Policy Statement

The use of monitored anesthesia care (MAC) may be considered medially necessary for gastrointestinal endoscopy, bronchoscopy, and interventional pain procedures when there is documentation by the proceduralist or anesthesiologist that specific high-risk factors or significant medical conditions are present. Those risk factors or significant medical conditions include any of the following:

- Increased risk for complications due to severe comorbidity (American Society of Anesthesiologists [ASA] class III, IV, or V [see Table PG1])
- Morbid obesity (body mass index [BMI] greater than 40 kg/m²)
- Documented clinically significant obstructive sleep apnea (OSA); see Policy Guidelines
- Inability to follow simple commands (cognitive dysfunction, intoxication, or psychological impairment)
- Spasticity or movement disorder complicating the procedure
- History of (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 18 years or older than 70 years
- 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 (see Policy Guidelines section)

Table PG1. ASA’s Physical Status Classification System

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal, healthy patient</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>ASA V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
</tr>
<tr>
<td>ASA VI</td>
<td>A declared brain-dead patient whose organs are being harvested</td>
</tr>
</tbody>
</table>

ASA: American Society of Anesthesiologists.

The use of monitored anesthesia care is considered not medically necessary for gastrointestinal endoscopic, bronchoscopic, or interventional pain procedures in patients at average risk related to use of anesthesia and sedation.

Note: For dental anesthesia procedures see Blue Shield Medical Policy: Dental Anesthesia.

Policy Guidelines

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

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

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

Procedural and Patient Risks

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

- Endoscopy in patients with adhesions after abdominal surgery
- Endoscopic retrograde cholangiopancreatography
- Stent placement in the upper gastrointestinal tract
- Complex therapeutic procedures such as sclerotherapy of the cardioesophageal junction

The Mallampati score is considered a predictor of difficult tracheal intubation and is routinely used in preoperative anesthesia evaluation. The score is obtained by having the patient extend the neck, open the mouth, and extend the tongue while in a seated position. Patients are scored from classes I through IV (see Table PG2).

Table PG2. Mallampati Scoring System

<table>
<thead>
<tr>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>The tonsils, uvula and soft palate are fully visible</td>
</tr>
<tr>
<td>II</td>
<td>The hard and soft palate, uvula and upper portion of the tonsils are visible</td>
</tr>
<tr>
<td>III</td>
<td>The hard and soft palate and the uvula base are visible</td>
</tr>
<tr>
<td>IV</td>
<td>Only the hard palate is visible</td>
</tr>
</tbody>
</table>

Patients 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.

Clinically Significant Obstructive Sleep Apnea (OSA)

Clinically significant OSA for adults includes either of the following:

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

Clinically significant OSA for children includes either of the following:

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

Coding

For reference, the add-on code for anesthesia for patient of extreme age is:

99100: Anesthesia for patient of extreme age, younger than 1 year and older than 70 (List separately in addition to code for primary anesthesia procedure)
Adequate sedation and analgesia are important parts of many diagnostic and therapeutic procedures. Various levels of sedation and analgesia (anesthesia) may be used, depending on the patient’s condition and the procedure being performed. Monitored anesthesia care (MAC) refers to a set of physician services, not a particular level of sedation. The services include the ability to convert a patient to general anesthesia (if needed) and to intervene in the event a patient’s airway becomes compromised.

### Related Policies

- Manipulation Under Anesthesia

### Benefit Application

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

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

### Regulatory Status

In 1989, propofol Diprivan® (AstraZeneca) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for the induction and maintenance of anesthesia. The current FDA-approved label for Diprivan® states that it is indicated for initiation and maintenance of MAC sedation, combined sedation, and regional anesthesia; the label also states that Diprivan® is indicated for the sedation of adults in the intensive care unit who have been intubated or mechanically ventilated. Moreover, Diprivan® is also approved for induction of general anesthesia in patients 3 years of age and older and maintenance of general anesthesia in patients 2 months of age and older.

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

### Rationale

#### Background

**Monitored Anesthesia Care**

Monitored anesthesia care (MAC) is a set of anesthesia services defined by the type of anesthesia personnel present during a procedure, not specifically by the level of anesthesia needed. The American Society of Anesthesiologists (ASA) defined MAC,¹² 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 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.

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 2014), 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

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

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 a patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering moderate sedation or analgesia (conscious sedation) should be able to rescue patients who enter a state of deep sedation or analgesia, while those administering deep sedation or analgesia should be able to rescue patients who enter a state of general anesthesia.

### Sedation for Diagnostic and Therapeutic Procedures

Multiple diagnostic and therapeutic procedures performed in the outpatient setting (e.g., endoscopy, colonoscopy, bronchoscopy, interventional pain management procedures) rely on some degree of sedation for anxiolysis and pain control. Regardless of sedation depth, sedation and anesthesia services provided in outpatient settings should be administered by qualified and appropriately trained personnel. Moderate sedation is generally sufficient for many diagnostic and uncomplicated therapeutic procedures. Moderate sedation using benzodiazepines, with or without narcotics, is frequently administered under the supervision of the proceduralist.

According to the ASA’s standard for monitoring, MAC should be provided by qualified anesthesia personnel, including physicians and nurse specialists.² 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. ASA 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

**Literature Review**

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 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 technology, two domains are examined: the relevance, and 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.

**Monitored Anesthesia Care**

**MAC 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 question addressed in this evidence review is: Does the use of MAC improve the net health outcome in patients with planned endoscopy and certain risk factors or significant medical conditions?
The following PICO(s) were used to select literature to inform this review.

**Patients**
The relevant populations of interest are patients 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 morbidity 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.

**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. 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, 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.

**Prospective and Retrospective Studies**
Enestvedt et al (2013) retrospectively reviewed 1318495 patients who underwent 1590648 endoscopic procedures and found the risk for serious adverse events with endoscopy increased with higher ASA physical status classification, especially class ASA III to V. These findings supported the use of ASA physical status class as a predictor of periendoscopic adverse events and as a tool for risk stratification.

Agostoni et al (2011) evaluated a prospective database of 17999 GI endoscopies performed under MAC from 2001 to 2009. The authors identified 6 variables predicting any sedation-related complication using multivariate logistic regression models: age (1-year odds ratio [OR], 1.02; 95% confidence interval [CI], 1.01 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 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 endoscopic retrograde cholangiopancreatography 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). 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).
Côté et al (2010) reported on another prospective observational study of 766 patients undergoing advanced endoscopic procedures (e.g., endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, small-bowel enteroscopy) who received propofol. These procedures are notable for their duration and complexity compared with diagnostic esophagogastroduodenoscopy. The primary outcome measure was airway modifications, with a comparison of defining characteristics of the group requiring at least 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.

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

Systematic Reviews
A Cochrane review by Singh et al (2008) summarized the results of RCTs comparing the use of propofol with traditional agents for sedation during colonoscopy. The Cochrane review did not address MAC. Outcomes of interest included the technical performance of colonoscopy, patient satisfaction, and complication rates. Twenty-two studies met reviewers' inclusion criteria. Eight studies evaluated propofol as a single agent; 7 trials were published in abstract-only format, including the largest trial from 2000 (total n=7286 patients), which reported on different rates of colonic perforation. Only 1 trial (published in 2006) was double-blind. The agents administered in the control arms included benzodiazepines alone (diazepam, midazolam) or a combination of a benzodiazepine and a narcotic (pethidine, fentanyl, remifentanil, or alfentanil). Doses of agents used varied across trials. The intended level of sedation when stated was defined in most studies as that needed for patients' tolerance of the procedure. Many studies had a potential of moderate-to-high risk of bias; moreover, combining data for some of the outcomes for meta-analysis was problematic.

Recovery time (reported in 11 studies; 776 patients) was shorter with propofol than with the control arm (weighted mean difference, -14.2 minutes; 95% CI, -17.6 to -10.8 minutes), with no significant heterogeneity (p=0.41). Discharge time (7 studies; 542 patients) was also reported as shorter with propofol (weighted mean difference =20.9 minutes; 95% CI, -30.9 to 10.8 minutes); however, there was significant heterogeneity among studies (p<0.001). There was higher patient satisfaction (10 studies; 819 patients) with the use of propofol (OR for dissatisfaction, 0.35; 95% CI, 0.23 to 0.53). There was no difference in procedure time (9 studies; 736 patients) or complication rates. There was also no difference in pain control with non-patient-controlled sedation (5 studies; 396 patients) between propofol and the control arm (OR=0.90; 95% CI, 0.58 to 1.39). Reviewers found only a single RCT (2011), reported in abstract format, for the secondary objective, comparison of propofol administration between anesthesiologists and endoscopists.

Randomized Controlled Trials
An RCT published by Shen et al (2015) evaluated the safety, complication rates, and patient and examiner satisfaction with 2 different sedation regimens in patients ages 60 to 80 years undergoing outpatient diagnostic gastroscopy. The trial included 720 patients randomized to etomidate-remifentanil (n=360) or propofol-remifentanil (n=360). Five subjects in the etomidate-remifentanil group were excluded from the analysis. Patients in the propofol-remifentanil group demonstrated decreases in their systolic and diastolic blood pressures and heart rates during and after the gastroscopy compared with baseline (p<0.05). For subjects in the propofol-remifentanil group, average systolic blood pressure dropped from 125 mm Hg preprocedure to 95 mm Hg during the gastroscopy; average diastolic blood pressure dropped from 67 to 52 mm Hg; and average heart rate dropped from 75 to 70 bpm (data extrapolated from graphs). The authors stated that “the decrease of these cardiopulmonary function parameters led to adverse effects in older patients,” but the adverse events are not specified. Compared with those in the etomidate-remifentanil group, patients in the propofol-remifentanil group were more likely to have hypoxemia (21.39% vs 12.68% p=0.002), injection pain (22.5% vs 0.85% p<0.001), and body
quiver (43.06% vs 19.15%; p<0.001). Those in the etomidate-remifentanil group were more likely to have myoclonus (4.51% vs 0.83%; p=0.002). There were no significant differences between groups for duration time, recovery time, and time to leave the recovery room.

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

In the single RCT included in the Cochrane review previously described, Poincloux et al (2011) randomized 90 adults (from a university center in France) undergoing colonoscopy to propofol administration by anesthesiologists (group A) or endoscopists (group B). The goal of propofol administration among anesthesiologists was anesthesia; the goal of propofol administration among endoscopists was sedation. There was no difference in procedure time (16.7 minutes for group A vs 17.7 minutes for group B) or patient satisfaction (average visual analog scale score, 90.8 vs 89). Subjects in group A indicated greater willingness to undergo further colonoscopies under the same conditions (95% vs 79% p=0.02). A higher proportion of patients administered propofol by an anesthesiologist experienced hypoxia, but no patient required an intervention.

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

De Paulo et al (2015) published a comparative observational study of 2000 outpatients undergoing GI endoscopy at a tertiary care hospital. A total of 1000 patients underwent MAC with propofol and 1000 had nonanesthesiologist administration of propofol (NAAP) administered by endoscopists. To comply with local regulations, an anesthesiologist was in the room when propofol was administered by endoscopists. Compared with the MAC group, the NAAP group had a greater proportion of patients who received fentanyl in addition to propofol (50.5% vs 61.1%; p<0.05), and fewer patients who underwent deep sedation (66.1% vs 44.7%; p<0.05). The proportion of patients experiencing hypoxemia did not differ significantly between groups, but when hypoxemia occurred, it lasted significantly longer in the NAAP group (mean, 7.26 seconds) than in the MAC group (mean, 4.22 seconds). The rate of bag-mask ventilation (3 [0.3%] in the NAAP group vs 6 [0.6%] in the MAC group) did not differ significantly between groups. Only 4 (0.4%) patients in the NAAP group and 3 (0.3%) in the MAC group expressed dissatisfaction (e.g., stated they would not repeat the procedure in the same manner).

Seg et al (2014) reported on outcomes from a prospective, multicenter study of endoscopist-directed sedation with propofol in 53 German outpatient gastroenterology practices. The study included 24441 subjects who underwent 13793 colonoscopies, and 4181 combination procedures. Propofol monosedation was used in 52% of the patients, while 48% received a combination of midazolam and propofol. Major adverse events occurred in 4 (0.016%) patients, including 3 requirements for mask ventilation and 1 laryngospasm. Minor adverse events included hypoxemia in 93 (0.381%) patients, intestinal bleeding in 12 (0.049%) patients, bradycardia in 7 (0.029%) patients, and persistent hypotension requiring intravenous fluids in 5 (0.02%) patients. Propofol monosedation was associated with a higher probability of hypoxemia (0.50%) compared with propofol-midazolam sedation (0.5% vs 0.25% p<0.000). Patient questionnaires were available for 15690 subjects. Of those, patients sedated with propofol had higher scores on a scale from 1 (very bad) to 9 (very good) describing how they felt compared...
with the previous day than those sedated with propofol-midazolam (mean, 7.225 vs 7.216, \( p < 0.02 \)).

**Section Summary: MAC With Endoscopy**

The evidence comparing different anesthetic methods is not robust, consisting primarily of nonrandomized comparisons and observational studies. A single RCT comparing propofol administration by anesthesiologists with that by nonanesthesiologists for sedation during colonoscopy did not show any differences in procedure time or patient satisfaction, and it reported a higher rate of hypoxia in patients treated with propofol. However, a Cochrane review of randomized studies concluded that recovery time, discharge time, and patient satisfaction were all improved with propofol compared with alternative agents. Reviewers did not find evidence of increased complications. However, the current evidence base does not rule out increased complication rates with propofol, because there were low complication rates in general, thus making it difficult to discern between-group differences in the absence of large RCTs.

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

The following PICOs were used to select literature to inform this review.

**Patients**

The relevant populations of interest are patients 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.

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. 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; \( p < 0.001 \)). Treatment success also favored the higher dose group (91.3% vs 41.25%, respectively; \( p < 0.001 \)).
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 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 question addressed in this evidence review is: Does the use of MAC improve the net health outcome in patients with planned interventional pain management procedures and certain risk factors or significant medical conditions?

The following PICOs were used to select literature to inform this review.

Patients
The relevant populations of interest are patients 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.

Bernards et al (2008) published a literature review on neurologic complications of regional anesthesia in anesthetized or heavily sedated patients. 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.

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.

Risk Factors Associated with Anesthesia Outcomes (Mixed Indications)
The ASA has recommended that any location providing MAC has the capability of cardiopulmonary resuscitation and monitoring equipment. Whippey et al (2013) published a case-control study of risk factors for unanticipated hospitalization following an outpatient...
procedure. They retrospectively identified 20657 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 one hour, high ASA physical status classification, older age, and higher BMI. Fleisher et al (2004) performed a retrospective claims data review on 564267 outpatient surgical procedures (360780 at a hospital outpatient department, 175288 at an ambulatory surgical center, 28199 at a physician’s office). The rates of all-cause death, emergency department visits, and inpatient admissions within seven 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=720000) Swedish registry of pregnant patients from the 1970s and 1980s, 5405 surgeries took place. Congenital malformations and stillbirths were not increased in the offspring of women having surgery. The incidence of low birth-weight infants was increased as a result of both prematurity and intrauterine growth retardation. Neonatal death was also increased in patients who had surgery. No specific types of anesthesia or surgery were associated with these outcomes. The contribution of the underlying condition that led to the need for surgery could not be separated from the effects of the surgery or sedation/anesthesia. Fetal heart rate monitoring is considered a more sensitive indicator of placental perfusion and fetal oxygenation than observations of maternal hemodynamic stability alone. In 2003, the American College of Obstetricians and Gynecologists recommended that use of intermittent or continuous fetal monitoring during surgery be individualized.

Physiologic changes in pregnancy may require changes in standard doses of anesthetic or sedative agents. However, propofol does not generally require a change in loading dose for induction. Physiologic changes in pregnancy may warrant MAC when airway protection becomes necessary, due to additional difficulties noted with emergent intubation in pregnant patients and the urgency to restore full oxygenation to the maternal and fetal patients. Section Summary: Risk Factors Associated With Anesthesia Outcomes (Mixed Indications)

The available literature suggests that prolonged procedure, high ASA physical status classification, older age, higher BMI, and pregnancy are factors that increase the risk associated with anesthesia. In these situations, MAC may be a reasonable option.

**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, an RCT, and observational studies. The relevant outcomes are overall survival, morbid events, hospitalizations, and treatment-related mortality and morbidity. A literature review for the AGAI identified potential indications requiring an anesthesia specialist. However, the evidence from RCTs is sparse. The single RCT comparing propofol administration by anesthesiologists for the purpose of anesthesia with propofol administered by nonanesthesiologists for sedation during colonoscopy reported that patients receiving propofol from anesthesiologists indicated greater willingness to undergo further colonoscopies under the same conditions. This trial did not show any differences in procedure time or patient satisfaction and reported a higher rate of hypoxia in patients treated by anesthesiologists with propofol. However, this trial may have been underpowered to detect differences in complication rates. 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. The 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. The 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
The ASA (2014) 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.”27

“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.”

The ASA (2016) updated its statement on anesthetic care during interventional pain procedures.28 The ASA indicated that:
“Many patients can undergo interventional pain procedures without the need for supplemental sedation in addition to local anesthesia. For most patients who require supplemental sedation, the physician performing the interventional pain procedure(s) can provide moderate (conscious) sedation as part of the procedure. For a limited number of patients a second provider may be required to manage moderate or deep sedation or, in selected cases other anesthesia services....

Significant anxiety may be an indication for moderate (conscious) sedation or anesthesia 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 sedation or anesthesia services. Examples of such procedures include but are not limited to sympathetic blocks (celiac plexus, paravertebral and hypogastric), chemical or radiofrequency ablation, percutaneous discectomy, trial spinal cord stimulator lead placement, permanent spinal cord stimulator generator, and lead implantation, and intrathecal pump implantation. Major nerve/plexus blocks are performed less often in the chronic pain clinic, but the Committee believes that these blocks may more commonly require moderate (conscious) sedation or anesthesia services (e.g., brachial plexus block, sciatic nerve block, and continuous catheter techniques).”

The ASA (2014) updated its statement on respiratory monitoring during endoscopic procedures.29 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

Guidelines on sedation during gastrointestinal endoscopy were released in 2018 by the ASGE. 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.”

The ASGE (2015) published quality indicators for all gastrointestinal endoscopic procedures. 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.”

The ASGE (2013) published guidelines for endoscopic modification for geriatric patients. 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.”

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

“Staff Recommendations for intra-procedure care based on level of sedation

- No sedation - One assistant...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)¾Sedation 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."

The ASGE, along with the American Association for the Study of Liver Diseases, American College of Gastroenterology, and American Gastroenterological Association (2009) issued a joint position statement on nonanesthesiologist administration of propofol (NAAP) for gastrointestinal endoscopy. The Societies found that NAAP was as safe and effective as anesthesiologist-administered propofol. They asserted that proper training and proper patient selection were necessary for the safe practice of NAAP sedation.

**European Society of Gastrointestinal Endoscopy et al**

The European Society of Gastrointestinal Endoscopy, as well as the European Society of Gastroenterology and Endoscopy Nurses and Associates (2015) updated their guidelines on NAAP. Table 2 summarizes the main recommendations.
Table 2. Recommendations on NAAP for GI Endoscopy

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Before NAAP, patient assessment of physical status, age, body mass index,</td>
<td>Strong</td>
<td>Moderate</td>
</tr>
<tr>
<td>Mallampati’s classification, and obstructive sleep apnea risk factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Primary involvement of an anesthesiologist for high-risk patients</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>3. Capnographic monitoring in high-risk patients, intended deep sedation, and</td>
<td>Weak</td>
<td>High</td>
</tr>
<tr>
<td>long procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Propofol monotherapy except in particular situations</td>
<td>Weak</td>
<td>High</td>
</tr>
<tr>
<td>5. Administration of propofol through intermittent bolus infusion or perfusor</td>
<td>Strong</td>
<td>High</td>
</tr>
<tr>
<td>systems, including target-controlled infusion and patient-controlled sedation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Patients listen to self-selected music during upper and lower GI endoscopy</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
<tr>
<td>procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Do not use pharyngeal anesthesia during propofol sedation for upper GI</td>
<td>Weak</td>
<td>Moderate</td>
</tr>
<tr>
<td>endoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Use post-anesthetic discharge scoring system to determine patient discharge</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>9. For patients of ASA class &gt;2, upon discharge, patient should be accompanied</td>
<td>Strong</td>
<td>Low</td>
</tr>
<tr>
<td>by a responsible person and refrain from driving, drinking alcohol, operating</td>
<td></td>
<td></td>
</tr>
<tr>
<td>heavy machinery, or engaging in legally binding decisions for 24 hours. Advice</td>
<td></td>
<td></td>
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<tr>
<td>should be provided verbally and in written form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. For patients of ASA classes 1-2 who have received low-dose propofol</td>
<td>Weak</td>
<td>Low</td>
</tr>
<tr>
<td>monotherapy, a 6-hour limit is suggested</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


ASA class ≥3, with a Mallampati’s class ≥3 or other conditions that put them at risk of airway obstruction, in patients receiving significant amounts of narcotic analgesics, or in long-lasting procedures.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

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

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>A Randomized Controlled Trial (RCT) of Efficacy and Safety of Sedation</td>
<td>132</td>
<td>Jun 2020</td>
</tr>
<tr>
<td></td>
<td>Compared to General Anesthesia for Endoscopic Retrograde</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cholangio-pancreatography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unpublished</td>
<td>Nurse Administered Propofol Sedation vs Midazolam With</td>
<td>128</td>
<td>Apr 2016</td>
</tr>
<tr>
<td></td>
<td>Fentanyl-sedation for Flexible Bronchoscopy: A Randomized, Single-</td>
<td></td>
<td>(unknown)</td>
</tr>
<tr>
<td></td>
<td>Blind, Controlled Study of</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Satisfaction and Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02174588</td>
<td>Moderate Sédation for Elective Upper Endoscopy With</td>
<td>22</td>
<td>Feb 2015</td>
</tr>
<tr>
<td></td>
<td>Balanced Propofol Versus Propofol Alone: a Randomized Clinical Trial</td>
<td></td>
<td>(completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
References


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**

- History and physical and/or consultation notes including:
  - Anesthesiologist or proceduralist pre-operative assessment
  - Procedure performed
  - Reason monitored anesthesia care is required

**Post Service**

- Operative report

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/NMN**

The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>00520</td>
<td>Anesthesia for closed chest procedures; (including bronchoscopy) not otherwise specified</td>
</tr>
<tr>
<td></td>
<td>00635</td>
<td>Anesthesia for procedures in lumbar region; diagnostic or therapeutic lumbar puncture</td>
</tr>
<tr>
<td></td>
<td>00731</td>
<td>Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified</td>
</tr>
<tr>
<td></td>
<td>00732</td>
<td>Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ERCP)</td>
</tr>
<tr>
<td></td>
<td>00811</td>
<td>Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified</td>
</tr>
<tr>
<td></td>
<td>00812</td>
<td>Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy</td>
</tr>
<tr>
<td></td>
<td>00813</td>
<td>Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum</td>
</tr>
<tr>
<td>Type</td>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td></td>
<td>01936</td>
<td>Anesthesia for percutaneous image guided procedures on the spine and spinal cord; therapeutic</td>
</tr>
<tr>
<td></td>
<td>01991</td>
<td>Anesthesia for diagnostic or therapeutic nerve blocks and injections (when block or injection is performed by a different physician or other qualified health care professional); other than the prone position</td>
</tr>
<tr>
<td></td>
<td>96373</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial</td>
</tr>
<tr>
<td></td>
<td>96374</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug</td>
</tr>
<tr>
<td>99100</td>
<td>Anesthesia for patient of extreme age, younger than 1 year and older than 70 (List separately in addition to code for primary anesthesia procedure)</td>
<td></td>
</tr>
<tr>
<td>HCPCS</td>
<td>G9654</td>
<td>Monitored anesthesia care (MAC)</td>
</tr>
</tbody>
</table>

**Policy History**

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/28/2013</td>
<td>BCBSA Medical Policy adoption</td>
</tr>
<tr>
<td>01/30/2015</td>
<td>Coding Update</td>
</tr>
<tr>
<td>06/30/2015</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td></td>
<td>Coding Update</td>
</tr>
<tr>
<td>09/30/2015</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>01/01/2016</td>
<td>Coding Update</td>
</tr>
<tr>
<td>01/01/2017</td>
<td>Policy revision without position change</td>
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<tr>
<td></td>
<td>Coding Update</td>
</tr>
<tr>
<td>01/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td></td>
<td>Coding Update</td>
</tr>
<tr>
<td>01/01/2019</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>02/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
</tr>
<tr>
<td>03/01/2020</td>
<td>Administrative Update. Policy statement and guidelines updated.</td>
</tr>
</tbody>
</table>

**Definitions of Decision Determinations**

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

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.
Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

<table>
<thead>
<tr>
<th>Prior Authorization Requirements (as applicable to your plan)</th>
</tr>
</thead>
</table>

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

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

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