

Clinical UM Guideline

Subject: Site of Care: Hospital-Based Ambulatory Surgical Procedures and Endoscopic Services

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Description

This document addresses the clinical features that may increase an individual's risk of requiring urgent access to care available in a hospital outpatient department, hospital outpatient clinic, or hospital-based outpatient surgery facility during outpatient procedures, including but not limited to endoscopic services.

Note:

In some plans, "level of care," "site of service" or another term such as "setting" or "place of service" may be the term used in benefit plans, provider contracts, or other materials instead of, or in addition to, "site of care" and, in some plans, these terms may be used interchangeably.

Note: Please see the following related documents for additional information:

- <u>CG-MED-34 Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures</u>
- CG-MED-59 Upper Gastrointestinal Endoscopy in Adults
- CG-MED-83 Site of Care: Specialty Pharmaceuticals
- CG-SURG-10 Ambulatory or Outpatient Surgery Center Procedures

Clinical Indications

Note: This guideline will be used for the evaluation of a subset of ambulatory procedures that will be determined and posted by individual lines of business. The medical necessity of the procedure may be separately reviewed against the appropriate criteria. This guideline is for determination of the medical necessity of an outpatient hospital facility site of care for the procedure. This guideline is not for determination of the medical necessity of inpatient site of care.

Medically Necessary:

- A. An outpatient surgery, including but not limited to endoscopic services, in a hospital-based facility is considered**medically necessary** when **all** of the following are present:
 - 1. The procedure requires that it be performed only by, or under, the general supervision of a licensed clinician; and
 - The individual's medical status or the procedure requires enhanced monitoring beyond what would routinely be needed for rendering such services in a free-standing ambulatory procedural setting; and
 - 3. The potential changes in the individual's medical status could require immediate access to specific services of a medical center/hospital setting, such as emergency resuscitation equipment and personnel, and inpatient admission or intensive care. For example, the individual is at significant risk of sudden life-threatening changes in medical status based on clinical conditions including but not limited to:
 - a. concerns regarding fluid overload status; \boldsymbol{or}
 - b. history of significant instability during a prior procedure that is considered a risk for other future procedures pr
 - c. at risk for excessive bleeding; or
 - d. acute mental status changes; or
 - e. under the age of 18; or
 - f. pregnancy; or
 - g. increased risk for complication due to severe comorbidity, such as that evidenced by an American Society of Anesthesiologist's (ASA) class III physical status or greater; **or**
 - h. prolonged anesthesia is anticipated.
- B. An outpatient surgery, including but not limited to endoscopic services, in a hospital-based facility is considered**medically necessary** when there are no other geographically accessible appropriate alternative sites for the member to undergo the procedure.

Not Medically Necessary:

All other uses of a hospital-based facility for an outpatient procedure are considerechot medically necessary.

Coding

Coding edits for medical necessity review are not implemented for this guideline. Where a more specific policy or guideline exists, that document will take precedence and may include specific coding edits and/or instructions. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Discussion/General Information

Outpatient, or ambulatory, surgical procedures are often referred to as 'minor surgeries' or 'same-day surgeries' and are defined by being low-risk and non-invasive enough that they do not routinely necessitate an overnight hospital stay. AHRQ estimates that 65% of all surgical procedures in the United States are performed on an outpatient basis (AHRQ, 2015). Approximately 25 million surgeries are performed annually in ambulatory surgery centers (AHRQ, 2014). The safety and efficacy of office-based and freestanding ambulatory center procedures is well established. Hospital-based ambulatory procedures are generally more appropriate for individuals whose health status necessitates the availability of a higher site of supportive care for the minimization of the risks associated with adverse health events.

There is limited evidence, consensus and guidance on the appropriate selection criteria for procedures performed in hospital-based

versus office-based or ambulatory care settings. In 2013, a retrospective case control study by Whippey and colleagues sought to determine risk factors for unanticipated hospital admissions following ambulatory surgery procedures. From a database containing 20,657 individuals who had undergone ambulatory procedures, random samples of 200 hospital admissions and 200 individuals who did not require hospitalization were enrolled. The incidence of unanticipated admissions following ambulatory procedures in this database was 2.67% over a 24 month period (June 2008-June 2010). Individuals identified as requiring admission prior to commencement of the procedure and those under 18 years of age were excluded from analysis. Computer software generated a list of randomly-selected files. Four different reviewers manually performed chart extraction for information not contained in the database. Inter-reviewer reliability was 95% accurate. After adjustment for the length of surgery, three risk factors were significantly associated with an increased likelihood of admission:

- American Society of Anesthesiologists' (ASA) Physical Status Classification of III ("A patient with severe systemic disease"; [ASA, 2020]) (odds ratio [OR]=4.60; 95% confidence interval [CI], 1.81-11.68) or
- ASA Class IV ("A patient with severe systemic disease that is a constant threat to life"; [ASA, 2020]) (OR=6.51; 95% CI, 1.66-25.59), over 80 years of age (OR=5.41; 95% CI, 1.54-19.01) and
- A BMI of 30-35 (OR=2.8; 95% CI, 1.31-6.04). The authors noted with regards to selection criteria, no specific comorbid illness
 was associated with an increased likelihood of unanticipated admission and that their findings support the use of the ASA
 classification system as an indication of perioperative risk.

Post-procedural bleeding is the most common serious adverse event among endoscopies and is estimated to occur at a rate of 1.64-6.4 per 1000 endoscopic procedures. This complication is most often related to a polypectomy during colonoscopy, but perforation is also a major contributor (Borgaonkar 2012). Therefore, individuals at excessive risk for bleeding may warrant access to a higher site of care for extended periods of observation and transfusion-related support in the event of unanticipated blood loss.

Although the appropriateness of ambulatory procedures for an individual with obstructive sleep apnea (OSA) remains controversial the Society of Ambulatory Anesthesia developed a consensus statement on selection criteria for individuals with OSA (Joshi, 2012). The statement summary is as follows:

Patients with a known diagnosis of OSA and optimized comorbid medical conditions can be considered for ambulatory surgery if they are able to use a continuous positive airway pressure device in the postoperative period. Patients with a presumed diagnosis of OSA, based on screening tools such as the STOP–Bang questionnaire, and with optimized comorbid conditions, can be considered for ambulatory surgery if postoperative pain can be managed predominantly with nonopioid analgesic techniques. On the other hand, OSA patients with nonoptimized comorbid medical conditions may not be good candidates for ambulatory surgery.

The consensus statement concludes that individuals with poorly controlled comorbid medical conditions are poor candidates for free-standing ambulatory centers and office-based procedures. "Poorly managed comorbid conditions" falls within the ASA III or higher classification, thus SAMBA's statement supports Whippey and colleagues' (2013) conclusion in the previously described study.

A recent retrospective study conducted by Hackett and colleagues (2015) assessed the ASA Physical Status Classification System's reliability as an independent predictor of unanticipated morbidity and mortality after surgery. A total of 2,297,629 cases were included in the study; investigators found that with each increasing level of ASA classification (II-V), the OR increased from 2.05 to 63.24 for complications (p < 0.001), and 5.77-2011.92 for mortality (p < 0.001), with non-overlapping 95% CIs. Authors concluded that the strong independent association of ASA class, independent of other comorbidities, across all procedure types validates its use a reliable prognostic tool for identifying those at risk for perioperative complications.

Similarly, Enestvedt and colleagues (2013) retrospectively analyzed 1,590,648 endoscopic procedures, specifically, to determine the predictive value of ASA score for immediate adverse events. An event occurred in 0.035% of procedures (n=5596). Authors concluded that increasing ASA score was significantly associated with risk of adverse event, particularly for colonoscopy and EGD. Agostoni and colleagues (2011) analyzed data for adverse events during monitored anesthesia care, also specifically for endoscopies, over an 8 year period. Cardiac and respiratory events were associated with an ASA score of III or higher (n=17,999). Berzin and colleagues (2011) similarly found cardiac and respiratory events associated with a higher ASA score in a smaller prospective study (n=528) of individuals undergoing ERCP.

Hung and colleagues (2015) used incidence of reversal of sedation in EGD and colonoscopy procedures as the outcome of interest in a retrospective study recently published that concluded a higher ASA score was associated with perioperative complications (adjusted OR=4.71; 95% CI, 1.7-13.1). Cote and colleagues (2015) performed the first prospective study of endoscopy procedures and incidence of sedation reversal in 799 individuals sedated with propofol. Study participants were enrolled over a 7-month period; 60.5% of individuals in this population sample were classified as ASA physical status of III or higher. Authors noted this was a uniquely complex sample; however, similar to previously described studies they also concluded that an ASA class of III or higher was a predictor of reversal of sedation even in this population with an excessively high burden of comorbidities (Adjusted OR=1.90; CI, 1.11-2.35; p=0.02).

Qin (2019a) conducted a large, retrospective cohort study comprised of 84,658 individuals who had undergone non-arthroplasty shoulder surgery. The authors queried the Humana Claims database for open procedures in the hospital-based outpatient department (n=56,819) or ambulatory surgical center (n=28,730). Primary outcomes included adverse events and readmission following surgery. Overall, there was a lower rate of perioperative morbidity and unplanned admissions in the ambulatory surgery center cohort. The authors concluded that this is evidence that proper selection of ambulatory surgery center candidates is occurring.

Qin and colleagues (2019b) conducted an additional retrospective cohort study using the Humana Claims Database to query individuals undergoing anterior cruciate ligament reconstruction (ACLR) in ambulatory surgery centers (n=5298) or hospital-based outpatient departments (n=8349). Analysis of the post-matched cohort revealed no differences between cohorts for mechanical failure, nerve injury, pulmonary embolism, septic joint, wound infection, revision surgery and readmission. Using logistic regression, ambulatory procedures were associated with a significantly decreased risk for deep vein thrombosis (OR=0.87, 95% CI, 0.83-0.93; p<0.01) and pulmonary embolism (OR=0.85, 95% CI, 0.78-0.95; p=0.01).

In another large, retrospective cohort, study 1,020,372 individuals with single and multiple comorbidities who had undergone a colonoscopy were enrolled from ambulatory surgery or hospital discharge datasets. Hospitalizations within 30 days post-op due to colonic perforation or gastro intestinal bleeding were the primary outcomes of interest. Ambulatory surgical centers had higher risks of adverse events amongst individuals with comorbidities when compared to hospital-based outpatient surgery centers (OR=2.85; 95% CI, 2.40-3.38). Study participants with comorbid conditions, systemic diseases, or advanced age had higher risks of experiencing an adverse event (Chukmaitov, 2019). The study provides support for referring individuals with chronic comorbidities to facilities such as hospital-based outpatient facilities, to reduce the incidence of adverse events.

American College of Surgeons (ACS) Guideline on Optimal Ambulatory Surgical Care and Office-based Surgery supports the use of ASA Physical Status Class for selection criteria in the office-based/ambulatory surgical setting (ACS, 2004).

There is no single age cut-off for individuals in a pediatric or geriatric age group that would clearly determine an individual to be at higher risk of adverse event during an ambulatory procedure. Several organizations have proposed age cut-offs for monitored sedation ranging from 19 to 21 years. Other organizations are silent regarding at what age an individual is no longer considered to be in the pediatric age group (American Academy of Pediatrics [AAP], 2006; American Society for Gastrointestinal Endoscopy [ASGE], 2014). Typically, by the age of 18 an individual will have finished growing in regards to facial structures and airway size. The U.S. Preventative Services Task Force (USPSTF) recommends against routine colonoscopy screening in adults over 76 years of age because of the increased risk of procedures in this population (USPSTF, 2008). Other studies suggest that individuals over 80 years of age are at increased risk during procedures (ASGE, 2013). In the aged, health status is likely a more reliable predictor of risk factors associated with adverse events during ambulatory care procedures rather than chronological age.

Definitions

Adverse event: An event that prevents completion of the planned procedure or results in admission to hospital, prolongation of existing hospital stay, or requires another procedure or subsequent medical consultation.

Comorbidity: Two or more disorders or illnesses occurring in the same person.

Endoscopic procedure: A procedure that allows a physician to examine the inside lining of the digestive tract. This examination is usually performed using a flexible, fiber-optic tube with a tiny camera at the end called and endoscope. An endoscopy is used for both diagnosis of gastrointestinal (GI) disease and treatment.

Obstructive sleep apnea (OSA): A sleep disorder that involves cessation or significant decrease in airflow in the presence of breathing effort.

Surgical procedures: Operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive procedures such as transplantation. They include the procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) as well as certain other invasive procedures such as minimally invasive procedures involving biopsies, placement of probes or catheters requiring the entry into a body cavity, and angioplasties.

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Peer Reviewed Publications:

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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

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History		
Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References Section.
Reviewed	08/11/2022	MPTAC review. Updated References Section.
Reviewed	08/12/2021	MPTAC review. Updated References Section.
Revised	08/13/2020	MPTAC review. Updated Description, Clinical Indications and Discussion/General Information section to address 'site of care' removing reference to 'level of care'.
		Revised Title to: Site of Care: Hospital-Based Ambulatory Surgical Procedures and
		Endoscopic Services. Updated References Section.
Revised	08/22/2019	MPTAC review. Formatting update in Clinical Indications and Discussion/General Information section. Updated References Section.
Reviewed	09/13/2018	MPTAC review. Updated References Section.
Reviewed	11/02/2017	MPTAC review. Revised Title. Updated header language from "Current Effective Date" to "Publish Date." Updated References Section.
Reviewed	05/04/2017	MPTAC review. Updated References Section.
Revised	05/05/2016	MPTAC review. Removed 'over the age of 70' from MN criteria. Updated Discussion/General Information and References sections. Appendix added.
New	11/05/2015	MPTAC review. Initial document development.

Appendix

American Society of Anesthesiology Physical Status Classifications:

ASA I A normal healthy patient

ASA II A patient with mild systemic disease

ASA III A patient with severe systemic disease

ASA IV A patient with severe systemic disease that is a constant threat to life

ASA V A moribund patient who is not expected to survive without the operation

ASA VI A declared brain-dead patient whose organs are being removed for donor purposes

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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