Surgery of the Shoulder

Policy Number: SURGERY 101.28
Effective Date: November 1, 2024

➲ Instructions for Use

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Related Policies

- Skin and Soft Tissue Substitutes

Coverage Rationale

Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:

- InterQual® CP: Procedures:
  - Arthroscopy or Arthroscopically Assisted Surgery, Shoulder
  - Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent)
  - Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder
  - Arthrotomy, Shoulder
  - Joint Replacement, Shoulder
  - Removal and Replacement, Total Joint Replacement (TJR), Shoulder
- InterQual® Client Defined, CP: Procedures, Revision, Total Joint Replacement (TJR), Shoulder (Custom) - UHG

Click here to view the InterQual® criteria.

Subacromial balloon spacers for the treatment of rotator cuff tears are unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the protocol titled Medical Records Documentation Used for Reviews.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty

CPT Code	Description
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement [e.g., total shoulder])
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)
29806	Arthroscopy, shoulder, surgical; capsulorrhaphy
29807	Arthroscopy, shoulder, surgical; repair of slap lesion
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (Mumford procedure)
29825	Arthroscopy, shoulder, surgical; with lysis and resection of adhesions, with or without manipulation
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (i.e., arch) release, when performed (List separately in addition to code for primary procedure)
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair
29828	Arthroscopy, shoulder, surgical; biceps tenodesis
29999	Unlisted procedure, arthroscopy

Clinical Evidence

Subacromial Balloon Spacers (SABS)

The InSpace™ Subacromial Tissue Spacer System (Stryker) is a new, minimally invasive, biodegradable balloon spacer for the treating massive, inoperable rotator cuff tears (MIRCTs). According to the manufacturer, it preserves musculoskeletal and bone tissues, does not require the use of an anchor, and does not require a permanent implant. It is used as a spacer to eliminate friction between the acromion and the humeral head or rotator cuff to restore shoulder function and reduce pain. It is designed to biodegrade over the course of twelve months. The current published literature is at high risk of bias due to the small sample size, single-center focus, retrospective design, and lack of randomization, blinding, and control. There are device-related complications, and long-term studies are necessary as short-term results appear to degrade over time. Furthermore, studies include individuals with varying rotator cuff tear sizes.

Sandler and associates (2024) conducted a dual-armed systematic review and meta-analysis of over 1000 individuals to compare the outcomes after SAB spacer placement versus arthroscopic debridement for MIRCTs. For the SAB arm, 14 of 449 studies were considered eligible for inclusion, while 14 of 272 were considered eligible for inclusion in the debridement arm. Uncovered by the investigation were 528 individuals eligible for inclusion in the SAB arm, 479 in the debridement arm, and 69.9% of those individuals undergoing SAB placement also underwent concomitant debridement. The results of the exploration found were decreases in the visual analog scale (VAS) pain score and increases in the Constant score were discovered to be significantly more following debridement [–0.7 points ($p < .001$) and ±5.5 points ($p < .001$), respectively], although the Patient Acceptable Symptom State (PASS) for the VAS was not attained after either procedure. Both SAB placement and debridement significantly improved the range of motion (ROM) in forward flexion/forward elevation, internal and external rotation, and abduction ($p < .001$). Rates of general complication were

greater following debridement versus SAB placement (5.2% ±5.6% vs. 3.5% ±6.3%, respectively; p < .001); however, there were no significant variances among SAB placement and debridement in rates of persistent symptoms necessitating a reintervention (3.3% ±6.2% vs 3.8% ±7.3%, respectively; p = .252) or reoperation rates (5.1% ±7.6% vs 4.8% ±8.4%, respectively; p = .552). The mean time to conversion to reverse total shoulder arthroplasty was 11.0 versus 25.4 months, respectively, for the SAB versus debridement arm. The limitations of the analysis consist of inconsistencies between follow-up times, with the follow-up time associated with debridement being nearly twice as long as the follow-up time related to SAB placement, are likely attributable to the recentness of SAB use globally, which may confuse evaluations with older debridement literature given the evolution in arthroscopic surgery over time. The time to reverse total shoulder arthroplasty (RTSA) was not uniformly reported between studies and was decided based on either individual patient data or weighted means. Also, there were alterations in using and reporting rotator cuff tears size and type, further obscuring direct comparisons. The authors concluded that while SAB placement was associated with adequate postoperative outcomes for treating MIRCTs, there was no clear advantage over debridement only. Shorter operative times combined with better postoperative results and prolonged times to conversion to reverse total shoulder arthroplasty gave debridement a more desirable choice. While there may be a role for SAB placement in poor surgical candidates, there is promising evidence to support debridement alone with no SAB placement for treating MIRCTs (level IV evidence).

In a 2024 systematic review and meta-analysis, Sirignano et al. sought to decide the efficacy of the subacromial balloon spacer implantation (SBSI) from both surgical and rehabilitative perspectives to improve outcomes for individuals with massive rotator cuff tear. To effectively evaluate the results of the literature, the authors assessed pre-surgery (baseline), 12-month (12-m), and 24-month (24-m) post-SBSI mean changes and compared them using one-way analysis of variance (ANOVA) and Scheffe post hoc tests and comparative study effect sizes were calculated (p ≤ 0.05). The review consisted of 27 studies with 894 individuals (67.8 ±5 years of age) and 29.4 ±17-month follow-up. Modified Coleman Methodology Scores (MCMS) revealed fair overall quality (mean = 61.4 ±11). Constant–Murley scores improved from 34.8 ±6 (baseline) to 64.2 ±9 (12-m) and 67.9 ±8 (24-m) (12-m, 24-m > baseline, p < 0.001). ASES scores improved from 35.1 ±14 (baseline) to 83.3 ±7 (12-m) and 81.8 ±5 (24-m) (12-m, 24-m > baseline, p < 0.001). VAS pain scores improved from 6.6 ±1 (baseline) to 2.6 ±1 (12-m) and 2.0 ±1 (24-m) (12-m, 24-m < baseline, p < 0.001). Flexion increased from 108.5 ±25° (baseline) to 128.5 ±30° (12-m) and 151.2 ±14° (24-m) (24-m > 12-m, baseline, p = 0.01). Abduction increased from 97.7 ±24° (baseline) to 116.3 ±23° (12-m) and 142.3 ±15° (24-m) (24-m > 12-m, baseline, p = 0.02). External rotation (ER) in adduction changed from 33.1 ±7° (baseline) to 32.5 ±4° (12-m) and 53.9 ±9° (24-m) (24-m > 12-m, baseline, p = 0.01). ER at 90° abduction increased from 56.3 ±3° (baseline) to 83.5 ±5° (12-m) and 77.1 ±4° (24-m) (24-m, 12-m > baseline, p = 0.01). Comparison studies, however, showed insignificant conclusions with small effect sizes. There are many limitations to this systematic review and meta-analysis. Most of the reviewed studies had relatively small sample sizes; all subjects included were middle-aged or elderly who, without effective surgical intervention, were destined for attempted partial rotator cuff repair with or without SBSI, attempted rotator cuff repair with scaffold supplementation, superior capsular reconstruction, tendon transfer or RTSA. Although the cohort studies were promising, they were less so when they included a control or comparison group of individuals who underwent attempted rotator cuff repair or debridement alone. Lastly, the perceptions of the surgeon and physical therapist may differ on the MCMS details needed to guide the clinical care provided by each healthcare professional. The authors concluded that although overall fair MCMS scores at 24-m post-SBSI, shoulder function increased, and pain decreased. Comparative studies that were more rigorous showed insignificant findings. Those with the potential for reestablishing the essential glenohumeral joint force couple that depresses the humeral head on the glenoid fossa and who follow physical therapy may be more prone to active success following SBSI. Outcomes may improve through improved preoperative healthcare team conversations, more comprehensive scoring options for the MCMS postoperative rehabilitation description questions, and a high agreement level among surgical and rehabilitation teams for surgical technique and postoperative rehabilitation description scores.

The 2023 systematic review and meta-analysis conducted by Berk et al. sought to review and synthesize the literature reporting on the trial outcomes following the implantation of a SABS for treating individuals with irreparable rotator cuff tears. Amongst included studies, a total of 894 shoulders (886 people), with an average follow-up of 30.4 (range, 12-56) months, were included. The results showed that all postoperative reported outcomes improved significantly from baseline, including the constant score (mean difference, 33.53; p < 0.001), American Shoulder and Elbow Surgeons (ASES) score (mean difference, 40.38; p < 0.001), Oxford Shoulder Score (mean difference, 12.05; p = 0.004), and VAS for pain/Numeric Pain Rating Scale values (mean difference, -3.79; p < 0.001). Forward elevation (mean difference, 24.44°; p < 0.001), abduction (mean difference, 52.30°; p = 0.02), and ER (mean difference, 15.22°; p < 0.001) improved. Device-related complications occurred at a rate of 3.6%, the most common of which were balloon migration (1.0%) and synovitis (0.6%). In the end, 5% of participants needed salvage reverse shoulder arthroplasty. The authors concluded that the short-term outcomes for SABS could be a safe and effective treatment and appears to be associated with early improvements in postoperative pain and function. Limitations to conclusively interpret the available evidence include clinical heterogeneity, use of concomitant procedures, and variations in patient selection. The therapeutic value of SABS is still unknown compared to other currently accepted treatment strategies. Additionally, the long-term implications of

SABS use on the outcomes of further salvage procedures and how long symptomatic improvement can be expected are unknown.

In 2023, Kunze and associates performed a systematic literature review to understand the propensity for clinically meaningful improvement after individuals received SBSI for massive rotator cuff repairs. Clinical outcomes were measured through the Freeman-Tukey double arcsine transformation to quantify the pooled rate of clinically meaningful improvements in outcomes as assessed using the minimal clinically important difference (MCID), PASS, and substantial clinical benefit (SCB). When data were irregularly presented to prevent misleading reporting, qualitative analysis was performed. The results showed an overall pooled rate of MCID achievement for the Constant-Murley score of 83% (95% CI, 71%-93%; range, 40%-98%), with 6 of 8 studies reporting rates equivalent to or more than 85%. One study registered a 98% rate of PASS achievement for the Constant-Murley score at a 3-year follow-up. The rate of MCID achievement for the ASES score varies between 83% and 87.5%. The rate of PASS achievement for the ASES score was 56% at a 2-year follow-up, while the rate of SCB achievement for the ASES score was 83% and 82% at a 1- and 2-year follow-up, correspondingly. At 1-year follow-up, 74% and 78% of participants reached the MCID for the Numeric Rating Scale and Oxford Shoulder Score, correspondingly. At three years, 69% of participants achieved the MCID for the Numeric Rating Scale, and 87% achieved it for the Oxford Shoulder Score. The authors concluded that those who underwent isolated SBSI for massive irreparable rotator cuff (MRCTs) showed a high rate of clinically significant improvement in results at short to mid-term follow-up. More studies are necessary to appropriately define and evaluate the rates of achieving the PASS and SCB after the implantation (included in the 2023 Hayes updated review).

Verma et al. (2022) - conducted a multicenter, single blinded randomized controlled trial (RCT) comparing the InSpace subacromial balloon spacer implant to partial repair of full thickness massive rotator cuff tears. One hundred eighty-four individuals met the inclusion criteria: ≥ age 40, magnetic resonance imaging (MRI) imaging showing a full thickness massive rotator cuff tear measuring ≥ 5cm and involving ≥ 2 tendons within nine months of study enrollment, functional deltoid muscle and preserved passive ROM on physical examination, VAS score greater than 30mm and who underwent failed conservative therapy for at least four months. Participants randomized to receive partial repair, underwent suture anchor repair of the posterosuperior rotator cuff, and concomitant procedures were done on both groups. Follow up was completed on days ten, weeks 6 and 3,6,12 and 24 months, and included examination, review of complications, reoperations, medications, and patient-reported outcomes. Post-operative rehabilitation was standardized for both groups. The primary outcome measure was the change from baseline to month 24 for the American Shoulder and Elbow Society (ASES) score, and secondary outcomes included the Western Ontario Rotator Cuff (WORC) score, Constant-Murley shoulder score, VAS score, EuroQol-5 Dimensions-5 Level (EQ-5D-5L) quality-of-life (QOL) score, and active ROM. The results showed that the InSpace demonstrated functional, and patient reported outcomes comparable to partial repair at month 12, maintained to month 24 (2 year follow up is well beyond the anticipated degradation timeframe, indicating clinical improvement is sustained even after the implant has biodegraded). The InSpace group showed earlier recovery at week six as shown by ASES, WORC, Constant-Murley scores and ROM improvements. These results are limited by a lack of standardized concomitant procedures performed in both groups, which may have affected the results. Furthermore, the repair techniques, and the non-blinding of the examiners are a potential source of bias. Further studies addressing these limitations, and longer-term follow-up are warranted. (Included in the 2022 ECRI report, Kunze et al. 2023, Sandler et al. 2024, and Sirignano et al. 2024.)

In a 2022 Hayes Evolving Evidence Review, it was concluded that there are minimal levels of support for using the InSpace Biodegradable Subacromial Spacer for treating irreparable rotator cuff tears. In 2023, Hayes updated the evolving evidence review to include four newly published clinical studies, two newly published systematic reviews, and one newly published guideline. The 2023 annual updated review of the evidence indicates an unlikely or no change in the current level of support. While a small evidence base is associated with improved patient-centered outcomes, the very poor quality of available studies suggests that the potential clinical benefit should be considered cautiously.

A 2021 ECRI clinical evidence assessment, updated in 2022, entitled InSpace Subacromial Tissue Spacer System (Stryker Corp.) for Treating Massive Rotator Cuff Tears concluded that based on the results of one systematic review, two RCTs and four nonrandomized comparison studies, the InSpace is safe and improves function and QOL for individuals with large to massive MRCT. However, rotator cuff tears included too few participants to form conclusions about its comparative effectiveness to arthroscopic repair or debridement, and none of the studies reported outcomes longer than two years. The 2024 update on InSpace's safety and efficacy shows that comparative evidence is inconclusive. Outcomes show improved pain; however, the evidence is low for clinically meaningful improvement from baseline, significant improvement compared to debridement alone or with partial repair. Larger RCTs comparing InSpace as a standalone treatment and as an adjunct treatment with other MRCT treatments and reporting on long-term patient-oriented outcomes are needed to confirm findings and address evidence gaps, which may be partially addressed in ongoing clinical trials.

Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

The interventional procedures guidance published by NICE in 2023 offers the following guidance for biodegradable subacromial spacer insertion for rotator cuff tears:

- When debridement is a suitable option, biodegradable subacromial spacer insertion for rotator cuff tears should not be used.
- When debridement is not a suitable option:
  - Biodegradable subacromial spacer insertion for rotator cuff tears should be used only in research.
  - Further research should ideally be randomized controlled trials. It should report details of patient selection (including demographics and the tear size), measures of shoulder function, pain relief, and QOL. Follow up should ideally be for at least 2 years.
  - Patient selection should be done by a multidisciplinary team experienced in managing the condition, including clinicians with specific training in the procedure.
  - The procedure should only be done by surgeons with specific training in inserting the device.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries of the shoulder are procedures and, therefore, not regulated by the FDA. However, devices and instruments used during the surgery may require FDA approval. Refer to the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 21, 2024)

On June 12, 2021, the FDA granted DeNovo classification of the InSpace™ Subacromial Tissue Spacer System (Stryker, Ortho-Space Ltd.). This Class II device is indicated for the treatment of massive, irreparable, full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis for individuals greater than or equal to 65 years of age whose clinical conditions would benefit from a treatment with a shorter surgical time compared to partial rotator cuff repair. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200039.pdf. (Accessed July 21, 2024)

References

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0556BB]

Berk AN, Cregar WM, Gachigi KK, et al. Outcomes of subacromial balloon spacer implantation for irreparable rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg. 2023 May 27: S1058-2746(23)00392-0.

ECRI Institute. Clinical Evidence Assessment. InSpace Subacromial Tissue Spacer System (Stryker Corp.) for Treating Massive Rotator Cuff Tears. 2021. Updated July, 2022.

Hayes, Inc., Evolving Evidence Review. InSpace Biodegradable Subacromial Spacer (Stryker) for Irreparable Rotator Cuff Tears. Hayes, Inc. March 2022. Updated March 2023.

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Sirignano M, Nyland J, Krupp R. Subacromial balloon spacer massive rotator cuff tear treatment systematic review and meta-analysis: Patient selection and physical therapy may be keys to outcome success. Knee Surg Sports Traumatol Arthrosc. 2024 Jun 23.

Verma N, Srikumaran U, Roden CM, et al; on behalf of the SPACE GROUP. InSpace implant compared with partial repair for the treatment of full-thickness massive rotator cuff tears: a multicenter, single-blinded, randomized controlled trial. J Bone Joint Surg Am. 2022 Jul 20;104(14):1250-1262.

Policy History/Revision Information

Date	Summary of Changes
11/01/2024	**Related Policies** • Added reference link to the Clinical Policy titled *Skin and Soft Tissue Substitutes* **Medical Records Documentation Used for Reviews** (previously titled *Documentation Requirements*) • Replaced list of *Required Clinical Information* with instruction to refer to the protocol titled Medical Records Documentation Used for Reviews **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version SURGERY 101.27

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.