Joint Resurfacing

MEDICAL POLICY NUMBER: 135

Effective Date: 10/1/2023

Last Review Date: 9/2023

Next Annual Review: 9/2024

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

Note: This medical policy does not address hip resurfacing which may be considered medically necessary.

Joint resurfacing is considered **not medically necessary** for all non-hip indications, including, but not limited to, the following:

- Glenohumeral (shoulder) joint, including total and hemi-resurfacing
- Knee resurfacing, including partial knee resurfacing and isolated patellar resurfacing (i.e., UniCAP, HemiCAP)
- Metatarsal phalangeal (MTP) toe joint resurfacing

Link to Evidence Summary

POLICY CROSS REFERENCES

- Robotic Surgical Systems, UM1
- Computer-Assisted Navigation, MP375

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

POLICY GUIDELINES

BACKGROUND

Osteoarthritis (OA)

Osteoarthritis (OA) is the most common form of articular disease, characterized by degenerative loss of articular cartilage, subchondral bony sclerosis, and cartilage and bone proliferation at the joint margins with subsequent osteophyte formation. Symptoms of OA include pain in and around the joint that worsens with weight bearing activities and improves with rest. Most commonly, OA affected individuals are older than 40 years old. Although the pathogenesis of OA is unknown, biomechanical stresses, biochemical changes, and genetic factors are possible causes. OA commonly affects the joints of the appendicular skeleton, including the knee and hip. Treatment of OA includes physical therapy, exercise, nonprescription analgesics, and nonsteroidal anti-inflammatory drugs (NSAIDs). Joint replacement is a treatment option for OA that is refractory to more conservative therapies.

Joint Resurfacing

Joint resurfacing has been purported as an alternative to joint replacement for the treatment of osteoarthritis. In contrast to total joint replacement, joint resurfacing only trims and smooths degenerated bone followed by the implantation of a prosthesis which covers and partially replaces the joint surface. Potential advantages of joint resurfacing over joint replacement include decreased risk of dislocation, more normal joint movement, and reversibility. Resurfacing is done by an orthopedic surgeon and can usually be performed in an outpatient setting under general anesthesia.

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.

Shoulder Resurfacing Prostheses

Shoulder resurfacing prostheses are approved under the FDA 510(k) premarket notification process. These devices are classified as prosthesis, shoulder, semi-constrained, metal/polymer, uncemented under product code “MBF”. Additional information may be found by searching the FDA 510(k) database for the MBF product code.

Knee Resurfacing Prostheses

Knee resurfacing prostheses are approved under the FDA 510(k) premarket notification process. These devices are classified as knee joint patella-femoral resurfacing prostheses under the product code “KRR”. Additional information may be found by searching the FDA 510(k) database for the KRR product code.

Metatarsal Phalangeal (MTP) Joint Resurfacing Prostheses

MTP joint resurfacing prostheses are approved under the FDA 510(k) premarket notification process. These devices are classified as prosthesis, toe, phalangeal under product code "KWD". Additional information may be found by searching the FDA 510(k) database for the KWD product code.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of shoulder, knee, metatarsal phalangeal, and facet joint resurfacing as a treatment for osteoarthritis. Below is a summary of the available evidence identified through August 2023.

Shoulder Resurfacing

No recent (within the last 5 years) high-quality systematic reviews or randomized controlled trials evaluating glenohumeral (shoulder) resurfacing for the treatment of osteoarthritis.

The recent body of evidence evaluating shoulder resurfacing is limited to nonrandomized studies and case series.[1-6] The validity of this evidence is hindered due to several methodological limitations, including the nonrandomized retrospective designs, small sample sizes, and lack of statistical analyses. Although conflicting, the results of these studies suggest the evidence is not in favor of shoulder joint resurfacing. Sweet et al. concluded that humeral head resurfacing is effective for the treatment of glenohumeral osteoarthritis; however, the other nonrandomized studies found high rates of postoperative glenoid wear and erosion,[2,4,5] revision,[1] and reduced bone stock.[3] Furthermore, three studies concluded that the long-term impact of joint resurfacing is unclear and total glenohumeral joint replacement remains the best treatment option.[2-4,6,7]

Knee Resurfacing

Systematic Reviews

- In 2022, Hayes updated a comparative effectiveness review of patellofemoral arthroplasty (PFA) versus total knee arthroplasty (TKA) for isolated osteoarthritis (PFOA) of the knee.[8] The review included 8 studies (1 RCT, 4 retrospective cohort studies, 1 retrospective matched-pair comparative study, and 2 retrospective uncontrolled registry studies. Sample sizes ranged from 30 to 4634 and follow-up was at least 2 years. Outcomes of interest included improvements in pain and functioning, range of motion, revision rates and complications.

  Studies assessing hospital length of stay (1 study) and pain outcomes (6 studies) reported mixed results. Studies assessing patient satisfaction (3 studies), operating times (1 study) and revision rates (6 studies) reported no significant differences between PFA and TKA. Seven of the 8 studies evaluating functional outcomes found improvements in patients undergoing TKA compared to those who received PFA. The overall quality of evidence was judged to be "poor" (1 "good quality" study and 7 "poor quality studies") with individual study weaknesses including small sample sizes, retrospective design, attrition, and lack of a comparator group, randomization or blinding.

Hayes assigned a "C" rating (potential but unproven benefit) for the use of PFA in patients with PFOA for whom previous treatments have failed. The review concluded that "uncertainty remains due to the low quality of the evidence primarily as a result of variability in treatment protocol, including implant type, comparator types, and outcome measures… contribut[ing] to a lack of clarity in the evidence about the clinical effectiveness of PFA."

- In 2023, ECRI updated a product brief evaluating Makoplasty using the Mako Robotic Arm-assisted Surgery System (Stryker Corp.) for knee resurfacing.[9] In a literature search through July 2023, ECRI identified 2 systematic reviews with meta analyses, 3 systematic reviews, and 1 RCT reporting over 11,000 patients undergoing PKA and 8,307 unique patients undergoing TKA. The studies evaluated Makoplasty and conventional partial knee replacement (PKR) in terms of patient functional status, pain, and adverse events. Results from the six controlled studies included for review suggested improved implant positioning, though whether the Mako system leads to improved overall health outcomes has not been determined. The ECRI authors cited, "A large body of evidence shows that TKA and UKA with Mako improve component alignment compared with that of mTKA; however, whether this translates into improvement for patient-oriented outcomes remains unclear. Studies suggest TKA with Mako may improve postoperative pain and function, and UKA with Mako may improve postoperative pain but provide too few data to confirm whether the improved pain and function are sustained or statistically different from manual approaches at long-term follow-up… Large multicenter RCTs that compare Mako with other robotic systems, computerized navigation systems, and manual approaches and report on patient- oriented outcomes (revision rates, pain, function) at a longer follow-up are needed to validate data."

- In 2018, Grassi and colleagues conducted of systematic review of overlapping meta-analyses comparing patellar resurfacing to patellar retention in primary total knee arthroplasty.[10] Investigators searched the literature through March 2017, systematically identified eligible studies (meta-analyses of RCTS or quasi-randomized controlled trials), assessed quality and extracted data. The outcomes of interest were re-operations rate, complications, anterior knee pain, and functional scores. In total, 10 meta-analyses (collectively assessed to be of "moderate" quality) were included for review. Among patients receiving resurfacing, 2 studies reported significant improvements in Knee Society Score and 4 meta-analyses reported lower incidence of anterior knee pain. However, 6 studies described a greater risk of re-intervention in the non-resurfacing groups. The most relevant meta-analysis reported no differences in functional scores and incidence of anterior knee pain between treatment and control groups.

  The generalizability of results is limited by the heterogeneous treatment parameters of studies included for review. Given this heterogeneity, pooling of results was impossible, and studies' most reliable findings were presented without statistical analysis. Only 1 of the 10 included studies performed a sensitivity analysis or a publication bias evaluation to address potential confounding. Investigators concluded that there is no clear superiority of patellar resurfacing compared to patellar retention.

- In 2016, van Jonbergen et al. conducted a systematic review to evaluate patient satisfaction and functional outcomes following secondary patellar resurfacing.[11] Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcomes of interest included patient satisfaction, functional measures, and reported complications.

Following systematic review, the authors identified 15 studies, encompassing 2 randomized controlled trials (RCTs) and 13 case series, as eligible for inclusion. Of 232 patients, 148 (64%) were satisfied with the outcomes of patellar resurfacing. Out of the 15 included studies, 8 reported knee specific function scores and a statistically significant improvement was found in all studies. A total of 11 studies evaluated complications and the number of knees requiring additional surgery following the resurfacing procedure. "Infection and impaired wound healing occurred in 6 (2.2%) of 266 patients, patellar instability in 6 (2.2%), and patellar fracture in 4 (1.5%). Other complications included hematoma (1 knee) and a stiff knee (1 knee). Further surgery was performed in 11 knees, with total knee revision in 7 knees."[11]

Methodological strengths of this systematic review include the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers, and assessment of heterogeneity. Significant limitations were present due to the poor quality of many included studies (nonrandomized retrospective case series), small sample size, inadequate data reporting, and significant inter-study heterogeneity. Ultimately, the authors concluded "(b)ecause the available evidence is of generally low quality, the results of this systematic review only support a weak recommendation for secondary patellar resurfacing if patient satisfaction and clinically important improvement of functional outcomes are the desired endpoints."[11]

Nonrandomized Studies

Six additional nonrandomized observational studies were identified which evaluated patellar resurfacing as the primary treatment of knee osteoarthritis or as an adjunct to total knee replacement.[12-17] Although 5 out of the 6 studies concluded results in favor of patellar resurfacing, the methodological limitations of these studies (nonrandomized design, small sample sizes, lack of statistical analysis, short-term follow-up) significantly affect the validity of these conclusions.

Metatarsal Phalangeal (MTP) Joint Resurfacing

The evidence review identified no current (within the last 5 years) systematic reviews or randomized controlled trials evaluating metatarsal phalangeal (MTP) joint resurfacing for the treatment of osteoarthritis.

A total of 9 nonrandomized studies were identified which evaluated MTP joint resurfacing for the treatment of toe joint osteoarthritis, specifically hallux rigidus.[18-26] Although the studies suggest MTP joint resurfacing may be efficacious, the studies' retrospective design and small sample sizes ($n < 60$) significantly limits generalizability. Additional, high-quality studies (randomized, controlled, blinded) are required to support the safety, efficacy, and medical necessity of resurfacing of the metatarsal phalangeal joint.

CLINICAL PRACTICE GUIDELINES

No clinical practice guidelines were identified which addressed metatarsal phalangeal (MTP) joint resurfacing.

Shoulder Resurfacing

American Academy of Orthopedic Surgeons

The 2020 AAOS evidence-based clinical practice guideline for the treatment of glenohumeral joint (shoulder) osteoarthritis, concluded the following regarding resurfacing:[27]

- "Limited evidence supports that clinicians may utilize stemmed, stemless or resurfacing prosthesis for patients with glenohumeral joint osteoarthritis undergoing total or hemi-arthroplasty" Strength of Recommendation: Limited. (Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention).

Knee Resurfacing

American Academy of Orthopaedic Surgeons

The 2022 AAOS evidence-based clinical practice guideline for the surgical management of osteoarthritis of the knee concluded, "(s)trong evidence supports no difference in pain or function with or without patellar resurfacing in TKA (total knee arthroplasty)." Strength of recommendation: strong evidence.[28]

EVIDENCE SUMMARY

The evidence is insufficient to support the safety and efficacy of glenohumeral joint resurfacing for osteoarthritis (OA). Additional studies of good methodological quality are required to establish the clinical utility of this treatment modality for OA. Additionally, the American Academy of Orthopedic Surgeons concludes there is no reliable evidence to support resurfacing of the glenohumeral joint. For these reasons, glenohumeral joint resurfacing is considered not medically necessary and is not covered.

The inconsistent evidence from recent randomized controlled trials and the results of systematic reviews suggest patellar resurfacing is not efficacious for the treatment of pain due to knee osteoarthritis. There is also insufficient evidence to support the clinical validity and clinical utility of patellar resurfacing as an adjunct to total knee arthroplasty (TKR). Furthermore, the American Academy of Orthopedic Surgeons identified strong evidence that supports no difference in pain or function with or without patellar resurfacing in total knee arthroplasty. Therefore, patellar resurfacing is considered not medically necessary and is not covered.

There is insufficient evidence to support the safety, efficacy, and clinical utility of resurfacing of the metatarsal phalangeal (MTP) joint to treat toe osteoarthritis (i.e., hallux rigidus). The body of evidence is limited to small, non-randomized studies which do not permit meaningful conclusions. Additional studies of high methodological quality are required to support the medical necessity of MTP joint resurfacing. No evidence-based clinical practice guidelines were identified which evaluate the use of MTP joint resurfacing to treat osteoarthritis. Thus, MTP joint resurfacing is considered not medically necessary and is not covered.

BILLING GUIDELINES AND CODING

There are no specific codes to represent joint resurfacing of many joints, including joint resurfacing of the knee, shoulder, or metatarsal phalangeal (MTP) toe joint, therefore, an unlisted code should be used to report joint resurfacing procedures instead.

Arthroplasty codes (e.g., 27447) may not be used to report joint resurfacing. Any one of the unlisted codes noted below may be used to report joint resurfacing. If arthroplasty codes are billed in conjunction with joint resurfacing, other than the hip, then they will be considered not medically necessary and not covered.

As indicated in the relevant Company policies (Reimbursement Policy for *Robotic Surgical Systems* [UM1] **and** Medical Policy for *Computer-Assisted Navigation (All Lines of Business Except Medicare)* [MP375]), the use of robotic or computer assistance for musculoskeletal procedures (i.e., MAKOplasty), regardless of code used (e.g., 0054T, 0055T, 20985, S2900, an unlisted code, etc.) will not be allowed coverage or separate payment, whether the primary surgical procedure is considered medically necessary or not.

The following HCPCS codes may be billed by the facility as part of the joint resurfacing procedure and are therefore not covered or separately reimbursable:

- C1776: Joint device (implantable)
- L8642: Hallux implant

CODES*		
CPT	23929	Unlisted procedure, shoulder
	27599	Unlisted procedure, femur or knee
	28899	Unlisted procedure, foot or toes

***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.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
4/2023	Interim update, change in coverage position from E/I to NMN.

10/2023	Annual update. No changes to criteria.