

Clinical Policy Title: Anesthesia services for gastrointestinal endoscopy

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Policy contains: anesthesia; esophagogastroduodenoscopy; esophagoscopy; gastrointestinal endoscopy;

propofol; sedation; transnasal; transoral

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state-or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control.

AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Monitored anesthesia (deep sedation or general anesthesia) for gastrointestinal endoscopy (colonoscopy or EGD) procedures in average-risk patients is investigational/not clinically proven, and therefore not medically necessary (American Society for Gastrointestinal Endoscopy Standards of Practice Committee, 2018).

<u>Prior authorization is required when monitored anesthesia (deep sedation or general anesthesia) is</u> administered for gastrointestinal endoscopy (colonoscopy or EGD) procedures.

Monitored anesthesia (deep sedation or general anesthesia) is clinically proven, and therefore medically necessary, for upper or lower gastrointestinal endoscopy when any of the following criteria are met (American Society for Gastrointestinal Endoscopy Standards of Practice Committee, 2018):

- The member is younger than 18 years of age; or
- The member is older than 70 years of age; or
- The member is pregnant; or
- The member is at increased risk for complications due to severe comorbidity (e.g., American Society of Anesthesiologists Physical Classification System class ASA IV); or
- Increased risk exists for airway obstruction due to anatomic variation, such as:
 - o <u>History of stridor.</u>
 - Dysmorphic facial features.
 - o Oral abnormalities (e.g., macroglossia).
 - Neck abnormalities (e.g., neck mass).

- o Jaw abnormalities (e.g., micrognathia).
- The member has one of the following:
 - History of adverse reaction to sedation;
 - o History of inadequate response to sedation;
 - Obstructive sleep apnea;
 - Morbid obesity (body mass index >40);
 - o Active or history of alcohol or substance abuse

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Gastrointestinal endoscopy includes a wide variety of procedures. In the United States, about 98% of patients are administered some level of sedation for these procedures (Aljebreen, 2010). These levels include:

- Moderate sedation, previously known as conscious sedation, a state during which the patient remains aware, is able to make purposeful responses to verbal or light tactile stimulation, and maintains ventilator and cardiovascular function.
- <u>Deep sedation, which renders the patient unable to respond to any stimuli except for those that are repeated or painful.</u>
- General anesthesia, under which the patient cannot be aroused by painful stimuli, and cardiovascular function may be impaired.

Individuals may require various levels of sedation for the same procedure. Patients are monitored before the procedure, after administration of a sedative or anesthetic, periodically (at least every five minutes) during the procedure, during initial recovery, and just before discharge. Care givers can detect any unusual changes in pulse, blood pressure, ventilator status, or cardiac electrical activity, and make needed changes in the sedative level (American Society for Gastrointestinal Endoscopy Standards of Practice Committee, 2018).

Midazolam (a benzodiazepine) and fentanyl (an opioid), used in combination, are the most commonly used agents of moderate sedation in the United States and other developed nations (Lin, 2017a).

Propofol sedation has become the most common anesthetic because of its ability to make endoscopic procedures painless. It is able to induce deep sedation (known as "monitored anesthesia care") in patients. There is controversy over whether this anesthetic can be administered by nurses or computer-guided methods, or requires anesthesiologists (Lin, 2017a).

From 2003 – 2013, the proportion of routine endoscopy cases that used propofol increased from 14% to 48% for Medicare patients, and from 14% to 53% for privately insured patients (Liu, 2012; Predmore, 2017).

Efforts to develop devices to administer gastrointestinal endoscopy procedures without the need for any type of sedation are improving. Ultrathin transnasal and transoral endoscopes are the most common devices used in these procedures (Lin, 2017a).

Computer-assisted propofol sedation was recently approved for use in sedating low-risk patients undergoing routine endoscopy (Lin, 2017b).

Findings

In 2018, an American Society of Gastrointestinal Endoscopy policy update outlined appropriate use of sedation and anesthesia in gastrointestinal endoscopy. The guideline states that monitored anesthesia care for average-risk patients undergoing standard upper and lower gastrointestinal endoscopy is not appropriate. Risk factors include extreme age (young and old); comorbid conditions such as severe pulmonary, cardiac, renal, or hepatic diseases; history of substance or alcohol abuse; uncooperative behavior; potentially difficult airways for positive-pressure ventilation; and anatomy making intubation more difficult (American Society of Gastrointestinal Endoscopy Standards of Practice Committee, 2018).

The Canadian Association of Gastroenterology Safety and Quality Indicators in Endoscopy Consensus

Group developed 19 safety compromise indicators in endoscopy, divided into three groups (medication-related, procedure-related early, and procedure-related delayed). Medication-related indicators include those pertinent to anesthesia (need for cardio-pulmonary resuscitation, use of reversal agents, hypoxia, hypotension, hypertension, sedation doses in patients > 70 years, allergic reactions, and laryngospasm (Borgaonkar, 2012).

In recent years, monitored anesthesia care for gastrointestinal endoscopy has risen sharply in the United States, according to a study of colonoscopy and esophagogastroduodenoscopy (14 million and 7 million procedures annually). From 2000 – 2009, the percent of colonoscopy with monitored anesthesia care rose from 8.6% to 35.4%, while from 2000 – 2006, the percent for esophagogastroduodenoscopy rose from 11% to 23.4% (Adams, 2016).

Several systematic reviews addressed safety outcomes for anesthesiologists versus non-anesthesiologists:

- In a 2002 2013 review of 508,053 esophagogastroduodenoscopy procedures, 23% were directed by anesthesia professionals and 77% used endoscopist-directed sedation; 880,182 colonoscopy patients had similar percentages (21% and 79%). The risk of severe adverse events for patients whose sedation was directed by anesthesia professionals was higher for esophagogastroduodenoscopy (odds ratio = 1.33), but similar for colonoscopy (0.93); whether anesthesiologists provided greater safety was unclear (Vargo, 2017).
- A systematic review of nine reports addressed outcomes of low-risk (non-mechanically ventilated)
 patients administered propofol for gastrointestinal endoscopy, cardiac catheterization, and
 procedural sedation for emergency room and radiology procedures. The review compared
 outcomes for non-anesthesia-trained (seven studies) and anesthesia-trained (two studies) health
 care providers administering propofol. Outcomes included procedure time, postoperative recovery
 time, and mean dosage. The authors concluded that non-anesthesia-trained providers with
 specialized training can safely administer propofol in low-risk patients (Gollaher, 2012).
- A systematic review/meta-analysis of five studies (n = 17,978) of low-risk patients who underwent routine endoscopy showed patients given propofol by endoscopists and anesthesiologists had similar rates of airway intervention (P = .92) and hypotension (P = .57). Patients whose anesthesia was managed by endoscopists had significantly higher rates of brachycardia (P = .001) but used significantly lower doses (P = .02) (Daza, 2018).

Several other systematic reviews assessed propofol and other often-used sedatives:

- A systematic review/meta-analysis of six trials (n = 1,115) compared two anesthetics commonly used in gastrointestinal endoscopy. Etomidate, compared with propofol, resulted in significantly less apnea or hyoxemia (P = .0002) and injection pain (P < .00001), and was associated with an increase in myoclonus (P < .0001). All other measures showed no difference between the two (Ye, 2017).
- A comparison of computer-assisted propofol sedation with midazolam and fentanyl was conducted for upper endoscopy (n = 55 and 75) and colonoscopy (n = 173 and 223). No significant difference in success rates was observed between the groups for upper endoscopy (98.2% versus 98.7%, P = .96) or colonoscopy (98.9% versus 98.8%, P = .59). Procedure times were similar between groups for both procedures, but mean recovery time was significantly lower after computer-assisted propofol sedation than after midazolam and fentanyl (26.4 minutes versus 39.1 minutes, P < .001) (Lin, 2017b).</p>
- A systematic review of six studies (n = 592) of pediatric patients receiving propofol for a gastrointestinal endoscopy procedure compared those who did and did not receive other anesthesia. Those with no other sedation had a higher rate of total complications (23.4% versus 18.2%), borderline significant at P = .053) (Narula, 2018).
- A systematic review/meta-analysis of five studies (n = 2,518) documented that propofol had a significant 39% lower rate of cardiopulmonary complications than traditional anesthesia for non-advanced procedures (colonoscopy, sigmoidoscopy, and esophagogastroduodenoscopy), but risks of the two types of anesthesia were not different for more advanced groups (Wadhwa, 2017).

A systematic review/meta-analysis of five studies (n = 1,402) compared removal of foreign bodies using rigid endoscopy (with general anesthesia) or flexible endoscopy (with sedation). No significant differences were found between groups in iatrogenic perforation, other complications, or overall complications. The authors observed that for this procedure, flexible endoscopy is recommended (Ferrari, 2018).

A systematic review/meta-analysis of 34 studies (n = 6,658) found the success rates for unsedated ultrathin transnasal and transoral routes were 94% (30 studies) and 97.8% (16 studies). No significant differences in success were observed for transnasal (under 5.9 mm) or transoral versus conventional esophagogastroduodenoscopy (nine studies) (Sami, 2015). Still, most patients in developed nations prefer sedation (Lin, 2017a).

A systematic review of 17 articles found unsedated transnasal esophagoscopy was effective for screening patients with dysphagia, globus pharyngeus, and reflux symptoms; detecting metachronous esophageal cancer; biopsy of suspicious lesions in the upper aerodigestive tract; placing wireless pH capsules; transnasal balloon dilation of the esophagus; secondary tracheoesophageal puncture; and managing foreign bodies. The procedure was well tolerated with few mild complications in an office with topical anesthesia (Sabirin, 2013).

References

On December 5, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were anesthesia, esophagogastroduodenoscopy, esophagoscopy, gastrointestinal endoscopy, and sedation. We included the

best available evidence according to established evidence hierarchies (typically systematic reviews, metaanalyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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