JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS23.05
		Effective Date	04/01/2024
		Approval Date	01/16/2024
	Subject **Site of Service - Outpatient Surgical Procedures**	*Supersesedes Date*	05/01/2023
		Page	1 of 11

This document applies to the following Participating Organizations:

Priority Partners US Family Health Plan

Keywords: ASC, Outpatient Hospital , Regulated Space , Site of Service, Surgical Procedures

I. ACTION

	New Policy	
X	Revising Policy Number	CMS23.05
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

A. The purpose of this policy is to provide clinical guidance for site of service redirection of select planned surgical procedures in Maryland hospitals.

B. It is the policy of Johns Hopkins Health Plans (JHHP) to apply criteria to determine whether an outpatient hospital site of service is medically necessary, or if a procedure may be safely and effectively performed at an alternate place of service, (e.g. a network ambulatory surgery center).

C. This policy applies to PPMCO & USFHP members and addresses site of service redirection for network providers.

D. For applicable procedure codes, for members 18 years of age and older refer to Appendix A; for members < 18 years of age refer to Appendix B.
E. Certain procedures may also require a medical necessity review of the procedure using clinical review criteria specific to the procedure, regardless of site of service (e.g. InterQual, JHHP Medical Policy, Tricare Policy) (Refer to Plan preauthorization requirements).
F. This policy takes into consideration the individual needs of the member and the availability of services in the contracted network, including their provider's credentials to perform the procedure in an ambulatory surgery center, and their ability to meet the member's needs.
G. This policy takes into consideration the availability of ambulatory surgery centers within the geographical access standards required by the member's Plan.

IV. POLICY CRITERIA

A. Surgery/Procedure Considerations: JHHP uses CMS guidelines to assist in determining surgeries and procedures that may be appropriate for an Ambulatory Surgery Center setting. Refer to the Addendum AA - ASC Covered Surgical Procedures and EE - Surgical Procedures Excluded files in Related Links: CMS Ambulatory Surgical Center (ASC) - Addenda.

B. Medical Considerations for members 18 years of age and older: (*Applicable to PPMCO & USFHP)* JHHP recognizes that outpatient surgery in an Ambulatory Surgery Center may not be the appropriate site of service for all members. The Outpatient Hospital setting will be considered medically necessary for members with any of the following indications/ conditions/comorbidities including but not limited to:
   1. Ambulatory Surgery Center does not have adequate resources to provide safe and effective or medically necessary timely surgical care (as stated/ documented by the surgeon or ASC).
   2. American Society of Anesthesiologists® Physical Status (ASA PS) score will be reviewed and members with ASA® PS score III or higher will be considered for approval in a hospital-based setting.
   3. Cardiovascular risk
      a. New York Heart Association (NYHA) Class III or IV or decompensated heart failure
      b. Coronary Artery Disease:
         i. Unstable coronary syndrome
         ii. Recent coronary intervention
            - Plain angioplasty within 90 days
            - Bare metal stents (BMS) placed within 90 days
            - Drug eluting stents (DES) placed within 1 year
            - Myocardial infarction within 3 months
      c. Uncontrolled/difficult to control hypertension
      d. Significant or new onset cardiac arrhythmia
      e. Significant valvular heart disease
      f. Implanted pacemaker/AICD
   4. Neurological Risk
      a. Cerebrovascular accident (CVA) or transient ischemic attack (TIA) within 3 months
      b. Preexisting dementia or cognitive impairment (increased risk of post-operative delirium with use of psychoactive and sedative-hypnotic medications)
   5. Endocrine Risk
      a. Uncontrolled/difficult to control diabetes

b. Uncontrolled/difficult to control thyroid disease
c. Uncontrolled/difficult to control adrenal disease
d. Uncontrolled/difficult to control pituitary disease

6. Liver Risk
   a. Liver disease with Model for End-Stage Liver Disease (MELD) Score >8
7. Pulmonary Risk
   a. Severe chronic obstructive pulmonary disease (COPD) (FEV1<50%)
   b. Uncontrolled asthma (active symptoms or FEV1 <80% despite treatment)
   c. Moderate to severe obstructive sleep apnea (OSA), or OSA with unmanaged comorbidities
   d. Moderately severe to severe restrictive lung disease (e.g. pulmonary fibrosis) (TLC ≤ 60% of predicted)
8. Renal Risk
   a. Severe (Stage 4) renal disease (estimated GFR 15-29 mL/min per 1.73m^2)
   b. End stage (Stage 5) renal disease (on dialysis)
9. Other medical conditions and situations
   a. BMI > 50
   b. BMI 40-50 with obesity-related condition or unmanaged comorbidities
   c. Pregnancy
   d. Bleeding disorder requiring replacement factor, blood products, or special infusion product (excluding DDAVP/Desmopressin)
   e. Alcohol dependence
   f. Recent history of drug abuse
   g. Anesthesia complications (personal or family history)
   h. Arterial or venous thromboembolism within 1 month
   i. Post-operative ventilation anticipated
   j. Transfusion anticipated
   k. Significant blood loss anticipated
   l. Surgery >3 hours anticipated
   m. Difficult airway anticipated
   n. History of *anaphylaxis* to medication, latex or iodine
   o. Significant geriatric frailty is defined as 3 or more of the following:
      i. Unintentional weight loss # 10 lbs. in prior year or # 5% weight loss in prior year
      ii. Weakness (grip strength in the lowest 20% at baseline)
      iii. Poor endurance and energy
      iv. Slowness (slow walking speed)
      v. Low physical activity level
10. Additional medical considerations (require secondary medical review with a medical director for approval for an outpatient hospital setting):
    a. Indications not listed, including other chronic unstable conditions affecting a major organ (heart, lung, liver, kidney, brain) that may predispose the member to complications.

C. Medical Considerations for members younger than 18 years of age: (*Applicable to PPMCO & USFHP)* JHHP recognizes that outpatient surgery in an Ambulatory Surgery Center may not be the appropriate site of service for all members. For select pediatric/adolescent elective procedures (e.g. Adenoidectomy, Tonsillectomy, Tympanostomy, Tympanoplasty,

Myringotomy, Septoplasty - Refer to Appendix B) The Outpatient Hospital setting will be considered medically necessary for members with any of the following indications/conditions/comorbidities including but not be limited to:

1. Ambulatory Surgery Center does not have adequate resources to provide safe and effective or medically necessary timely pediatric surgical care (as stated/ documented by the surgeon or ASC) including but not limited to the following:
    a. No available pediatric anesthesiology provider
    b. Pediatric surgical supplies not available
2. The member was assigned ASA PS score of III or higher based on preoperative assessment
3. Airway Risk
    a. Known or anticipated difficult airway management
4. Pulmonary Risk
    a. Severe asthma (Asthma that is uncontrolled despite adherence with maximal optimized therapy and treatment of contributory factors, or that worsens when high dose treatment is decreased.)
    Note: Spirometry depends on patients' ability to carry out the test and it is not a reliable tool to assess airflow obstruction in children younger than 6 years old.
    b. Severe obstructive sleep apnea syndrome (OSAS):
        i. apnea-hypopnea index of 10 or more obstructive events/hour, oxygen saturation nadir less than 80%, or both, OR;
        ii. use of CPAP or BiPAP
    c. Congenital pulmonary disease
5. Cardiac Risk
    a. Cyanotic, palliated or complex congenital heart disease
    Note: Cardiac lesions, atrial septal defect (ASD), ventricular septal defect (VSD), or patent ductus arteriosus (PDA) that are hemodynamically insignificant are appropriate for an ASC.
    b. Known history of pulmonary hypertension
    c. Diagnosed and symptomatic cardiac arrhythmia that has not been ablated or requires a pacemaker
6. Endocrine Risk
    a. Uncontrolled/difficult to control diabetes
    b. Uncontrolled/difficult to control thyroid disease
    c. Uncontrolled/difficult to control adrenal disease
    d. Uncontrolled/difficult to control pituitary disease
7. Renal Risk
    a. Severe (Stage 4) renal disease (estimated GFR 15-29 mL/min per 1.73m^2)
    Note: GFR values for CKD staging are for children older than 2 years of age because the GFR values for younger children are low due to ongoing renal maturation.
    b. End stage (Stage 5) renal disease (on dialysis)
8. Hematological Risk
    a. Bleeding disorder requiring replacement factor, blood products, or special infusion products (excluding DDAVP/Desmopressin)
    b. Blood dyscrasia (e.g. sickle cell disease, beta thalassemia major)
    c. Any transfusion dependent disease
9. Syndromic/ Genetic Risks
    a. Craniofacial syndrome (s) with known association or history of difficult airway

b. Any family history of malignant hyperthermia, muscular dystrophy or myopathy (unless genetically tested as being negative for disease process)
c. Mucopolysaccharoidoses
d. Mitochondrial Disease
e. Myotonic Dystrophy
f. Congenital neuromuscular disease
g. Congenital cardiovascular disease

10. Other indications/conditions/comorbidities
    a. Former premature infants less than 35 weeks gestation age who are less than 1 year postnatal age
    b. BMI > 30
    c. Pregnancy
    d. Alcohol dependence
    e. Recent history of drug abuse or history of drug addiction and is currently prescribed antidote medications
    f. Severe psychiatric illness (e.g. schizophrenia, PTSD, bipolar, suicide ideations)
    g. Severe behavioral disorder (e.g. severe agitation/disruptive behaviors, or requires restraints in public)
    h. History of *anaphylaxis* to medication, latex or iodine
    i. Anesthesia complications (personal or family history)
11. Surgical Risk
    a. Post-operative ventilation anticipated
    b. Transfusion anticipated
    c. Significant blood loss anticipated
    d. Surgery >3 hours anticipated
    e. Post-operative 23-hour observation stay anticipated/required
    f. Craniofacial abnormalities (e.g. Down syndrome, Pierre Robin syndrome, etc.)
12. Additional medical considerations (require secondary medical review with a medical director for approval for an outpatient hospital setting):
    a. Indications not listed, including other chronic unstable conditions affecting a major organ (heart, lung, liver, kidney, brain) that may predispose the member to complications

D. Documentation requirements include but are not limited to physician notes with all pertinent clinical information:
    1. To support medical necessity for site of service in the outpatient hospital setting.
    2. To support medical necessity for procedures that also require a medical necessity review using clinical review criteria specific to the procedure, regardless of site of service.

V. DEFINITIONS

American Society of Anesthesiologists® Physical Status (ASA PS) Score (American Society of Anesthesiologists, 2018)

- 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 purpose

Medical Necessity Review: A process to consider whether a covered service is clinically appropriate based on evidence-based clinical standards of care. Medically necessary services are accepted health care services provided by health care entities, appropriate to evaluation and treatment of a disease, condition, illness or injury (NCQA).

Planned Surgical Procedure: A surgical procedure not done on an emergency basis that has been scheduled for a future date.

Site of Service

- Office: Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis (Place of Service Code, 11) (Centers for Medicare & Medicaid Services, 2021).
- Off Campus-Outpatient Hospital: A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (Place of Service Code, 19) (Centers for Medicare & Medicaid Services, 2021).
- On Campus-Outpatient Hospital: A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization (Place of Service Code, 22) (Centers for Medicare & Medicaid Services, 2021).
- Ambulatory Surgery Center (ASC): A freestanding facility, other than a physician's office, that operates for the purpose of providing surgical services to patients on an ambulatory basis, not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission (Place of Service Code, 24) (Centers for Medicare & Medicaid Services, 2021).

USFHP Access Standards: Travel time for specialty care shall not exceed one hour under normal circumstances, unless a longer time is necessary because of the absence of providers (including providers not part of the network) in the area. (Tricare Policy Manual Chapter 199.17)

PPMCO Access Standards: Geographical access for core specialty types, including surgery are as follows:

- In urban areas, within 30 minutes or 15 miles;
- In suburban areas, within 45 minutes or 30 miles; and
- In rural areas, within 75 minutes or 60 miles (COMAR 10.67.05.06)

VI. BACKGROUND

Since the early 1980s, there has been substantial growth in the prevalence of outpatient surgery, with over 32.0 million procedures performed in 2005 (Munnich, 2014). Analysts at the CDC have suggested that medical advancements and technological advancements (including improvements in anesthesia and pain control methods, and the increased utilization of less invasive procedures) were the two major drivers for this change (Hall, 2017).

As per the American Society of Anesthesiologists®, outpatient surgery is also referred to as "same-day, ambulatory, or office-based surgery" (American Society of Anesthesiologists, 2018). Ambulatory surgery can be performed in the hospital setting (referred to as "hospital outpatient department surgery") or in facilities independent of the hospital setting (referred to as ambulatory surgery centers, or ASCs) (Hall, 2017). Differences between the two sites include services provided, as an

outpatient hospital department can provide additional services beyond outpatient surgery, while an ASC is structured to provide only those services in support of the ambulatory procedure (Munnich, 2014).

Not all outpatient surgeries are identified as being appropriate for both sites of service (CMS, 2023). Since the early 1980s, however, there has been considerable growth in the number of surgeries that can be performed in ambulatory surgery centers, and therefore, an increase in the percentage of all outpatient surgeries that are performed in this site of service (Munnich, 2014). As of 2018, there were around 3,500 Healthcare Common Procedure Coding System (HCPCS) codes that Centers for Medicare and Medicaid Services (CMS) would cover in the ASC setting (MedPAC, 20238).

The appropriate site of service for outpatient procedures is dependent on multiple factors. These include, but are not limited to, the procedure itself, the health status of the patient, and the accessibility of the site of service for both the provider and the patient. It has been suggested in the literature that there is significant cost-saving potential for site of surgery in the ambulatory surgery center as compared to the outpatient hospital setting, making this an important consideration (Munnich, 2014; American Society of Anesthesiologists, 2018). Ultimately, site of service determination for outpatient surgery is an important step in the provision of cost-effective, appropriate, high-quality medical care.

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all-inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

CPT® CODES	DESCRIPTION
Multiple Codes	Refer to Appendix A & B for applicable codes

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Effective Dates: 01/02/2019, 10/01/2019, 09/01/2020, 05/02/2022, 05/01/2023, 7/15/2023 (Appendix), 04/01/2024