Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Title: Monitored Anesthesia Care

Description/Background

Overview of Monitored Anesthesia Care (MAC)
MAC is a spectrum 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) has defined MAC,[1, 2] and the following is derived from 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 pre-procedure visit, intraprocedure care, and post-procedure 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 of 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.
>
> MAC may include varying levels of sedation, analgesia, and anxiolysis, as necessary. The provider of MAC 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), ASA defined 4 levels of sedation/ 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 to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable even with painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Adapted from American Society of Anesthesiologists (2013).[3]
ASA: American Society of Anesthesiologists

Because sedation is a continuum, it is not always possible to predict how an individual 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 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 non-anesthesiologists. 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. ASA has offered practice guidelines for the provision of sedation by non-anesthesiologists, 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 induction of general anesthesia in patients three years of age and older and maintenance of general anesthesia in patients two months of age and older.

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

Medical Policy Statement

Use of monitored anesthesia care may be considered established for gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures when criteria are met. In addition, MAC may be considered established for these procedures when there is documentation by the proceduralist and/or anesthesiologist that indicates MAC is recommended.

Inclusionary and Exclusionary Guidelines

MAC is considered medically necessary for patients with risk factors and/or significant medical conditions that increase the risk of sedation, including but not limited to any of the following:

- Increased risk for complications due to severe comorbidity (ASA P3* or greater)
- Morbid obesity (BMI [body mass index] ≥35kg/m^2)
- History of adverse reaction to sedation
- History of failed airway
- Documented sleep apnea
- Certain infectious, cardiometabolic, hepato-renal, digestive disorder, central neurologic, and psychiatric comorbidities that may be reasonably expected to

contribute to adverse events, including diabetes, hypertension, arrythmia, chronic renal failure, liver disease, dysphagia, inflammatory bowel disease, gastroparesis, painful anorectal conditions and prior colon surgery, epilepsy and phobia
- Coagulopathy and bleeding disorders
- Prior esophageal surgery
- Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
- Spasticity or movement disorder complicating procedure
- History or anticipated intolerance to standard sedatives, such as
  - Chronic opioid use
  - Chronic benzodiazepine use
- Patients with active medical problems related to drug or alcohol abuse
- Patients younger than age 18 or age 70 years or older
- Patients who are pregnant
- Patients with increased risk for airway obstruction due to anatomic variation, such as:
  - History of stridor
  - Dysmorphic facial features
  - Oral abnormalities (e.g., macroglossia)
  - Neck abnormalities (e.g., neck mass)
  - Jaw abnormalities (e.g., micrognathia)
- Acutely agitated, uncooperative patients
- Prolonged or therapeutic gastrointestinal endoscopy procedures requiring deep sedation (e.g., endoscopic retrograde cholangiopancreatography [ERCP], transduodenal biopsy, double balloon enteroscopy).
- MAC may be considered established for these procedures when there is documentation by the proceduralist and/or anesthesiologist that indicates MAC is recommended.

**American Society of Anesthesiologists (ASA) physical status classification system for assessing a patient before surgery:*

ASA PS Category	Preoperative Health Status	Examples
ASA PS 1	Normal healthy patient	No organic, physiologic, or psychiatric disturbance; excludes the very young and very old; healthy with good exercise tolerance
ASA PS 2	Patients with mild systemic disease	No functional limitations; has a well-controlled disease of one body system; controlled hypertension or diabetes without systemic effects, cigarette smoking without COPD; mild obesity, pregnancy
ASA PS 3	Patients with severe systemic disease	Some functional limitation; has a controlled disease of more than one body system or one major system; no immediate danger of death; controlled CHF, stable angina, old heart attack, poorly controlled hypertension, morbid obesity, chronic renal failure; bronchospastic disease with intermittent symptoms
ASA PS 4	Patients with severe systemic disease that is a constant threat to life	Has at least one severe disease that is poorly controlled or at end stage; possible risk of death; unstable angina, symptomatic COPD, symptomatic CHF, hepatorenal failure
ASA PS 5	Moribund patients who are not expected to survive without the surgery	Not expected to survive > 24 hours without surgery; imminent risk of death; multiorgan failure, sepsis syndrome with hemodynamic instability, hypothermia, poorly controlled coagulopathy
ASA PS 6	A declared brain-dead patient whose organs are being removed for donor purposes	

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

00520	00635	01991	00731	00732
00811	00812	00813	96373	96374

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of 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, two domains are examined: the relevance, and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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.

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

MAC with Endoscopy

Clinical Context and Therapy Purpose

The purpose of MAC in individuals 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 **PICOs** were used to select literature to inform this review.

Populations
The relevant populations of interest are individuals with planned endoscopy and certain risk factors or significant medical conditions

Interventions
The therapy being considered is MAC. MAC is administered intravenously during outpatient surgical procedures by anesthesiologists.

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

Outcomes
The general outcome of interest is morbid events (e.g., vomiting, nausea).

This mild level of sedation wears off with 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.

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 is relevant for this evidence review.[5] The AGAI review recommended that use of an anesthesia professional should be strongly considered for American Society of Anesthesiologists (ASA) physical status 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 1,899 patients undergoing endoscopic cholangiopancreatography who had deep sedation with MAC (n=1284) versus general endotracheal anesthesia (n=615).[13,] Five studies were included (1 RCT, 2 prospective studies, and 2 retrospective studies). Outcomes included procedure success, all-cause and

anesthesia-associated adverse events, and post-procedure recovery time. Results revealed that total anesthesia-associated adverse events were not different between the groups (odds ratio [OR], 1.33; 95% confidence interval [CI], 0.27 to 6.49). When evaluating anesthesia-associated events by type, MAC resulted in fewer episodes of clinically significant hypotension (OR, 0.32; 95% CI, 0.12 to 0.87), increased hypoxemic events (OR, 5.61; 95% CI, 1.54 to 20.37), and no difference in cardiac arrhythmias (OR, 0.48; 95% CI, 0.13 to 1.78). Additionally, the groups were similar with regard to all-cause total adverse events (OR, 1.16; 95% CI, 0.29 to 4.70) and time to recovery from anesthesia; however, mean procedure time was reduced with MAC. The procedure success rate was similar between the groups (OR, 1.16; 95% CI, 0.51 to 2.64). The authors noted there was significant heterogeneity among included studies (e.g., differences in patient population with regard to age, gender, body mass index (BMI), and ASA status; indications for endoscopic cholangiopancreatography) and concluded 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); 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 (AEs) and as a useful tool for risk stratification.

Agostoni et al (2011) evaluated a prospective database of 17,999 GI endoscopies performed under MAC during from 2001 to 2009.[17] The authors identified six variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year odds

ratio [OR], 1.02; 95% confidence interval [CI], 0.01 to 1.02), body mass index [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 1-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<0.001).[18] Patients with obesity experienced respiratory events almost twice as often as patients who were not obese (p=0.03). Higher ASA class was not associated with adverse respiratory events under MAC (OR=1.2, p=0.25) but was associated with cardiovascular events (OR=2.88, p<0.001).

Coté et al (2010) reported on another prospective observational study on 766 patients undergoing advanced endoscopic procedures (e.g., ERCP, endoscopic ultrasound, and small bowel enteroscopy) who received propofol.[19] These procedures are notable for their duration and complexity compared with diagnostic esophagogastroduodenoscopy (EGD). The primary outcome measure was airway modifications (AM), with a comparison of defining characteristics of the group requiring at least one airway modification (e.g., chin lift, nasal airway), to those requiring no modification. No patients in the study required endotracheal intubation. BMI, 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: MAC with Endoscopy
The evidence comparing different anesthetic methods is not robust, consisting primarily of nonrandomized comparisons and observational 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'.

MAC with Bronchoscopy

Clinical Context and Therapy Purpose
The purpose of MAC in individuals 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 **PICOs** were used to select literature to inform this review.

Populations
The relevant populations of interest are individuals with planned bronchoscopy and certain risk factors or significant medical conditions.

Interventions
The therapy being considered is MAC. MAC is administered intravenously during outpatient surgical procedures by anesthesiologists.

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

Outcomes
The general outcome of interest is morbid events (e.g., vomiting, nausea).

This mild level of sedation wears off with minutes after the sedative is discontinued, so short-term follow-up is of interest.

Review of Evidence
No RCTs or nonrandomized comparative studies evaluating MAC and non-anesthesiologist 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 two 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 2mg/kg or 6.5 mg/kg, followed by additional doses per protocol. All patients received a preprocedural dose of fentanyl. The primary end point 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; $p<0.001$). Treatment success also favored the higher dose group (91.3% vs. 41.25, respectively; $p<0.001$). 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: MAC 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.

MAC with Interventional Pain Management

Clinical Context and Therapy Purpose
The purpose of MAC in individuals 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 **PICOs** were used to select literature to inform this review.

Populations
The relevant populations of interest are individuals with planned interventional pain management procedure and certain risk factors or significant medical conditions.

Interventions
The therapy being considered is MAC. MAC is administered intravenously during outpatient surgical procedures by anesthesiologists.

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 outcome of interest is morbid events (e.g., vomiting, nausea).

This mild level of sedation wears off with minutes after the sedative is discontinued, so short-term follow-up is of interest.

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 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.[27]

Section Summary: MAC 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.

SUMMARY OF EVIDENCE
For individuals who have planned endoscopy and certain risk factors or significant medical conditions who receive MAC, the evidence includes systematic reviews, a randomized controlled trial (RCT), and observational studies. Relevant outcomes are overall survival, morbid events, hospitalizations, and treatment-related mortality and morbidity. A literature review for the American Gastroenterological Association Institute identified potential indications requiring an anesthesia specialist. 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, systematic reviews and RCTs claiming to evaluate MAC appear to be evaluating 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have planned bronchoscopy and certain risk factors or significant medical conditions who receive MAC, the evidence includes no studies that directly address this issue. Relevant outcomes are overall survival, morbid events, hospitalizations, treatment-related mortality and morbidity. There is a lack of published evidence on MAC for

bronchoscopy procedures; no RCTs, nonrandomized comparative studies, or large case series were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have planned interventional pain management procedures and certain risk factors or significant medical conditions who receive MAC, the evidence includes no studies that directly address this issue. Relevant outcomes are overall survival, morbid events, hospitalizations, treatment-related mortality and morbidity. There is a lack of published evidence on MAC for interventional pain management procedures; no RCTs, nonrandomized comparative studies, or large case series were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Society of Anesthesiologists (ASA)

In 2019, the ASA released an updated 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,] The ASA indicated that: " 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, 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 (ASGE)
Guidelines on sedation during endoscopy were released in 2018 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, ASGE published quality indicators for all GI 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, ASGE published guidelines for endoscopic modification for geriatric patients.[28] Specific to this evidence review, ASGE recommended "standard monitoring and procedures in the elderly during moderate sedation with heightened awareness of this populations' increased response to sedatives."

In 2014, ASGE issued guidelines on the safety of the endoscopy unit, which made several recommendations regarding 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 o' 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 endoscopic ultrasound, ERCP, 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial	No. of Participants	End Date
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			
NCT02046590	A Randomized Controlled Trial (RCT) of Efficacy and Safety of Sedation Compared to General Anesthesia for Endoscopic Retrograde Cholangiopancreatography	132	Jun 2022

NCT: national clinical trial

Government Regulations

National:

There are no Medicare national coverage determinations that address the use of monitored anesthesia care in GI endoscopy, bronchoscopy, or interventional pain procedures.

Local:

There is no local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/16	6/21/16	7/20/16	Joint policy established
9/1/17	6/20/17	6/20/17	Updated rationale and references. No change in policy status.
5/1/18	2/20/18	2/20/18	Deleted codes 00740 & 00810, effective 12/1/17. Updated ASA and ASGE guidelines. Added references 29, 32 and 34. No change in policy status.
5/1/19	2/19/19		Policy updated with literature review; Code update; Reference 30 added; No change in policy status.
5/1/20	2/18/20		Routine policy maintenance, no change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Deleted code 01936. Updated rationale, added reference #13 and removed reference #35. No changes in policy status.
5/1/23	2/21/23		Updated rationale section, added reference #14. No change in policy status. (ds)
5/1/24	2/20/24		MPS changes made along with changes to inclusion/exclusion section. Updated rationale, added references. No change in policy status. Vendor managed: N/A (ds)
5/1/25	2/18/25		Annual review Vendor managed: N/A (ds)

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: MONITORED ANESTHESIA CARE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.