


MEDICAL POLICY	Joint Resurfacing
<p><b>Effective Date: 10/1/2021</b></p>  <p style="text-align: right;">10/1/2021</p>	<p>Medical Policy Number: 132</p> <p>Technology Assessment Committee Approved Date: 1/07; 5/09; 5/10; 6/13; 5/14; 5/15; 4/16</p> <p>Medical Policy Committee Approved Date: 4/12; 8/16; 6/17; 11/17; 1/18; 9/18; 2/19; 3/2020; 9/2020; 09/2021</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 Ayin 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.

**POLICY CRITERIA**

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

Joint resurfacing is considered **investigational and is not covered** 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 (i.e., MAKOpasty) and isolated patellar resurfacing (i.e., UniCAP, HemiCAP)
- Metatarsal phalangeal (MTP) toe joint resurfacing

Link to [Policy Summary](#)

**BILLING GUIDELINES**

<b>MEDICAL POLICY</b>	<b>Joint Resurfacing</b>
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Arthroplasty codes (ex., 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 denied as investigational and not covered.

If CPT code 20985 is billed for joint resurfacing, other than the hip, it will be denied as not covered.

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

### CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
C1776	Joint device (implantable)
Not Covered	
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be <b>denied as not covered</b> .	
23929	Unlisted procedure, shoulder
27599	Unlisted procedure, femur or knee
28899	Unlisted procedure, foot or toes

### DESCRIPTION

#### 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.

## REVIEW OF EVIDENCE

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 2021.

### 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.<sup>1-6</sup> 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,<sup>2,4,5</sup> revision,<sup>1</sup> and reduced bone stock.<sup>3</sup> Furthermore, three studies concluded that the long-term impact of joint resurfacing is unclear and total glenohumeral joint replacement remains the best treatment option.<sup>2-4,6,7</sup>

### Knee Resurfacing

#### Systematic Reviews

- In 2020, ECRI updated a product brief evaluating Makoplasty using the Mako Robotic Arm-assisted Surgery System (Stryker Corp.) for knee resurfacing.<sup>8</sup> In a literature search through September 2020, ECRI identified 3 systematic reviews, 4 nonrandomized comparison studies, and 3 cost-effectiveness studies reporting on 6,205 unique 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, "This is

because, despite having data on more than 14,000 patients, all studies reporting patient outcomes provided very-low-quality evidence. Three systematic reviews (SRs) did not perform meta-analysis, and very few of the included studies reported on patient outcomes; the SRs reported outcomes separately for each study. Results need further confirmation in randomized controlled trials (RCTs) comparing Mako with conventional TKA and PKA and reporting longer-term (>5 years) outcomes.”

- In 2020, Hayes updated a health technology assessment evaluating partial knee arthroplasty with the Mako robotic-arm assisted surgery for the treatment of osteoarthritis.<sup>9</sup> The review included 5 studies (1 RCT, 1 retrospective cohort study, 1 retrospective registry analysis, 1 retrospective pretest/posttest study, and 1 prospective survey). Sample sizes ranged from 61 to 797. Follow-up times varied from 18 months to 5 years. Among the studies assessing knee function and pain, results were mixed and/or inconclusive. Revision rates from surgery ranged from 0% to 6%, at ≤5 years post-surgery follow-up. Reported complications among patients included ongoing knee pain (16%-20%), wound infection (0.5%-5.2%), reoperations (1.9%-3.6%), and cellulitis (3%).

Hayes assessed the overall body of evidence to be of “very-low-quality” (3 “poor quality” studies and 2 “very poor quality” studies) due to significant methodological limitations in study design and a lack of prospective comparative trials. Hayes assigned a “D2” rating (insufficient evidence) concluding that “long-term follow-up is necessary to determine whether the higher accuracy in component positioning obtained with a robotic system translates into improvements in pain and reductions in revision over manual surgical procedures.”

- In 2021, Hayes updated a comparative effectiveness review of patellofemoral arthroplasty (PFA) versus total knee arthroplasty (TKA) for isolated osteoarthritis (PFOA) of the knee.<sup>10</sup> 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 2018, Grassi and colleagues conducted a systematic review of overlapping meta-analyses comparing patellar resurfacing to patellar retention in primary total knee arthroplasty.<sup>11</sup> 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.<sup>12</sup> 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.”<sup>12</sup>

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.”<sup>12</sup>

#### Randomized Controlled Trials (RCTs)

- In 2016, Eshnazarov et al. conducted a RCT to compare radiological outcomes after total knee arthroplasty (TKA) with or without patellar resurfacing in patients with grade IV osteoarthritis (OA) on patellofemoral joint.<sup>13</sup> A total of 123 patients with grade IV OA were enrolled. At the operating room, patients were randomly assigned to undergo patella resurfacing (n=62) or patella retention

(n=61). The primary outcome of interest was preoperative and postoperative radiological results (mechanical femorotibial angle, patellar tilt and congruence angles) between the two groups.

Of the 123 patients, 114 were available for 2 year follow-up (n=59 resurfacing; n=55 retention). Preoperative radiological measures showed no significant differences between groups for the 3 radiological outcomes. No statistically significant differences were found between groups for postoperative radiological assessment of patellar tilt (p=0.47), mechanical femorotibial angles (p=0.34), and congruence angle (p>0.05).

Strengths of this study include the randomized controlled design and extended 2-year follow-up. Methodological limitations are present due to the small sample size, lack of intention-to-treat analysis, and losses to follow-up. The authors concluded that “primary TKA (total knee arthroplasty) without patella resurfacing is a good treatment option in patients with high grade osteoarthritis of the patellofemoral joint.”<sup>13</sup>

- In 2016, Ali and colleagues conducted a randomized study to compare the outcome of knee pain after total knee arthroplasty (TKA) with and without patellar resurfacing.<sup>14</sup> The authors prospectively enrolled 74 patients with primary osteoarthritis who underwent TKA. The patients were then randomized to patellar resurfacing or no resurfacing. The preoperative outcomes of interest included visual analog scale (VAS) pain score, knee injury and osteoarthritis outcome score (KOOS), and physical performance measures. Postoperative outcomes included VAS pain score, KOOS, patient satisfaction, and physical performance measures at 3, 12, and 72 months postoperatively.

The results indicated no statistically significant differences between the resurfacing and no resurfacing groups for VAS pain, patient satisfaction, and KOOS at 3, 12, and 72 months postoperatively. Furthermore, no significant differences were identified between groups for physical performance measures. Additionally, no secondary resurfacing was performed in the group with no resurfacing during the 72 months follow-up.

This study has several methodological strengths, including:

- Randomized controlled robust study design
- The use of intention-to-treat analysis
- Use of an internationally validated index for scoring pain and function
- Adequately powered to determine a clinically relevant difference

Limitations include the shorter-follow up period, small sample size, and subjective primary outcome measure. The authors concluded, “(p)atellar resurfacing in primary Triathlon CR TKA is of no advantage regarding pain, physical performance, KOOS 5 subscales, or patient satisfaction compared to no resurfacing. None of the patients were reoperated with secondary addition of a patellar component within 6 years. According to these results, routine patellar resurfacing in primary Triathlon TKA appears to be unnecessary.”<sup>14</sup>

- In 2016, Aunan et al. conducted a randomized double-blind study to evaluate patellar resurfacing in total knee arthroplasty (TKA).<sup>15</sup> A total of 129 knees in 115 patients were enrolled and evaluated at 1 year and 3 years postoperatively. Immediately before operation, patients were randomized to patellar resurfacing or no patellar resurfacing. Throughout the study, the patients and the outcome

assessor were blind regarding the randomization allocation. The primary outcome measure was the knee injury and osteoarthritis outcome score (KOOS). Secondary outcome measures included the knee society score (KSS), the Oxford knee score, and patient satisfaction measured with a visual analog scale (VAS).

The postoperative mean subscores for the KOOS were statistically significantly different between groups, in favor of patellar resurfacing. “The greatest difference between the 2 groups at 3 years after surgery was seen in the subscore sport/recreation, with a 10-point difference between the groups ( $p = 0.01$ ). In the other subscores, the differences were 8 points for knee-related QoL ( $p = 0.03$ ), 6 points for pain ( $p = 0.02$ ), and 5 points for symptoms ( $p = 0.04$ ). In the subscore for ADL, there was a 5-point difference between the 2 groups, but this was not statistically significant ( $p = 0.06$ ).”<sup>15</sup> However, no statistically significant differences between groups were observed for the KSS, Oxford knee score, or patient satisfaction.

Strengths of this study include the randomized controlled design, blinding of patients and outcome assessors, extended 3-year follow-up, and use of intention-to-treat analysis. Methodological limitations are present in the small sample size, losses to follow-up, and subjective primary outcome measure. The authors concluded, “(i)n the present study, the KOOS—but no other outcome measure used—indicated that patellar resurfacing may be beneficial in TKA.”<sup>15</sup>

### 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.<sup>16-21</sup> 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.<sup>22-30</sup> 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 2009 (reaffirmed 2014) AAOS evidence-based clinical practice guideline for the treatment of glenohumeral joint (shoulder) osteoarthritis, concluded the following regarding resurfacing:<sup>31</sup>

“The body of evidence supports the use of total shoulder arthroplasty or hemiarthroplasty for glenohumeral osteoarthritis. However, there is no reliable evidence for the use of humeral resurfacing in the existing literature for the treatment of glenohumeral joint osteoarthritis.” The AAOS guideline suggests further “trials designed to collect prospective data on resurfacing arthroplasty and to evaluate the indications for resurfacing.”

**Knee Resurfacing**American Academy of Orthopedic Surgeons

The 2015 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).”<sup>32</sup> Strength of recommendation: strong evidence.

**CENTERS FOR MEDICARE & MEDICAID**

As of August 2021, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses glenohumeral, knee, or metatarsal phalangeal joint resurfacing for osteoarthritis.

**POLICY 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 investigational 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 investigational 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 investigational and is not covered.

## 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

### U.S. Food and Drug Administration (FDA)

#### **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.

### 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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