


MEDICAL POLICY	Surgical Site of Service
<p>Effective Date: 07/01/2021</p>  <p style="text-align: right;">7/1/2021</p>	<p>Medical Policy Number: 184</p> <p>Medical Policy Committee Approved Date: 04/2020; 05/2020; 06/2021</p>
<p>Medical Officer Date</p>	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request:

- Medical records to include documentation of all of the following:
 - History
 - Physical examination including patient weight and co-morbidities
 - Surgical plan
 - American Society of Anesthesiologists Physical Classification (ASA-PS) score

POLICY CRITERIA

Notes:

- For Medicare members, this policy may only apply to services *not* on the Centers for

Medicare & Medicaid Services Inpatient Only list. The list may be located in the 2021 NFRM OPSS Addenda download on the [Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment \(NFRM\) 2021 webpage](#).¹ After downloading the 2021 NFRM OPSS Addenda .zip file, open either of the two *2021 NFRM Addendum E.11302020* files.

- For definitions or scores referenced in criteria, see the Policy Guidelines immediately following this section.

General Site of Service Criteria

I. Procedures listed in [Table 1](#) of the Policy Guidelines **medically necessary and covered in the inpatient setting** when **any one or more** of the following criteria (A. – E.) are met:

A. American Society of Anesthesiologists (ASA) Score is 3 or higher:

<u>ASA PS Classification</u>	<u>Definition</u>	<u>Adult Examples, Including, but not Limited to:</u>
ASA III	A patient with severe systemic disease	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 < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
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

- B. Advanced liver disease with a [MELD](#) score > 8
- C. Bleeding disorder, anticoagulation use, or anticipated need for transfusion
- D. Currently pregnant
- E. Moderate to severe obstructive sleep apnea (OSA) (AHI ≥ 15)

Procedure-Specific Site of Service Criteria

Note: If criteria I. above are not met, the following may be approved for an inpatient setting based on the criteria below.

Total Knee Arthroplasty

- II. Total knee arthroplasty may be considered **medically necessary and covered in the inpatient setting** when **one or more** of the following criteria (A. – E.) are met:
- A. Bilateral total knee arthroplasty is planned
 - B. Infected joint treatment
 - C. Revision of a prior knee arthroplasty
 - D. Documentation by provider states that patient and/or caregiver does not fully understand the surgical procedure and/or post procedure compliance
 - E. Documentation by provider states that caregiver is not able to manage patient care postoperatively

Site of Service Criteria Not Met

- III. If general site of service criteria (I.A.-E.) or procedure-specific site of service criteria as applicable are not met, the procedure will be considered **not covered as medically necessary in the inpatient setting**.

Link to [Policy Summary](#)

POLICY GUIDELINES

Application of the General Site of Service Criteria

Table 1: Procedures Subject to General Site of Service Criteria

Procedures:	Information:
<i>Total knee arthroplasty</i>	Total knee arthroplasty in the inpatient setting will be reviewed for medical necessity utilizing criteria I. and II. above

Body Mass Index (BMI)²

Metric BMI Formula: BMI= weight (kg) ÷ height² (m²)

Imperial BMI Formula: BMI= weight (lb) ÷ height² (in²) x 703

- Obesity is defined as a BMI of 30.0 kg/m² or higher.
- Obesity is frequently divided into categories:
 - Class I: BMI of 30 kg/m² to < 35 kg/m²
 - Class II: BMI of 35 kg/m² to < 40 kg/m²
 - Class III: BMI of 40 kg/m² or higher
 - A BMI of 40-49.9 kg/m² is considered morbidly obese.
 - A BMI of 50 kg/m² or more is considered superobesity or super morbid obesity.

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American Society of Anesthesiologists (ASA) Physical Status Classification System (ASA-PS)³

Current Definitions and ASA-Approved Examples

ASA PS Classification	Definition	Adult Examples, Including, but not Limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	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 < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
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

**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)*

New York Heart Association (NYHA) Classification⁴

1. Class I – No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
2. Class II – Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
3. Class III – Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
4. Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

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Model for End-Stage Liver Disease (MELD)⁵

The MELD score calculation uses:

- Serum Creatinine (mg/dL)*
- Bilirubin (mg/dL)
- INR
- Serum Sodium (mEq/L)

*For patients who have had dialysis twice within the last week, or 24 hours of CVVHD, the creatinine value will be automatically set to 4 mg/dL.

BILLING GUIDELINES

When billed with **facility code 21** (inpatient hospital) the following codes will require pre-authorization (see CPT/HCPCS CODES section below). Billing with other facility codes will not require pre-auth.

CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required when Billed with Facility Code 21	
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component

DESCRIPTION

Surgical Sites of Service

Numerous procedures other than total knee arthroplasty (TKA) may be subject to review for site of service appropriateness in the future. Currently, the scope of this policy only includes review of TKA site of service. Future additions to the policy will be limited to those not included in the CMS inpatient only list.

Total Knee Arthroplasty

Total knee replacement may also be referred to as total knee arthroplasty (TKA). A TKA is a surgical procedure that consists of removing the damaged articular surfaces of the knee, and then resurfacing with metal or polyethylene prosthetic components.

Mostly commonly, a TKA is indicated for damaged joint cartilage caused by osteoarthritis (OA), rheumatoid arthritis/inflammatory arthritis, posttraumatic degenerative joint disease, or osteonecrosis/joint collapse with cartilage destruction.⁵ In OA, cartilage is degraded and causes remodelling of the underlying bone. The cascading effect is a response of chondrocytes in the articular cartilage and the inflammatory cells in the surrounding tissues. The most common joints affected by osteoarthritis are the small joints of the hands and feet, and the hip and knee joint. A TKA performed for damage caused by OA is indicated for severe pain that inhibits normal functioning that is refractory to nonsurgical management. Rheumatoid arthritis and other inflammatory arthritides may also lead to total degradation of the knee joint, though this has declined since the introduction of antirheumatic pharmacologics. A TKA may also be considered for posttraumatic arthritis following an acute injury, tumor involving the bone, avascular necrosis (osteonecrosis), tibial plateau, or femoral condyle.

Depending on the condition of the patient, a TKA may be safely performed as an outpatient procedure or an inpatient procedure. Outpatient settings may include but are not limited to ambulatory surgical centers (ASC), outpatient hospital care, or medical centers. The preferred site of service is the most appropriate for the condition of the member, safe, and cost effective.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the safety and efficacy of inpatient versus outpatient sites of service for surgical procedures. Below is a summary of the available evidence identified through April of 2021.

Site of Service Patient Selection Criteria

Determining patient risk for adverse effects associated with outpatient surgical settings for elective procedures may be approached with broad patient characteristic identification, and procedure-specific patient stratification depending on the complexity of the surgery. By observing patients immediately after surgery, various algorithmic approaches have been proposed to mitigate risk. These methods have been studied and refined over decades.

In 2007, Gawande et al., reported results of a randomized retrospective review of patient records used to develop a 10-point score of risk of major complication or death within 30 days of surgery.⁶ The authors evaluated patient characteristics at the end of colectomy (N = 303), and validated the risk algorithm in two prospective, randomly selected cohorts in colectomy (N = 102) and general or vascular surgery (N = 767). This scoring system utilizes a patient's estimated amount of blood loss, lowest heart rate, and lowest mean arterial pressure during general or vascular operations to predict risk of major complication or death within 30 days. While being highly predictive, these traits rely on post-procedure data collection.

In response to the Centers for Medicare & Medicaid Services trending towards policy aimed to increase both patient and surgeon input for shared-decision making, Bilimoria et al. (2013) recognized the need for highly predictive models and evaluated 1.4 million patient records representing 1,557 unique CPT codes to develop a universal Surgical Risk Calculator model.^{7,8} Data from all subspecialties in 393 hospitals were sourced from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) between January 1, 2009 and June 30, 2012. The authors found the Surgical Risk Calculator to have excellent performance for mortality (c-statistic=0.944; Brier=0.011[where scores

approaching zero are better]), morbidity (c-statistic=0.816, Brier=0.069), and 6 additional complications (c-statistics>0.8). After comparing universal and procedure-specific models, the authors concluded that the scoring system was reliable between surgeons. The ACS NSQIP relies on CPT codes or procedure names to calculate risk score, and therefore may not be available for all desired procedures.

For emergency general surgery (EGS), Havens et al., reported a narrative review in 2018, evaluating risk stratification tools combining knowledge from numerous scoring systems aimed to objectify the clinical triage process and to quantify probability of serious morbidity and mortality.⁹ The authors evaluated trauma and critical care scoring systems, splitting the surgical risk stratification tool (RSTs) into two general categories: physiologic scores and risk prediction models. Thirteen RST were evaluated by the study team, including American Society of Anesthesiologists Physical Status Grading (ASA-PS), which was first introduced in 1941. The authors note that a few studies have identified that the scale may overestimate mortality. While the ASA-PS was not an ideal RST for the emergency setting the authors were most interested in, compared to other tools, it may be a conservatively safe approach to patient stratification.

Total Knee Arthroplasty

The evidence evaluating the safety and efficacy of inpatient versus outpatient total knee arthroplasty consists primarily of nonrandomized studies, often times without prospective comparative review. Because the body of evidence is quite large, the focus of this summary is on recent systematic reviews with pooled analysis, comparing the safety and efficacy of inpatient versus outpatient total knee arthroplasty.

In 2021, Dey and colleagues published a systematic review with meta-analysis evaluating complications and readmission rates after total hip arthroplasty (THA) and total knee arthroplasty (TKA).¹⁰ Of the 17 studies included, there were 613,155 patients undergoing either THA or TKA; seven studies (331,211 patients) provided data on readmission for TKA. Pool analysis identified day-case surgery for TKA had decreased odds of readmission following surgery as compared to inpatient (odds ratio: 0.55 [0.42, 0.72]). Heterogeneity among studies was noted for patients undergoing TKA only (I²=81%, p<0.0001). Observed heterogeneity was mainly attributable to two studies. The authors identified heterogeneity and patient selection bias amongst the studies evaluated, and recommended a consolidated outpatient protocol for future investigations to standardize comparisons.

In 2020, Xu et al. reported results of a systematic review with meta-analysis comparing complication rates in outpatient versus inpatient total joint arthroplasty (TJA) in hips and knees.¹¹ Seven studies were included and evaluated according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Four of the studies included total knee arthroplasty (TKA); 2 with 30 days of follow-up and 2 with 90 days of follow-up; all of the studies were retrospective observational design. The authors found no evidence of publication bias in the total complication rates as assessed by funnel plot. When considering both hip and knee, the authors found no significant difference in total complications between outpatient and inpatient TJA (RR: 0.82, 95% CI: 0.67 to 1.01, I² = 57%, P = 0.06). There were also no differences between the outpatient and inpatient TJA groups with regards to major complications, readmissions, deep vein thrombosis (DVT), urinary tract infection (UTI), pneumonia, and wound complications. Reoperation rates increased for outpatients as compared to inpatients (RR: 1.60, 95% CI: 1.08 to 2.36, I² = 0%, P = 0.02). However, there was a significant reduction in transfusion rate for outpatients compared to inpatients (RR: 0.61, 95% CI: 0.37 to 1.00, I² = 85%, P = 0.05). For TKA

subgroup analysis, the authors also found no difference in total complications between the outpatient and inpatient groups (RR: 0.86, 95% CI: 0.68 to 1.11, I² = 10%, P = 0.25), major complications (RR: 1.11, 95% CI: 0.81 to 1.54, I² = 0%, P = 0.51), readmissions (RR: 1.03, 95% CI: 0.61 to 1.75, I² = 23%, P = 0.90), UTI (RR: 0.85, 95% CI: 0.36 to 1.97, I² = 0%, P = 0.70) and wound complications (RR: 0.85, 95% CI: 0.39 to 1.86, I² = 0%, P = 0.68). Similar to the TJA, there was an increase in reoperation rate for outpatients as compared to inpatients (RR: 1.76, 95% CI: 1.07 to 2.92, I² = 0%, P = 0.03), and there was also a significant reduction in transfusion rate for outpatients compared to inpatients (RR: 0.62, 95% CI: 0.46 to 0.84, I² = 0%, P = 0.002). Overall, the authors concluded that TJA performed in the inpatient versus outpatient setting had comparable total complication rates, though careful pre-operative patient selection will be required for optimal outcomes.

CLINICAL PRACTICE GUIDELINES

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS Evidence-based Clinical Practice Guideline for Surgical Management of Osteoarthritis of the Knee is supported by the American Society of Anesthesiologists and endorsed by a multitude of other professional organizations.¹² The purpose of the guideline is to improve surgical management of patients with OA of the knee, based on the best available evidence. The authors included BMI as a risk factor amongst recommendations rated as strong (evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention), stating, “Strong evidence supports that obese patients have less improvement in outcomes with total knee arthroplasty (TKA).” Of the recommendations rated as moderate (evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention) diabetes as a risk factor was included. The AAOS found moderate evidence to support that patients with diabetes are at higher risk for complications with TKA.

CENTERS FOR MEDICARE & MEDICAID

In recent years, the Centers for Medicare & Medicaid (CMS) have adopted and updated policies that have increased opportunity for patient choice under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. According to the 2020 update of the CMS regulation titled, Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment (NFRM):¹

“This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2020 based on our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system.”

On January 1, 2018 CMS removed TKA from the Medicare Inpatient-Only (IPO) list:¹³

“CMS policy does not dictate a patient’s hospital admission status and has no default determination on whether a TKA procedures should be done on an inpatient or outpatient basis.

Rather, CMS continues its long-standing recognition that the decision to admit a patient as an inpatient is a complex medical decision, based on the physician's clinical expectation of how long hospital care is anticipated to be necessary, and should consider the individual beneficiary's unique clinical circumstances."

To further increase choice and encourage site neutrality, CMS issued the CY 2020 OPPS/ASC Payment System final rule with comment period in 2019.¹⁴ Under CY 2020, TKA was added to the ambulatory surgical center (ASC) Covered Procedures List (CPL), effective January 1, 2020. The ASC CPS is a list of covered surgical procedures that are eligible for payment under Medicare when they occur in an ASC.

Current information can be found on the [FY 2021 IPPS Final Rule Home Page](#).¹⁵

POLICY SUMMARY

The evidence regarding patient selection and risk stratification to predict incidence and severity of surgical complications is comprised of pre-surgical, post-procedure, generalized, and procedure-specific tools. Given this breadth in scope, the evidence has been summarized to capture the greatest anesthesia risk based on the American Society of Anesthesiologists and American Heart Association standards and guidelines, along with elements incorporated from American College of Surgeons National Surgical Quality Improvement Program. To properly select the most appropriate site of service for a surgical procedure, the Centers for Medicare & Medicaid Services (CMS) encourage patient and provider choice, based on shared decision making as delineated in the 2020 update of the CMS regulation titled, Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment. Therefore, a procedure reviewed under this policy may be considered medically necessary and covered in the inpatient setting when general or procedure-specific (as applicable) criteria are met. Due to a lack of evidence and clinical practice guidelines based on evidence, if general site of service criteria or procedure-specific site of service criteria (as applicable) are not met, the procedure will be considered not covered as medically necessary in the inpatient setting.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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