relevant outcomes include: • Overall survival • Morbid events • Hospitalizations • Treatment-related mortality • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: •With planned interventional pain management procedure and certain risk factors or significant medical conditions	Interventions of interest are: •Monitored anesthesia care	Comparators of interest are: •Sedation or analgesia without monitored anesthesia care	Relevant outcomes include: •Overall survival •Morbid events •Hospitalizations •Treatment-related mortality •Treatment-related morbidity

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.

OBJECTIVE

The objective of this evidence review is to evaluate in which situations outpatient monitored anesthesia care should be used during diagnostic or therapeutic procedures involving outpatient endoscopy, bronchoscopy, or interventional pain management.

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.[1,2,] 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.

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.

POLICY

A. Use of monitored anesthesia care may be considered **medically necessary** for gastrointestinal endoscopy, bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs 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:

1. Increased risk for complications due to severe comorbidity (American Society of Anesthesiologists class III, IV, or V [Table PG1])
2. Morbid obesity (BMI [body mass index] >40 kg/m^2)
3. Documented sleep apnea
4. Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
5. Spasticity or movement disorder complicating the procedure
6. History or anticipated intolerance to standard sedatives, such as:
   a. Opioid dependent
   b. Benzodiazepine dependent
7. Individuals with active medical problems related to drug or alcohol abuse
8. Individuals younger than 13 years or 70 years or older
9. Individuals who are pregnant
10. Individuals with increased risk for airway obstruction due to anatomic variation, such as:
    a. History of stridor
    b. Dysmorphic facial features
    c. Oral abnormalities (e.g., macroglossia)
    d. Neck abnormalities (e.g., neck mass)
    e. Jaw abnormalities (e.g., micrognathia)
11. Acutely agitated, uncooperative individuals
12. Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section).

B. Use of monitored anesthesia care is considered **not medically necessary** for gastrointestinal endoscopic, bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization or PTCAs in individuals at average risk related to use of anesthesia and sedation.

POLICY GUIDELINES

This policy only addresses anesthesia services for diagnostic or therapeutic procedures involving gastrointestinal endoscopy, bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs 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
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.

A. Monitored Anesthesia Care
Monitored anesthesia care can be provided by qualified anesthesia personnel with training and experience in:
1. Patient assessment
2. Continuous evaluation and monitoring of patient physiological functions
3. Diagnosis and treatment (both pharmacologic and nonpharmacologic) of any and all deviations in physiological function.

B. Procedural and Patient Risks
1. 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, and complex therapeutic procedures such as plication of the cardioesophageal junction.
2. 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, as follows:
   Class I: The tonsils, uvula and soft palate are fully visible
   Class II: The hard and soft palate, uvula and upper portion of the tonsils are visible
   Class III: The hard and soft palate and the uvula base are visible
   Class IV: Only the hard palate is visible

3. 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 monitored anesthesia care, it may be considered in determining risk for airway obstruction. Other tests to predict difficult tracheal intubation include the upper lip bite test, the intubation difficulty scale, and the Cormack-Lehane grading system.

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.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through September 30, 2024.

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 neuromusclar 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); NCT02850887[13],	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); NCT04099693[14],	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); NCT04087668 [15],	Intraprocedural 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); NCT02850887[13,]	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); NCT04099693[14,]	4. Race/ethnicity of participants not described; study conducted in Saudi Arabia	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	
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.[2,]

"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.[24,] 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).[25,] 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.[26,] 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.[27,] 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.[28,]:

"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.[29,] 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.

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)
Ongoing			
NCT04107038	A Randomized Controlled Trial Comparing Monitored Anesthesia Care Versus General Anesthesia With Transesophgeal Echocardiography for Transcatheter Aortic Valve Replacement	170	Dec 2025
Unpublished		**Actual Enrollment**	
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.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
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
01920	Anesthesia for cardiac catheterization including coronary angiography and ventriculography (not to include Swan-Ganz catheter)
01922	Anesthesia for non-invasive imaging or radiation therapy
01991	Anesthesia for diagnostic or therapeutic nerve blocks and injections (when block or injection is performed by a different provider); other than prone position
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 or drug

REVISIONS	
09-10-2010	Description Section updated
	In Policy Section: ▪ Added the following not medically necessary statement: "A. Monitoring of sedation by an anesthesia provider for gastrointestinal endoscopies, CT scans, MRIs, cardiac catheterizations, and PTCAs is generally considered not medically necessary."

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	▪ Rephrased "sleep apnea" to "9. Patients with increased risk for airway obstruction due to anatomic variation including a history of sleep apnea or stridor, dysmorphic facial features, and certain oral (e.g., macroglossia), neck (e.g., neck mass), and jaw (e.g., micrognathia) abnormalities." ▪ Added the following medically necessary indications in B.: "7. Prolonged or therapeutic endoscopic procedures requiring deep sedation, or "8. Acutely agitated uncooperative patients, or " ▪ Added the following not medically necessary indication: "C. Use of monitored anesthesia care is considered not medically necessary for procedures in patients at average risk related to use of anesthesia and sedation."
	Rationale Section added
	In Diagnosis Section: ▪ Added the following Gastrointestinal diagnosis code ranges: 152.0-152.9, 153.0-153.9, 154.0-154.8, 155.1, 156.1-156.9, 157.0-157.9, 211.3, 574.00-576.9, 577.0-577.9, V12.72, V16.0, V18.51, V76.51 ▪ Converted diagnosis codes to code ranges.
	References Section updated
01-28-2011	In Policy Section: ▪ Added the word "HOWEVER" between Item A and Item B. ▪ No change in the policy language was made.
	In Coding Section: ▪ Added, "…to include ASCs" to read, "Unusual anesthesia is an additional level of services that are applicable to endoscopies to address those patients who receive services in a hospital setting, to include ASCs. Claims for this level should be billed using 00740 or 00810 with modifier 23 describing unusual anesthesia only when performed as inpatient or outpatient at a hospital setting, to include ASCs."
02-05-2014	Policy reviewed.
	In Coding section: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
10-01-2015	Published 05-18-2016. Effective 10-01-2015 with ICD-10 coding implementation.
	In Coding section: Added ICD-10 Code: E66.01
07-01-2016	Published 05-25-2016. Effective 07-01-2016.
	Title revised from "Monitored and General Anesthesia Services" to "Monitored Anesthesia Care"
	Description section updated
	In Policy section: ▪ Removed "Monitoring of sedation by an anesthesia provider for gastrointestinal endoscopies, CT scans, MRIs, cardiac catheterizations, and PTCAs is generally considered not medically necessary. HOWEVER," ▪ In Item A removed "or general anesthesia" and "billed with any of the following conditions:" and added "Use of", "bronchoscopy, interventional pain procedures" and "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:" to read "Use of monitored anesthesia care may be considered medically necessary for gastrointestinal endoscopy, bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs 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:"

REVISIONS	
	▪ Revised Item A 1 to read "Increased risk for complications due to severe comorbidity (ASA P3* or greater)" ▪ Revised Item A 2 to read "Morbid obesity (BMI [body mass index] >40) ▪ Revised Item A 3 to read "Documented sleep apnea" ▪ Added Item A 4 "Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)" ▪ Added Item A 5 " Spasticity or movement disorder complicating procedure" ▪ In Item A 6 removed "alcohol" and revised to read "History or anticipated intolerance to standard sedatives, such as: a. Opioid dependent b. Benzodiazepine dependent" ▪ Added Item A 7 "Patients with active medical problems related to drug or alcohol abuse" ▪ Revised Item A 8 to read "Patients younger than 13 years or 70 years or older" ▪ Revised Item A 9 to read "Patients who are pregnant" ▪ Revised Item A 10 to read "Patients with increased risk for airway obstruction due to anatomic variation including a history of such as: a. History of stridor b. Dysmorphic facial features c. Oral abnormalities (e.g., macroglossia) d. Neck abnormalities (e.g., neck mass) e. Jaw abnormalities (e.g., micrognathia)" ▪ In Item A 12 added "gastrointestinal" and "(See Policy Guidelines)" to read " Prolonged or therapeutic gastrointestinal endoscopic procedures requiring deep sedation (See Policy Guidelines)" ▪ Added asterisk reference of "* American Society of Anesthesiologists (ASA) physical status classification system for assessing a patient before surgery: P1 – A normal, healthy patient P2 – A patient with mild systemic disease P3 – A patient with severe systemic disease P4 – A patient with severe systemic disease that is a constant threat to life P5 – A moribund patient who is not expected to survive without the operation P6 – A declared brain-dead patient whose organs are being harvested" ▪ In Item B added "bronchoscopy, interventional pain procedures" to read "Use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopy, bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs in patients at average risk related to use of anesthesia and sedation." Policy Guidelines added
	Rationale section updated
	In Coding section: ▪ Updated Coding notations. ▪ Added ICD-10 Codes: C15.3, C15.4, C15.5, C15.8, C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C34.01, C34.02, C34.11, C34.12, C34.2, C34.31, C34.32, C34.81, C34.82, D14.31, D14.32
	References updated
10-01-2016	Published 09-15-2016. Revision effective 10-01-2016.
	In the coding section: ▪ ICD-10 Codes Effective 10-01-2016: C49A1, C49A2, K85.00, K85.01, K85.02, K85.10, K85.11, K85.12, K85.20, K85.21, K85.22, K85.30, K85.31, K85.32, K85.80, K85.81, K85.82, K85.90, K85.91, K85.92, K86.81, K86.89, O00.00, O00.01, O00.80,

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	O00.81,O00.90, O00.91, O11.4, O11.5, O12.04, O12.14, O12.24, O13.4, O14.05, O14.15, O14.24, O14.94, O16.4, O24.415, O24.425, O24.435, O33.7XX1, O33.7XX2, O33.7XX3, O33.7XX4, O33.7XX5, O33.7XX9, O34.211, O34.212, O44.21, O44.22, O44.23, O44.31, O44.32, O44.33, O44.42, O44.43, O44.51, O44.52, O44.53, Z33.3 ▪ ICD-10 Codes Termed 09-30-2016: K85.0, K85.1, K85.2, K85.3, K85.8, K85.9, K86.8, O00.0, O00.8, O00.9, O33.7, O33.8 ▪ Revised ICD-10 Codes Effective 10-01-2016: O09.11, O09.12, O09.13, O15.02, O15.03, O15.1, O15.2, O24.011, O24.012, O24.013, O24.02, O24.03, O24.111, O24.112, O24.113, O24.12, O24.13, O44.01, O44.02, O44.03, O44.11, O44.12, O44.13
01-01-2017	Policy Published 12-20-2016. Policy effective 01-01-2017.
	Corrected July 2016 Revision date from "07-01-2015" to "07-01-2016"
	Description section updated
	In Policy section ▪ In Item A removed "gastrointestinal endoscopy" to read "Use of monitored anesthesia care may be considered medically necessary for bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs when there is documentation by the proceduralist and anesthesiologist that specific risk factors or significant medical conditions are present." ▪ Removed Item A 12 "Prolonged or therapeutic gastrointestinal endoscopic procedures requiring deep sedation (See Policy Guidelines)" ▪ In Item B removed "gastrointestinal endoscopy" to read "Use of monitored anesthesia care is considered not medically necessary for bronchoscopy, interventional pain procedures, CT scans, MRIs, cardiac catheterization and PTCAs in patients at average risk related to use of anesthesia and sedation." ▪ Updated Policy Guidelines
	Rationale updated
	In Coding section: ▪ Removed CPT Codes: 00740, 00810 ▪ Removed ICD-9 Codes: 152.0-152.9, 153.0-153.9, 154.0-154.8, 155.1, 156.1-156.9, 157.0-157.9, 211.3, 574.00-576.9, 577.0-577.9, V12.72, V16.0, V18.51, V76.51 ▪ Removed ICD-10 Codes: C49A1, C49A2, D12.0, D12.1, D12.2, D12.3, D12.4, D12.5, D12.6, K63.5, K80.00, K80.01, K80.10, K80.11, K80.12, K80.13, K80.18, K80.19, K80.20, K80.21, K80.32, K80.33, K80.34, K80.35, K80.36, K80.37, K80.40, K80.41, K80.42, K80.43, K80.44, K80.45, K80.46, K80.47, K80.50, K80.51, K80.60, K80.61, K80.62, K80.63, K80.64, K80.65, K80.66, K80.67, K80.70, K80.71, K80.80, K80.81, K81.0, K81.1, K81.2, K81.9, K82.0, K82.1, K82.2, K82.3, K82.4, K82.8, K82.9, K83.0, K83.1, K83.2, K83.3, K83.4, K83.5, K83.8, K83.9, K85.00, K85.01, K85.02, K85.10, K85.11, K85.12, K85.20, K85.21, K85.22, K85.30, K85.31, K85.32, K85.80, K85.81, K85.82, K85.90, K85.91, K85.92, K86.0, K86.1, K86.2, K86.3, K86.81, K86.89, K86.9, K87, K91.5
	References update
01-01-2017	Policy published 01-18-2017. Policy retro-effective to 01-01-2017.
	Description section updated to remove information regarding endoscopy.
	Rationale section updated to remove information regarding endoscopy.
	In Coding section: ▪ Removed ICD-10 Codes regarding endoscopy: B25.2, C15.3, C15.4, C15.5, C15.8, C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C17.0, C17.1, C17.2, C17.3, C17.8, C17.9, C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20, C21.0, C21.1, C21.2, C21.8, C22.1, C24.0, C24.1, C24.8, C24.9, C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9, Z12.11, Z80.0, Z83.71, Z86.010 ▪ Removed the following coding notation: "Unusual anesthesia is an additional level of services that are applicable to endoscopies to address those patients who receive

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	services in a hospital setting, to include ASCs. Claims for this level should be billed using 00740 or 00810 with modifier 23 describing unusual anesthesia only when performed as inpatient or outpatient at a hospital setting, to include ASCs."
	Reference section updated to remove information regarding endoscopy.
10-01-2017	In Coding Section: ▪ Added ICD Codes: O36.8311, O36.8312, O36.8313, O36.8314, O36.8315, O36.8319, O36.8321, O36.8322, O36.8323, O36.8324, O36.8325, O36.8329, O36.8331, O36.8332, O36.8333, O36.8334, O36.8335, O36.8339, O36.8391, O36.8392, O36.8394, O36.8395, O36.8399
10-01-2018	In Coding Section: ▪ Added ICD Codes: O30.131, O30.132, O30.133, O30.139, O30.231, O30.232, O30.233, O30.239, O30.831, O30.832, O30.833, O30.839
03-09-2021	Description section updated
	Rationale section updated
	References section updated
01-13-2022	Updated Description Section
	Updated Rationale Section
	Updated Codes Section ▪ Changed ICD-10 codes to code ranges
	Updated References Section
01-30-2023	Updated Description Section
	Updated Policy Section ▪ Section A and B Added "gastrointestinal endoscopy" to Statement. ▪ Section A1 changed "P3* or greater" to "Class III, IV, or V[table PG1]" ▪ Removed "*American Society of Anesthesiologists' physical status classification system for assessing a patient before surgery: ▪ P1 – A normal, healthy patient ▪ P2 – A patient with mild systemic disease ▪ P3 – A patient with severe systemic disease ▪ P4 – A patient with severe systemic disease that is a constant threat to life ▪ P5 – A moribund patient who is not expected to survive without the operation ▪ P6 – A declared brain-dead patient whose organs are being harvested ▪ policy only addresses anesthesia services for diagnostic or therapeutic procedures involving gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures performed in the outpatient setting."
	Updated Rationale Section
	Updated Coding Section ▪ Added 00520, 00635, 00731, 00732, 00811, 00812, 00813, 01936, 01991, 96373, 96374 ▪ Removed Coding Bullets o 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). o For other medical conditions increasing the risk in requiring monitored or general anesthesia services for these procedures such as behavioral, dysmorphic, and neurological conditions, please attach Modifier-22 and submit medical records.
	Updated References Section
01-05-2024	Updated Description Section
	Updated Policy Section

REVISIONS	
	▪ Under section A added A 12 "Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (see Policy Guidelines section)"
	Updated Policy Guidelines 4. Under section B added B1 "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, and complex therapeutic procedures such as plication of the cardioesophageal junction."
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section
12-23-2024	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed deleted code 01936
	Updated References Section

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