

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Monitored Anesthesia Care (MAC) for Gastrointestinal Endoscopic Procedures

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Criteria

For Medicare Members

| Source | Policy |
|--|---|
| CMS Coverage Manuals | None |
| National Coverage Determinations (NCD) | None |
| Local Coverage Determinations (LCD) | 4/09/2018 Noridian Retired LCD for Monitored Anesthesia Care (MAC) (L34100). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. Medical necessity review is no longer required for Medicare members. However, providers are expected to validate medical necessity per Medicare's guidance in retired LCD L34100 (see |
| | above). |
| Local Coverage Article | None |

For Non-Medicare Members

Effective until September 1, 2025

No medical necessity review required.

Effective September 1, 2025

Clinical criteria is retired.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

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Each year in the United States, 145,000 people will be diagnosed with colon cancer; 54,000 will die. Getting recommended colorectal cancer screening could potentially save the lives of up to 60% of these patients. Increasing patient participation in routine screening is a matter of serious concern.

With the increased emphasis on prevention and the importance of the role of colonoscopy as a tool there is a need to evaluate the use of monitored anesthesia care in conjunction with endoscopic evaluation. Kaiser Permanente has developed this policy in response to our findings.

Medical Technology Assessment Committee (MTAC)

Monitored Anesthesia Care (MAC) for Gastrointestinal Endoscopic Procedures 2/22/2010: MTAC REVIEW

Evidence Conclusion: The following are conclusions based on a review of several systematic reviews, metaanalyses, randomized controlled trials, and published internal data on sedation involving propofol compared to standard sedation: There is good evidence of improved patient satisfaction and reductions in discharge and recovery times with propofol used alone or in combination with other agents compared to standard sedation for colonoscopy exams. There is fair evidence from a KP SCAL-based comparative study of improved cecal intubation rates with propofol used as a single agent for sedation during colonoscopy. The evidence is of insufficient quantity or quality to draw definitive conclusions on differences in polyp detection. There is less comparative data on EGD procedures, but some evidence of improved recovery and patient satisfaction with propofol sedation. The evidence is of insufficient quantity and/or quality to draw definitive conclusions on comparative risk of serious adverse events, including death, neurologic injury, endotracheal intubations, bleeding, and colonic perforations during these procedures. There does not appear to be a significant difference in the risk of cardiopulmonary and respiratory events with propofol compared to standard sedation and no evidence of greater risk for serious adverse events for either colonoscopy or EGD procedures in lower risk patients (ASA I or II). Following the review of one systematic review and two comparative observational studies, the evidence is of insufficient quantity and quality to draw definitive conclusions on the safety of anesthesiologist- versus non anesthesiologist-directed or administered propofol sedation in GI endoscopy. Controlled prospective studies with standardized protocols, patient selection, and reporting are needed. Serious Adverse Events. The best available comparative evidence from the United States is a large observational registry study that suggests comparable rates of serious adverse events for anesthesiologist-directed propofol under monitored anesthesia care and gastroenterologist-administered propofol during colonoscopy procedures (0.16% and 0.14%) but a significantly increase risk of serious adverse events with gastroenterologist-administered propofol for upper endoscopy procedures, including EGDs (0.16% vs 0.5%). However, it is likely that these events differentially occurred in higher risk patients (ASAI III) who were also included in the study. Overall Cardiopulmonary Adverse Events. There is evidence from the same study of a significant increased risk of overall cardiopulmonary events with endoscopic-administered propofol in ASA I or II patients undergoing colonoscopy and upper endoscopy. The majority of the cardiopulmonary events are most likely to be of minor clinical consequence, but the challenge remains to identify which cardiopulmonary events are more likely to result in serious adverse events and what risk factors are specific to upper versus lower endoscopy procedures. The evidence is of insufficient quantity and quality to draw conclusions on the safety of RN-administered propofol as compared to standard sedation for colonoscopy and EGD in ASA I and II patients. Based on a review of several systematic reviews and randomized controlled trials, there is no evidence of a significant increase in risk of adverse events with propofol compared to standard sedation and the risks appear to be comparable. However, these studies were not adequately sampled to detect or compare rates of serious adverse events. Comparative data from large and well-designed observational studies is needed. The existing series of RN-administered propofol are large and report low rates of adverse events.

Articles: The Kaiser Evidence Search Articles Clarke AC, Chiragakis L, Hillman LC, Kaye GL. Sedation for endoscopy: the safe use of propofol by general practitioner sedationists. Med J Aust 2002;176(4):158-161. Cohen LB, Hightower CD, Wood DA, Miller KM, Aisenberg J. Moderate level sedation during endoscopy: a prospective study using low-dose propofol, meperidine/fentanyl, and midazolam. Gastrointest Endosc 2004;59(7):795-803. Cohen LB, Dubovsky AN, Aisenberg J, Miller KM. Propofol for endoscopic sedation: A protocol for safe and effective administration by the gastroenterologist. Gastrointest Endosc 2003;58(5):725-732. Cohen LB. Nurse-administered propofol sedation for upper endoscopic ultrasonography: not yet ready for prime time. Nat Clin Pract Gastroenterol Hepatol 2009;6(2):76-77. Cote GA, Hovis RM, Ansstas MA et al. Incidence of Sedation-Related Complications With Propofol Use During Advanced Endoscopic Procedures. Clin Gastroenterol Hepatol 2009. Gasparovic S, Rustemovic N, Opacic M et al. Clinical analysis of propofol deep sedation for 1,104 patients undergoing gastrointestinal endoscopic procedures: a three-year prospective study. World J Gastroenterol 2006;12(2):327-330. Heuss LT, Schnieper P, Drewe J, Pflimlin E, Beglinger C. Risk stratification and safe administration of propofol by registered nurses supervised by the gastroenterologist: a prospective

Criteria | Codes | Revision History

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The effect of sedation on the quality of upper gastrointestinal endoscopy: an investigator-blinded, randomized study comparing propofol with midazolam. Endoscopy 2007;39(4):345-349. McQuaid KR, Laine L. A systematic review and meta-analysis of randomized, controlled trials of moderate sedation for routine endoscopic procedures. Gastrointest Endosc 2008;67(6):910-923. Morse JW, Fowler SA, Morse AL. Endoscopist-administered propofol: a retrospective safety study. Can J Gastroenterol 2008;22(7):617-620.Pambianco DJ. Whitten CJ. Moerman A. Struvs MM. Martin JF. An assessment of computer-assisted personalized sedation: a sedation delivery system to administer propofol for gastrointestinal endoscopy. Gastrointest Endosc 2008;68(3):542-547. Poon CM, Leung TL, Wong CW, Chan YL, Leung TC, Leong HT. Safety of nurse-administered propofol sedation using PCA pump for outpatient colonoscopy in Chinese patients: a pilot study. Asian J Surg 2007;30(4):239-243. 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MDCRPC voted to adopt the Kaiser evidence review conclusions.

MONITORED ANESTHESIA CARE (MAC) FOR CHRONIC MARIJUANA USERS UNDERGOING GASTROINTESTINAL ENDOSCOPIC PROCEDURES BACKGROUND

Marijuana use

Marijuana is the most commonly used federally illegal drug in the United States. Its use has significantly increased across the country in recent years, especially among young people and in the states that have legalized the recreational cannabis use. It is estimated that approximately 3 in 10 people who use marijuana have marijuana use disorder, the risk of which is higher among those who begin using it before the age of 18, The National Survey on Drug Use and Health National Institute on Drug Abuse estimated that 5.1% (or about 14.2 million people) aged 12 or older in 2020 had a cannabis use disorder in the past 12 months (2020 National Survey on Drug Use and Health National Institute on Drug Abuse and CDC website).

Th term "Marijuana" is commonly used interchangeably with "Cannabis"; however, they don't mean exactly the same thing. Cannabis refers to all products derived from the plant Cannabis sativa that includes more than 500 compounds among which are cannabinoids, terpenoids, and flavonoids. Marijuana on the other hand refers to the dried flowers, leaves, stems, and seeds of the cannabis plant that contain substantial amounts of tetrahydrocannabinol (THC) that is primarily responsible for the effects of marijuana on a person's mental state. The main cannabinoids in the cannabis are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), each with its own effects and uses. THC is the main psychoactive compound in cannabis and is responsible for the "high" that most people associate with cannabis. CBD is also a psychoactive cannabinoid, but is non-intoxicating and non-euphoric, i.e., does not cause a "high". It is often used to help reduce inflammation and pain, and also to ease nausea, migraine, seizures, and anxiety. (Andre et al, 2016, Boninin et al, 2018, Bakshi, et al 2019, Balant, et al 2021, Irvine , et al 2022, and the CDC website

Marijuana use has negative clinical effects on different body organs and systems including the respiratory, cardiovascular, and central nervous system, gastrointestinal tract, and others. These vary by the quantity and chronicity of the marijuana used. However, it can be difficult to the quantity the active compound of the marijuana consumed as the formulations of the products and their CBD-to-THC-content ratios are very heterogeneous. Research suggests that cannabis users require significantly higher doses of sedation for upper endoscopic procedures compared with nonusers. Propofol, a primary anesthetic agent, is metabolized through similar enzymatic pathways as the THC and cannabis users may present a higher-than-normal risk for subanesthetic dosing, leading to greater incidence of awareness or recall. They are also at a higher risk of adverse events such as bronchospasm, laryngospasm, tachycardia, and others (Twardowski, et al 2019, Imasogie et al 2021, Ladha et al, 2021).

With the increasing prevalence of cannabis use among adults, and with the known effects of marijuana on the different systems it is important that anesthesia professionals consider the potential effects of cannabis use when providing perioperative care to chronic marijuana users.

Monitored anesthesia care (MAC)

Monitored anesthesia care is defined by the American Society of Anesthesiologists (ASA) as a planned procedure during which the patient undergoes local anesthesia together with sedation, and analgesia provided by an anesthesiologist. I.e., it is an anesthesia technique combining local anesthesia with parenteral drugs for sedation © 2012, Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top

and analgesia. The purpose of the conscious sedation during MAC is providing the patient with safe sedation, comfort, and control of pain and anxiety. The patients under conscious sedation maintain ventilatory and cardiovascular function and are able to respond to verbal and tactile stimulation. The discretion and judgment of an experienced anesthesiologist are required for the safety and efficacy as the airway of the patient is not secured. The attending anesthesiologist should be aware of the possibility of airway obstruction, desaturation, or even aspiration due to the possibility of deep sedation after infusion of a combination of two or more drugs (GHISI, et al 2005, Sohn and Ryu 2016. In contrast, moderate sedation /analgesia (conscious sedation) is a drug induced depression of consciousness during which patients respond purposefully to verbal commands alone or with

light tactile stimulation. No interventions are required to maintain a patent airway, spontaneous ventilation is adequate and cardiovascular function is usually maintained.

MAC allows for the safe administration of a maximal depth of sedation more than that provided during moderate sedation. The qualified anesthesiologist /provider is able to adjust the sedation level from full consciousness to general anesthesia during the procedure according to the patient needs and procedural requirements. An essential component of MAC is the periprocedural anesthesia assessment and understanding of the comorbidities and management of the patient's actual or anticipated physiological instabilities during a diagnostic or therapeutic procedure. MAC may include the administration of sedatives and/or analgesics often used for moderate sedation, however the qualified MAC provider is focused exclusively and continuously on the patient for any attendant airway, hemodynamic and physiologic instabilities, and must be prepared and qualified to convert to general anesthesia. The provider's ability to intervene to rescue a patient's airway from any sedation-induced compromise is required. On the other hand, moderate sedation is not expected to induce the level of sedation that would impair the patient's respiratory function or ability to maintain the integrity of his or her airway, and the moderate sedation provider or anesthesiologist focus is on the procedure itself. (ASA 2018)

The use of MAC is increasing for a variety of diagnostic and therapeutic procedures in and outside of the operating room due to the rapid postoperative recovery with the use of relatively small amounts of sedatives and analgesics compared to general anesthesia. Procedures performed with MAC include eye surgery, otolaryngologic surgery, cardiovascular procedures, pain procedures, and endoscopy. Sedation and analgesia during MAC are provided by an anesthesia care team following the same preoperative evaluation, perioperative management, monitoring, and postoperative recovery care used for general or regional anesthesia (Sohn and Ryu 2016).

Some researchers found that the overall rate of complications during and after MAC may be similar to that for general anesthesia. These potential complications associate with MAC include

- Respiratory complications, including airway obstruction, respiratory depression with hypoxemia and hypercarbia, and aspiration due to depression of airway reflexes.
- Cardiovascular compromise, including hypotension, cardiac ischemia, cardiac arrest, and arrhythmias.
- · Complications related to patient movement
- Burn injuries, particularly involving the head and neck
- Local anesthetic systemic toxicity (LAST

10/10/2022: MTAC REVIEW

Evidence Conclusion: To date, there are no published literature on the comparative efficacy and safety of monitored anesthesia care and moderate sedation for patients on chronic marijuana use undergoing gastrointestinal endoscopic procedures.

Additional research is needed to determine the efficacy and safety of MAC in these patients. <u>Articles:</u> The literature search did not reveal any published RCTs or observational studies that compared the outcomes of MAC versus moderate conscious sedation for GI endoscopic procedures in adults on chronic marijuana use. The published literature mainly discussed the effects of cannabis use on the anesthesia risk, the dose of propofol required, the need for using adjuncts such as fentanyl and ketamine, and or the risk of adverse cardiac or respiratory events during or immediately after anesthesia.

The use of Monitored Anesthesia Care (MAC) For Chronic Marijuana Users Undergoing Gastrointestinal Endoscopic Procedures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Medical necessity no longer required:

| CPT® | Description |
|-------|--|
| Codes | |
| 00731 | Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; not otherwise specified |
| 00811 | Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; not otherwise specified |
| 00812 | Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum; screening colonoscopy |
| 00813 | Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum |

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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| Date Created | Date Reviewed | Date Last Revised |
|-----------------|--|----------------------|
| 09/10/2012 | 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/03/2014 ^{MPC} , 04/07/2015 ^{MPC} , 05/05/2015 ^{MPC} , 03/01/2016 ^{MPC} , 01/03/2017 ^{MPC} , 11/07/2017 ^{MPC} , 09/04/2018 ^{MPC} , 09/03/2019 ^{MPC} , 09/01/2020 ^{MPC} , 09/07/2021 ^{MPC} , 09/06/2022 ^{MPC} , 04/02/2024 ^{MPC} , 04/01/2025 ^{MPC} | 04/01/2025 |

^{MDCRPC} Medical Director Clinical Review and Policy Committee ^{MPC} Medical Policy Committee

| Revision | Description | |
|------------|--|--|
| History | | |
| 05/05/2015 | Slight changes were made to the existing policy, which included the following: | |
| | Removal of the 70-age limit | |
| | Definition of pediatric age group as 16 years and younger | |
| | Clarification of "high dose" & "unstable" | |
| | "as documented by anesthesia" language was added | |
| 09/08/2015 | Revised LCD L34100 | |
| 10/3/2016 | Added prolonged procedure clarification | |
| 09/06/2017 | Changed BMI to 40 | |
| 10/19/2017 | Added examples of prolonged procedures | |
| 04/09/2018 | MA retired LCD 34100 | |
| 05/23/2018 | Removed the language regarding the Mallampati score | |
| 09/04/2018 | Added specific language regarding marijuana use | |
| 05/05/2020 | MPC approved to adopt updates to align with ASA class ASGE recommendations. Requires 60-day notice, effective date 9/1/2020. Removed deleted CPT codes 00740 and 00810 and added CPT code 00732. | |
| 06/16/2020 | Removed 00732 (ERCP) | |
| 11/02/2021 | MPC approved to remove the prior-authorization requirement for Medicare members, effective January 1, 2022. | |
| 09/06/2022 | MPC approved the MAC criteria update for ASA class from IV to III and the inclusion of coverage for members with current suboxone use. 60-day notice required; effective 2/1/2023. | |
| 12/06/2022 | Updated MAC effective date to 3/1/2023 per Provider Relations. | |
| 12/07/2022 | Added MTAC Review for Monitored Anesthesia Care (MAC) For Chronic Marijuana Users | |
| | Undergoing Gastrointestinal Endoscopic Procedures to criteria. | |
| 05/02/2023 | MPC approved to support KPWA executive leaderships recommendation to remove prior | |
| | authorization and medical necessity criteria for MAC. 60-day notice expedited; effective September | |
| | 1, 2023. | |
| 04/01/2025 | MPC approved to retire clinical criteria for Monitored Anesthesia Care, effective 09/01/2025. | |

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