Policy Statement

Procedures which are performed in an inpatient or outpatient hospital setting but meet the medically necessary criteria for an ambulatory surgery center (ASC) or other outpatient facility, may be considered to not be provided in the most appropriate care setting. Providers who request these services to be performed in a hospital may be re-directed to a more appropriate care setting.

Policy Statement:
The use of an ambulatory surgery center (ASC) or outpatient facility may be considered medically necessary on an ambulatory basis when all of the following criteria are met:

- Immediate access to unique services of a medical center or hospital setting including, but not limited to post-operative recovery in an inpatient facility is not anticipated to be required for the preoperative disease or condition being treated or due to co-morbidities (e.g., infection, coagulopathy, altered mental status, dangerous arrhythmia, hypotension, hypoxemia, tachycardia, tachypnea)
- The treating health care professional has privileges for the requested procedure at an ASC
- In the event of unforeseen complications requiring an inpatient level of care, the requesting provider must either have the ability to care for the patient in the inpatient setting (including privileges) or have a written agreement in place with another qualified provider to accept and care for the patient if a transfer to an inpatient facility is needed
- ASC must be accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations [JCAHO])
- Procedure is non-emergent
- Procedure is low-risk or patient is not a high anesthetic risk (or high-risk for surgery; see Policy Guidelines section)
- Cardiac clearance has been done for patients with stents and arrhythmias not considered to be low risk
- There is no significant increased risk related to drugs (see Policy Guidelines section)
- There is no significant risk due to living situation (outpatient care; see Policy Guidelines section)
- Patient is cooperative and able to understand and follow instructions
- Patient has good social support readily available to assist with any of the following if needed:
  - Pre-operative preparatory education
  - Accompany the patient home
  - Accompany the patient to their physical therapy and post-operative appointments as needed until the patient is independently mobile

The use of an ASC or outpatient facility is considered not medically necessary for patients requiring a complex surgical approach or situation, including but not limited to any of the following:

- Open approach is required instead of the usual endoscopic, transcatheter, or other less invasive procedure
- A difficult approach is required due to a previous operation
- Airway monitoring is required after open neck or other procedure
- Medical conditions that are commonly associated with a difficult airway (e.g., Pierre-Robin, Treacher-Collins, Goldenhar’s Syndrome, Epidermolysis Bullosa)
- Unusually extensive dissection is needed
- Additional complicating feature requiring inpatient care (e.g., complex drain management)
The use of an ASC or outpatient facility is considered **not medically necessary** for all other indications outside of the medically necessary criteria.

### Policy Guidelines

#### High Anesthetic Risk and High-Risk Conditions

Conditions that are considered high anesthetic risk or at high-risk for surgery include, but are not limited to any of the following:

- American Society of Anesthesiologists class III or greater* (severe systemic disease impairing function) American Society of Anesthesiologists (ASA) Physical Status Classification System² (see Table 1)
- Severe frailty
- Age 85 years or older
- Severe cardiac valvular disease (e.g., aortic stenosis)
- Symptomatic coronary artery disease, or heart failure
- High risk for severe postoperative abnormalities (e.g., electrolyte abnormality, dangerous arrhythmia)
- Symptomatic chronic lung disease, including any of the following:
  - Asthma (FEV1 less than 80% despite medical management)
  - Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%)
  - Chronic lung disease of prematurity
- Severe renal disease (e.g., glomerular filtration rate (GFR) less than 30 mL/min/1.73m² [0.5 mL/sec/1.73m²] or on dialysis)
- Cirrhosis or esophageal varices
- Hypercoagulability
- At risk laboratory results, including any of the following:
  - Hemoglobin (Hgb) less than 12 gm/dl
  - Albumin (Alb) less than 3.4 g/dl
  - HbA1c greater than 7.5 %
  - Platelets less than 150,000 per microliter
- Morbid obesity (e.g., body mass index [BMI] greater than 40 BMI Calculator) with hemodynamic or respiratory problems (e.g., severe obstructive sleep apnea, hypoventilation)
- Moderate or severe obstructive sleep apnea (OSA)

*Note: Some patients who are ASA class III may be safe for using an ASC on exception based on both the planned procedure and clinical information.

#### Table 1. ASA Physical Status Classification System

<table>
<thead>
<tr>
<th>ASA PS Classification</th>
<th>Definition</th>
<th>Examples, including, but not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal healthy patient</td>
<td>Healthy, non-smoking, no or minimal alcohol use</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
<td>Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30&lt;BMI&lt;40), well-controlled DM/HTN, mild lung disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
<td>Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA &lt;60 weeks, history (&gt;3 months) of MI, CVA, TIA, or CAD/stents.</td>
</tr>
</tbody>
</table>
ASA PS Classification | Definition | Examples, including, but not limited to:
---|---|---
ASA IV | A patient with severe systemic disease that is a constant threat to life | Examples include (but not limited to): recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V | A moribund patient who is not expected to survive without the operation | Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI | A declared brain-dead patient whose organs are being removed for donor purposes

*The addition of “E” denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

BMI: body mass index; DM: diabetes mellitus; HTN: hypertension; COPD: chronic obstructive pulmonary disease; ESRD: end-stage renal disease; PCA: Post conceptional age; MI: myocardial infarction; CVA: cerebrovascular accident; TIA: transient ischemic attack; CAD: coronary artery disease; DIC: disseminated intravascular coagulation; ARD: acute respiratory distress.

Drug-Related Risks
Drug related risks may include any of the following:
- Procedure requires discontinuing drugs or other therapy (e.g., antiarrhythmic medication, antiseizure or anticoagulant medication), necessitating preoperative or postoperative inpatient monitoring or treatment
- Preoperative use of drugs that may interact with anesthetics (e.g., cocaine, amphetamines, monoamine oxidase inhibitor) to the extent that longer postoperative monitoring or treatment is needed

Inadequate Outpatient Care Situations
An inadequate outpatient care situation may include any of the following scenarios:
- Patient lives remote from a medical facility and the procedure requires an urgent complication potential, and temporary nearby residence cannot be arranged
- Patient requires longer general anesthesia (GA) or procedure side effect resolution time, and a competent person to stay with patient on the first postoperative night at home or alternative level of care (LOC) cannot be arranged
- Patient will have postprocedure incapacitation and has inadequate assistance at home, or alternative level of care (LOC) cannot be arranged

Exclusion Criteria
Patients requesting surgery with the following conditions (not an all-inclusive list) are to be excluded from the use of an ASC or outpatient facility and advised to seek medical treatment at a medical center or hospital setting or post-operative recovery in an inpatient facility:
- Advanced liver disease (Model for End-Stage Liver Disease [MELD] Score greater than 8)
- Alcohol dependence who is at risk for withdrawal syndrome
- Automatic implantable cardioverter-defibrillator (AICD) or pacemaker dependent patients
- Brittle diabetes (instable diabetes that results in disruption of life and often recurrent/prolonged hospitalization)
- High potential to require a transfusion of blood products (DDAVP® tablets [desmopressin acetate] is not blood product)
- History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) within the past 3 months
- History of myocardial infarction (MI) within the past 3 months
- Hyperthermia: Patients with known or family history of malignant hyperthermia (MH) unless results of a negative MH diagnostic test are available
- Infection: Previous total joint infection, an incompletely treated skin or wound infection, or an active respiratory infection
- Lymphedema (significant)
- Medical conditions that are commonly connected with difficult airway (e.g., Pierre-Robin, Treacher-Collins, Goldenhar’s Syndrome, and Epidermolysis Bullosa)
- Multiple coexisting cardiac or pulmonary problems that are poorly controlled (e.g., hypertension [HTN] or angina)
- Neuromuscular disorders (stroke with deficits on the operative side, Parkinson, Cerebral Palsy [CP], post-polio)
- Non-ambulatory patients
- Pregnant patients
- Renal failure patients
- Resistant hypertension (poorly controlled despite use of 3 antihypertensive agents of different classes)
- Severe pulmonary hypertension, hypertrophic cardiomyopathy, or previous Tetralogy of Fallot
- Transplant patients
- Uncompensated chronic heart failure (New York Heart Association [NYHA] class III or IV)

### Description

Ambulatory surgery centers (ASCs) are freestanding medical facilities which offer patients the opportunity to have selected surgical and procedural services performed outside the hospital and/or physician’s office setting, in an environment appropriate for low risk procedures for patients with low risk health status. Patients who choose to have surgery in an ASC arrive on the day of their procedure, have their surgery in a fully equipped operating room and recover under the care of a highly skilled clinical team, all without hospital admission. These facilities are either independent (i.e., not a part of a provider of services or any other facility) or operated by a hospital.

### Related Policies

- N/A

### 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

Ambulatory surgery centers (ASCs) are health care facilities that are required to meet many statutes and regulations at both the federal and state levels. These laws cover all aspects of ASCs from their daily operations. ASCs are required to be reviewed regularly by state and federal quality agencies to ensure patient safety and quality.

Most ASCs provide care to Medicare beneficiaries and, thus, must demonstrate continual compliance with Medicare standards. There are additional federal laws all ASCs must comply with, such as the Health Insurance Portability and Accountability Act (HIPAA). In addition, ASCs must meet specific requirements and obtain a state license in virtually every state.
The Centers for Medicare & Medicaid Services (CMS) described the regulations it deleted or revised as part of the recently issued "Burden Reduction Final Rule". The changes apply to deemed ambulatory surgical centers (ASCs) and Federally Qualified Health Centers (FQHCs). In response, The Joint Commission has revised its ambulatory care standards to align with these CMS changes. A summary of the changes include:

- Removal of the expectation for ASCs to have written hospital transfer agreements
- Providing increased flexibility for pre-surgical history & physicals (H&Ps) in ASCs
- Revision of timelines for emergency preparedness plan review, testing and staff training

These ambulatory care standards changes are effective March 15, 2020 and are currently posted and available for review on The Joint Commission’s website pre-publication standards page.

**Rationale**

**Background**

Ambulatory surgery centers, or ASCs, are facilities where surgeries that do not require hospital admission are performed. ASCs are facilities that provide surgical procedures exclusively on an outpatient basis. ASCs provide cost-effective services and a convenient environment that is less stressful than what many hospitals can offer. Patients who choose to have surgery in an ASC arrive on the day of their procedure, have their surgery in a fully equipped operating room and recover under the care of highly skilled nurses, all without hospital admission. Whether they are young or old or somewhere in between, patients and their families benefit from the comfortable environment ASCs offer.

ASCs may perform surgeries in several specialties or dedicate their services to one specialty, such as eye care or pain management.

ASCs are not physicians' offices, rural health clinics, urgent care centers or ambulatory care centers that provide diagnostic or primary health care services. ASCs treat only patients who have already seen a health care provider and selected surgery as the appropriate treatment for their condition. All ASCs must have at least one dedicated operating room and the equipment needed to perform surgery safely and ensure quality patient care.

The first ASCs were established in the early 1970s, with Medicare first offering coverage for ASC services under Part B in 1982. At that time there were only 30 surgical procedures that met government guidelines for coverage. Since the 1980s, the share of surgeries performed in outpatient settings has grown significantly. In 1981, approximately 81 percent of surgeries were performed in hospitals on an inpatient basis. By 1999, inpatient surgeries represented only 37 percent of all surgeries, compared to 63 percent for outpatient surgeries. These shares have remained stable for the past several years.

At the same time, there has been a steady movement of surgery away from hospital outpatient settings toward ASC and physician offices. In 1981, the vast majority (93 percent) of outpatient surgeries were performed in hospital outpatient departments. The share of surgeries performed in hospital outpatient departments (HOPDs) (or hospital-owned facilities) fell to 45 percent by 2005, with the share of surgeries performed in freestanding facilities increasing almost four-fold.

In 2008, there were approximately 5,149 Medicare-certified ASCs in the United States, excluding 23 ASCs located in Puerto Rico and 2 in Guam. This number has increased steadily over the past ten years. The vast majority of ASCs remain under private ownership. The number of HOPDs, on the other hand, has remained fairly stable over the years, despite an overall increasing trend in the number of outpatient surgeries. There were slightly more than 4,800 HOPDs in 2008. ASCs are concentrated heavily in California, Florida, and Texas, with 694, 387, and 347 facilities in each state in 2008, respectively.
Literature Review

Specialties Served in Ambulatory Surgery Centers

ASCs offer a variety of surgical services (see Table 1). In 2007 Medicare reported thirty-five percent of ASCs are multi-specialty providers in that they provide a mix of surgical services. A number of facilities were identified as specializing in either gastrointestinal procedures or ophthalmology.4

Table 1. Specialties Performed in Medicare-Certified ASCs (2007)

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal</td>
<td>24%</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>19%</td>
</tr>
<tr>
<td>Mixed or Multiple Specialty</td>
<td>35%</td>
</tr>
<tr>
<td>Pain Management</td>
<td>8%</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>7%</td>
</tr>
<tr>
<td>Otorhinolaryngology</td>
<td>1%</td>
</tr>
<tr>
<td>Urology</td>
<td>2%</td>
</tr>
<tr>
<td>Vascular</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>General Surgery</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Dental</td>
<td></td>
</tr>
<tr>
<td>Endoscopy</td>
<td></td>
</tr>
<tr>
<td>Obstetrics/Gynecology</td>
<td></td>
</tr>
<tr>
<td>Ophthalmology</td>
<td></td>
</tr>
<tr>
<td>Orthopedic</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Otolaryngology</td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Plastic</td>
<td></td>
</tr>
<tr>
<td>Podiatry</td>
<td></td>
</tr>
</tbody>
</table>

Source: 2007 Medicare Physician/Supplier Procedure Summary (PSPS) file.5

More recently, the following specialties are typically performed in Medicare-Certified ASCs (see Table 2)6:

- Dental
- Endoscopy
- Obstetrics/Gynecology
- Ophthalmology
- Orthopedic
- Other
- Otolaryngology
- Pain
- Plastic
- Podiatry
Table 2. Specialties Performed in Medicare-Certified ASCs (2019)\(^6\)

![Specialties Performed in Medicare-Certified ASCs](image)

![Single-Specialty, Medicare-Certified ASCs by Specialty Type](image)

*Based on data provided by the Centers for Medicare & Medicaid Services (CMS), June 2019*
Hollenbeck et al (2014) performed a retrospective cohort study of Medicare beneficiaries undergoing outpatient surgery between 2001 and 2010. The literature compared population-based rates of outpatient surgery in Hospital Service Areas (HSAs) with freestanding ASCs to those without. After adjusting for differences using multiple propensity score methods, the impact of ASC opening in a HSA previously without one on rates of outpatient surgery were assessed. Adjusted outpatient surgery rates increased from 2,806 to 3,940 per 10,000 and the number of ASC operating rooms grew from 7,036 to 11,223 (both p < 0.001 for trend). By the 4th year after opening, rates of outpatient surgery increased by 10.9% (from 3,338 to 3,701 per 10,000) in HSAs adding an ASC for the first time. In contrast, outpatient surgery rates grew by only 2.4% and 0.6% in HSAs where an ASC was always or never present, respectively (p < 0.001 for test between 3 slopes). Rather than redistributing patients from one setting to another, the opening of ASCs increases outpatient surgery use. However, the 10.9% increase is more modest than previously suggested by state-level data.7

Over the last decade, the rate of outpatient surgery among Medicare Beneficiaries increased by 40%. Concurrent with this trend, the capacity for delivering these procedures grew by nearly 60% with the addition of 4,187 new operating rooms in freestanding ASCs. Rates of outpatient surgery in HSAs with ASCs were approximately 10% higher relative to those without in every year of the 2014 retrospective cohort study mentioned above. When an ASC was added to a market previously without one, rates of outpatient surgery quickly caught up to those in markets where an ASC was always present. Specifically, at four years after opening, rates grew by approximately 11% in markets where an ASC was added for the first time. Similar trends were evident in procedure groups representing specialties that commonly use ASCs.7

**Anesthesia in the Ambulatory Surgery Center Setting**

Prabhakar et al (2017) published a review noting that ambulatory surgery has grown in recent decades in volume and represents a significant number of anesthetics delivered throughout the United States of America. Preoperative anesthetic assessment in the ambulatory setting has become important because patients with numerous complex comorbidities are now commonplace in this arena. Disease states involving the lungs, the heart, the kidneys, and
subpopulations including those who are obese and the elderly commonly receive anesthetics in an ambulatory setting. The review presented key aspects of current thinking with regard to preoperative assessment and considerations for different critical disease states and subpopulations that are now being managed under ambulatory surgery. Same day surgery centers require patient safety, and expectations are high for patient satisfaction. Advancements in surgical and anesthetic technique have allowed for more complex patients to partake in ambulatory surgery. Anesthesiologists must be familiar with guidelines, state-of-the-art pain management, and standards of preoperative patient evaluation to accurately stratify patient risk and to advocate for patient safety.8

**Medicare National Coverage**

The Centers for Medicare & Medicaid Services (2009) implemented Conditions for Coverage (CfCs) & Conditions of Participations (CoPs) for Ambulatory Surgical Centers (ASCs) which contain the health and safety standards that all ASCs must meet. Covered topics include, but are not limited to: requirements for the ASC’s governing body and management; the provision of surgical services; patient rights; infection control; and patient admission, assessment and discharge.9

**References**

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>04/01/2020</td>
<td>New policy</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.

Prior Authorization Requirements (as applicable to your plan)

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.