Surgical Site of Service

MEDICAL POLICY NUMBER: 184

Effective Date: 7/1/2023
Last Review Date: 6/2023
Next Annual Review: 6/2023

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).
**PLAN PRODUCT AND BENEFIT APPLICATION**

☒ Commercial  ☒ Medicaid/OHP*  ☐ Medicare**

*Medicaid/OHP 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.

**Medicare Members

This Company policy may be applied to Medicare Plan members only when directed by a separate Medicare policy. Note that investigational services are considered “not medically necessary” for Medicare members.

**COVERAGE CRITERIA**

Notes:
- 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 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:

<table>
<thead>
<tr>
<th>ASA PS Classification</th>
<th>Definition</th>
<th>Adult Examples, Including, but not Limited to:</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a</td>
<td>Examples include (but not limited to): recent (&lt; 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe</td>
</tr>
</tbody>
</table>
constant threat to life | 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

Notes:
- If criteria I. above are not met, the following may be approved for an inpatient setting based on the criteria below.
- Revisions of total hip and total knee arthroplasties are considered medically necessary in inpatient settings.

Partial or Total Knee and Total Hip Arthroplasty

Note:
- In addition to any inpatient site of service review, all total hip arthroplasty codes also require general medical necessity review for all Plan members, using criteria found in separate total hip arthroplasty medical policies. Refer to the following medical policies: “Hip: Total Joint Arthroplasty (Company)” and “Hip: Total Joint Arthroplasty (Medicare).”

II. Partial or total knee arthroplasty and total hip arthroplasty may be considered medically necessary in the inpatient setting when one or more of the following criteria (A. – D.) are met:

A. Bilateral procedure is planned
B. Infected joint treatment
C. Documentation by provider states that patient and/or caregiver does not fully understand the surgical procedure and/or post procedure compliance
D. 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 medically necessary in the inpatient setting.

Link to Evidence Summary
POLICY CROSS REFERENCES

- Hip: Total Joint Arthroplasty, MP130 (Company)
- Hip: Total Joint Arthroplasty, MP133 (Medicare)

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

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

DEFINITIONS

Application of the General Site of Service Criteria

Table 1: Procedures Subject to General Site of Service Criteria

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total knee arthroplasty</td>
<td>Total knee arthroplasty in the inpatient setting will be reviewed for medical necessity utilizing criteria I. and II. above.</td>
</tr>
<tr>
<td>Partial knee arthroplasty</td>
<td>Partial knee arthroplasty in the inpatient setting will be reviewed for medical necessity utilizing criteria I. and II. above.</td>
</tr>
<tr>
<td>Total hip arthroplasty</td>
<td>Total hip arthroplasty in the inpatient setting will be reviewed for medical necessity utilizing criteria III. above.</td>
</tr>
</tbody>
</table>

Body Mass Index (BMI)\(^1\)

*Metric BMI Formula:* BMI = \( \frac{\text{weight (kg)}}{\text{height}^2 (\text{m}^2)} \)

*Imperial BMI Formula:* BMI = \( \frac{\text{weight (lb)}}{\text{height}^2 (\text{in}^2)} \times 703 \)

- Obesity is defined as a BMI of 30.0 kg/m\(^2\) or higher.
- Obesity is frequently divided into categories:
  - Class I: BMI of 30 kg/m\(^2\) to < 35 kg/m\(^2\)
  - Class II: BMI of 35 kg/m\(^2\) to < 40 kg/m\(^2\)
  - Class III: BMI of 40 kg/m\(^2\) or higher
    - A BMI of 40-49.9 kg/m\(^2\) is considered morbidly obese.
    - A BMI of 50 kg/m\(^2\) or more is considered superobesity or super morbid obesity.
American Society of Anesthesiologists (ASA) Physical Status Classification System (ASA-PS)²

Current Definitions and ASA-Approved Examples

<table>
<thead>
<tr>
<th>ASA PS Classification</th>
<th>Definition</th>
<th>Adult 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>
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<td>ASA V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
<td>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</td>
</tr>
</tbody>
</table>

*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) Classification³

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.

Model for End-Stage Liver Disease (MELD)⁴

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.

BACKGROUND

Surgical Sites of Service

Currently, the scope of this policy is limited to review of select partial knee arthroplasty, total knee arthroplasty (TKA) and total hip arthroplasty (THA) codes for site of service appropriateness; however, procedures other than these services may be added for site of service appropriateness review in the future.

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 prostatic 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. 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.

Partial Knee Arthroplasty

Partial knee arthroplasty (PKA) is a surgical treatment for severe osteoarthritis (OA) that avoids the high morbidity associated with total knee arthroplasty (TKA) and potentially offers faster mobilization. PKA is the replacement of the articular surfaces in 1 compartment of the knee with metal and polyethylene.
prosthetic components. In contrast, TKA is the complete replacement of all 3 compartments of the knee joint with prosthetic components. 5

Total Hip Arthroplasty

In a total hip replacement (also called total hip arthroplasty (THA)), the damaged bone and cartilage is removed and replaced with prosthetic components. The damaged femoral head is removed and replaced with a metal stem that is placed into the hollow center of the femur. The femoral stem may either cemented or "press fit" into the bone. A metal or ceramic ball is placed on the upper part of the stem. This ball replaces the damaged femoral head that was removed. The damaged cartilage surface of the socket (acetabulum) is removed and replaced with a metal socket. Screws or cement are sometimes used to hold the socket in place. A plastic, ceramic, or metal spacer is inserted between the new ball and the socket to allow for a smooth gliding surface.6

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 2023.

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.7 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. 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. 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). 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. 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.¹³ 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.

EVIDENCE 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.

**BILLING GUIDELINES AND CODING**

Certain CPT codes require prior authorization when billed with facility code 21 (inpatient hospital). See coding table below. Billing with other facility codes will not require pre-authorization.

<table>
<thead>
<tr>
<th>CODES*</th>
<th>Prior Authorization Required when Billed with Facility Code 21</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>27130</td>
<td>Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft</td>
</tr>
<tr>
<td>27445</td>
<td>Arthroplasty, knee, hinge prosthesis (eg, Wallidius type)</td>
</tr>
<tr>
<td>27446</td>
<td>Arthroplasty, knee, condyle and plateau; medial OR lateral compartment</td>
</tr>
<tr>
<td>27447</td>
<td>Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td>None</td>
</tr>
</tbody>
</table>

*Coding Notes:*
- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
- See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

**REFERENCES**


**POLICY REVISION HISTORY**

<table>
<thead>
<tr>
<th>DATE</th>
<th>REVISION SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/2023</td>
<td>Converted to new policy template.</td>
</tr>
<tr>
<td>7/2023</td>
<td>Annual update. Policy split out by line of business. No changes to criteria or coding.</td>
</tr>
</tbody>
</table>