



## ANESTHESIA ASSISTANCE WITH GASTROINTESTINAL ENDOSCOPIC PROCEDURES

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### **Overview**

All patients undergoing planned gastrointestinal (GI) endoscopic procedures require a pre-procedural evaluation to assess the risks of the procedure and manage problems related to preexisting medical conditions. Selected patients may undergo GI endoscopic procedures without sedation, analgesia, or both however the majority of patients receive some level of sedation and analgesia. The purpose of sedation and analgesia provided with GI endoscopic procedures is to relieve patient anxiety and discomfort and improve the outcome of the examination. The level of sedation and analgesia required to perform endoscopic procedures varies.<sup>1</sup> Patient age, health status, concurrent medications, pre-procedural anxiety, and pain tolerance influence the level of sedation required to achieve the desired result, as do procedural variables such as the degree of invasiveness and the duration of the procedure. Patients should be informed of and agree to the administration of sedation and analgesia with endoscopic procedures, including a discussion of the benefits, risks, limitations, and possible alternatives.

Procedural (standard) sedation refers to the administration of intravenous medications, usually a benzodiazepine and a narcotic, by or under the supervision of the physician performing the procedure. A moderate level of sedation/analgesia is targeted. Most gastrointestinal endoscopic procedures can be performed adequately and safely under standard sedation. (ASGE Position Statement: Non-Anesthesiologist Administration of Propofol for GI Endoscopy, 2009) At the level of moderate sedation/analgesia, the

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<sup>1</sup> An emerging concept of great importance to the anesthesia community is that of the continuum of sedation. The purpose of the continuum of sedation is to teach the concept that patients can move in between the states of sedation. Although clinicians may target a specific level of sedation, it is not possible to predict how a patient will respond to sedation. The concept of targeting implies that a certain level of sedation is the goal, but acknowledges that in practice some patients will transiently be in lighter or deeper levels of sedation. Due to the potential for rapid often unanticipated changes in level of sedation, clinicians administering moderate sedation must be able to rescue patients who enter deep sedation, while those administering deep sedation must be able to rescue patients who enter a state of general anesthesia.

The continuum of depth of sedation/analgesia, from least intense to most intense:

Minimal sedation/analgesia ⇒ moderate sedation/analgesia (formerly referred to as conscious sedation) ⇒ deep sedation/analgesia ⇒ general anesthesia

(ASA. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia. October 2009)

patient is able to make purposeful responses to verbal or tactile stimulation.<sup>2</sup> Moderate sedation/analgesia is not expected to induce depths of sedation that would impair a patient's cardiovascular function or ability to maintain the integrity of his or her own airway.<sup>3</sup> Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Non-anesthesiologists providing moderate sedation must be capable of rescuing a patient who unintentionally transitions to deep sedation. Most gastroenterologists in the U.S. administer moderate sedation/analgesia to their patient's undergoing office-based or outpatient endoscopic procedures.

Deep sedation/analgesia may be medically necessary for patients with risk factors for sedation related complications and for patients undergoing prolonged or complex GI endoscopic procedures. (American Society for Gastrointestinal Endoscopy, 2008) The same combinations of medications that are used to achieve moderate sedation/analgesia can be used to achieve deep sedation/analgesia (but in higher doses). In addition, other agents, such as droperidol<sup>4</sup> and propofol, may be used to achieve deep sedation. Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Practitioners administering deep sedation/analgesia should be trained to rescue patients who enter a state of general anesthesia.

Propofol is an ultra-short acting sedative agent with no analgesic properties which provides sedative and amnesic effects. Propofol is FDA-approved for the induction and maintenance of anesthesia and should be administered only by persons trained in the administration of general anesthesia. Since its introduction in the 1980s, its clinical applications have expanded to include procedural sedation and monitored anesthesia care. Compared to standard sedatives, propofol provides a more rapid onset of action and considerably shorter recovery time. The average recovery time after colonoscopy was much shorter for patients receiving propofol than for patients receiving a combination of benzodiazepine and a narcotic (15 minutes and 55 minutes respectively). (McQuaid et al., 2008; Vargo et al., 2007) The very narrow therapeutic window of propofol that distinguishes it from conventional sedatives increases the risk for cardiovascular and respiratory complications and many gastroenterologists are reluctant to administer propofol, and in addition, there is no reversal agent for propofol.<sup>5</sup>

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<sup>2</sup> Moderate sedation/analgesia is achieved through the administration of intravenous medications, usually midazolam, and a narcotic such as meperidine or fentanyl. Diazepam is also used quite commonly either alone or in conjunction with midazolam.

<sup>3</sup> Complications due to sedatives, although infrequent, are the most common type of complication seen during endoscopic procedures. (Eisen et al. 2002) Sedatives may cause cardiopulmonary compromise and other complications such as allergic reactions, interactions with other drugs, and idiosyncratic or dose-related adverse events.

<sup>4</sup> Droperidol is a neuroleptic agent with sedative effects. Randomized clinical trials have demonstrated the efficacy of droperidol in patients undergoing complex endoscopic procedures, particularly in patients who are difficult to sedate. However, because of severe adverse reactions, droperidol was taken off the market in Europe in 2001, and has an FDA black box warning in the U.S. Droperidol is only approved for use when first-line sedatives fail to provide adequate sedation.

<sup>5</sup> In a nationwide survey of gastroenterologists, approximately two-thirds of respondents indicate that they would like to administer propofol but are reluctant to do so because of the increased risks of complications. (Cohen et al. (2006) Non-anesthesiologist administered

Monitored anesthesia care (MAC) is a specific anesthesia service provided to a patient undergoing a planned diagnostic or therapeutic procedure. In such a case, the anesthesiologist is in control of the patient's vital signs, and is available to administer general anesthesia or provide other medical care as appropriate. The standard of care for patients receiving MAC is the same as for patients undergoing general anesthesia, and should include a complete preoperative assessment, intraoperative monitoring, and postoperative in the recovery room prior to discharge. The administration of sedation/analgesia is often, but not always, the reason MAC is indicated. In some patients who may only require moderate sedation/analgesia, MAC may be medically necessary because even small doses of sedatives could precipitate adverse responses that would necessitate acute intervention.

In recent years, anesthesia assistance with GI endoscopic procedures has increased dramatically. A number of factors are driving this trend, notably the use of propofol. Studies have demonstrated the advantage of sedation with propofol over sedation with benzodiazepines and narcotics for patients with risk factors for sedation related complications and for patients undergoing prolonged or complex therapeutic procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasoundography (EUS). However, the incremental cost of MAC far exceeds the threshold which is widely considered to be an acceptable level of cost-effectiveness for patients without risk factors or contraindications undergoing routine GI endoscopic procedures, such as upper GI endoscopy and colonoscopy. In a joint statement issued by the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE), "clinically important benefits for the use of propofol compared to standard doses of benzodiazepines and narcotics have not been consistently demonstrated in average risk patients undergoing routine upper and lower endoscopy, therefore, the use of MAC for these patients is not warranted." If there is a role for the anesthesiologist in endoscopy, it is in the management of patients with risk factors for sedation related complications or in prolonged or complex endoscopic procedures.

## Definitions

**Endoscope:** A lighted optical instrument used to examine internal organs. An endoscope can be rigid or flexible. Endoscopes are named depending where they are intended to look. Examples include: cystoscope (bladder), nephroscope (kidney), bronchoscope (bronchi), laryngoscope (larynx + the voice box), otoscope (ear), arthroscope (joint), laparoscope (abdomen), and gastrointestinal endoscope.

**Minimal sedation** – a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

**Moderate Sedation (formerly conscious sedation)** – a drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a

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propofol is termed gastroenterologist-directed propofol (GD-P). Off-label administration of propofol by gastroenterologists is prevalent in other countries however the FDA-approved label has been used as evidence in U.S. courts in cases related to the off-label use of propofol by non-anesthesiologists.

painful stimulus is not considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

**Deep sedation** – a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain respiratory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

**General anesthesia** – a drug-induced loss of consciousness during which patients are not arousable, even with painful stimulation. The ability to independently maintain respiratory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

**Monitored anesthesia care (MAC)** – an anesthesia service provided by an anesthesiologist (or certified registered nurse anesthetist under the supervision of an anesthesiologist) to a patient undergoing a planned diagnostic or therapeutic procedure. MAC includes all aspects of anesthesia care including a pre-procedure visit, intra-procedure monitoring and management, and post-procedure care. Indications for MAC include the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to general anesthesia.

## Policy

**Anesthesia assistance for upper GI endoscopy (CPT code 00740) and/or lower GI endoscopy (CPT code 00810) requires prior authorization by FCHP.**

Anesthesia assistance for plan members without risk factors for sedation-related complications undergoing routine endoscopic procedures has not been shown to improve safety or procedural outcome, FCHP considers anesthesia assistance in these circumstances not medically necessary.

FCHP expects that physicians and other providers will inform patients of services they did not know or could not reasonably have been expected to know were not medically necessary (informed consent). FCHP recognizes the right of any patient to receive the services of an anesthesiologist if they desire. Such patient should sign a statement accepting financial responsibility prior to the procedure.

FCHP urges referring physicians to submit a request for prior authorization for anesthesia assistance before scheduling GI endoscopy for a plan member who requires anesthesia assistance with GI endoscopy.

1. FCHP considers anesthesia assistance medically necessary for plan members with one of the following risk factors for sedation related complications that justifies the presence of an anesthesiologist during a GI endoscopic procedure:
  - a. ASA Class III-IV (see Appendix A), i.e., severe systemic disease that limits physical activity

- b. Anticipated intolerance to regimens used for moderate sedation (i.e., benzodiazepines and/or narcotics), e.g., plan members with a history of long-term use/abuse of benzodiazepines, narcotics, alcohol, or neuropsychiatric medications
  - c. Age under 18 years (i.e., to the 18th birthday)
  - d. Uncooperative or extremely agitated plan members, such as plan members with senile dementia
  - e. Pregnancy
  - f. Previous problems with anesthesia or sedation
  - g. Increased risk for airway obstruction or anatomic variant associated with difficult intubation
    - i. History of stridor or sleep apnea
    - ii. Dysmorphic facial features, such as Pierre-Robin syndrome or Trisomy 21
    - iii. Oral abnormalities, such as a small opening (< 3 cm in an adult), edentulous, protruding incisors, high arched palate, macroglossia, tonsillar hypertrophy, or a nonvisible uvula
    - iv. Neck abnormalities, such as obesity involving the neck and facial structures, short neck, limited neck extension, decreased hyoid-mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis
    - v. Jaw abnormalities such as micrognathia, retrognathia, trismus, or significant malocclusion
2. Plan members undergoing prolonged or complex endoscopic procedures requiring deep sedation, such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasoundography (EUS).

No coverage is provided for anesthesia assistance with GI endoscopy unless prior authorization by FCHP has determined medical necessity.

### Codes

Codes	Number	Description
CPT	00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum
	00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum

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### Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

Ø Summit ElderCare® PACE (Note: With the exception of emergency care, all services for Summit ElderCare® PACE participants must be authorized and arranged by the Summit ElderCare (SE) Interdisciplinary Team (IDT) overseeing the care for that participant. The applicable team can be determined by the site code on the participant ID card. The site codes and corresponding telephone numbers are: SW1-SE East Mtn St. Worcester-508-852-2026, SW2-SE Grafton St. Worcester-508-373-7400, SC1-SE Charlton-508-434-3200, SL1-SE Leominster-978-401-3100.)

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### Committee review dates:

Technology Assessment Subcommittee: 05/25/10

Technology Assessment Committee: 06/02/10, 01/25/11

#### IMPORTANT NOTE:

**Not all services are covered for all products or employer groups.** This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.

## Appendix A

### ASA Physical Status Classification System

#### ASA I

Patients are considered to be normal and healthy. Patients are able to walk up one flight of stairs or two level city blocks without distress. Little or no anxiety. Little or no risk.

#### ASA II

Patients have mild to moderate systemic disease or are healthy ASA I patients who demonstrate a more extreme anxiety and fear toward dentistry. Patients are able to walk up one flight of stairs or two level city blocks, but will have to stop after completion of the exercise because of distress. Minimal risk during treatment.

**Examples:** History of well-controlled disease states including diabetes, hypertension, obesity, epilepsy, asthma, or thyroid conditions; ASA I with a respiratory condition, pregnancy, and/or active allergies.

#### ASA III

Patients have severe systemic disease that limits physical activity, but is not incapacitating. Patients are able to walk up one flight of stairs or two level city blocks, but will have to stop enroute because of distress. **Examples:** History of angina pectoris, myocardial infarction, or cerebrovascular accident, congestive heart failure over six months ago, diabetes with vascular complications, poorly controlled hypertension, morbid obesity.

#### **ASA IV**

Patients have severe systemic disease that limits physical activity and is a constant threat to life. Patients are unable to walk up one flight of stairs or two level city blocks. Distress is present even at rest. Patients pose significant risk since patients in this category have a severe medical problem of greater importance to the patient than the planned dental treatment. Whenever possible, elective dental care should be postponed until such time as the patient's medical condition has improved to at least an ASA III classification. **Examples:** History of unstable angina pectoris, myocardial infarction or cerebrovascular accident within the last six months, severe congestive heart failure, severe chronic obstructive pulmonary disease, uncontrolled diabetes, hypertension, epilepsy, or thyroid condition, advanced pulmonary, renal or hepatic dysfunction.

#### **ASA V**

Patients are moribund and are not expected to survive more than 24 hours with or without an operation. These patients are almost always hospitalized, terminally ill patients. **Examples:** ruptured abdominal aneurysm, pulmonary embolus, head injury with increased intracranial pressure.

#### **ASA VI**

Clinically dead patients being maintained for harvesting of organs.