# Surgery of the Shoulder

**Guideline Number**: MMG117.U
**Effective Date**: November 1, 2023

Instructions for Use

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| Related Policies |
|---|
| None |

## 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**.

## Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

| Required Clinical Information |
|---|
| **Surgery of the Shoulder** |
| Medical notes documenting the following, when applicable:<br>• Pertinent physical examination of the relevant joint<br>• Severity of pain and details of functional disability(ies) interfering with activities of daily living (ADLs) |

| Required Clinical Information |
|---|
| **Surgery of the Shoulder** |
| • Upon request, we may require the specific diagnostic image(s) that shows the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images<br>  ○ **Note**: When requested, diagnostic image(s) must be labeled with:<br>  ▪ The date taken<br>  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s)<br>  ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted<br>• Reports of all recent imaging studies and applicable diagnostic tests, including the following, when applicable:<br>  ○ C-reactive protein (CRP)<br>  ○ Erythrocyte sedimentation rate (ESR)<br>  ○ Microbiological findings<br>  ○ Synovial fluid cytology<br>• Condition requiring procedure, including relevant past history with dates<br>• Physician's treatment plan, including pre-op discussion<br>• Feasibility of arthroscopic approach<br>• Co-morbid medical condition(s)<br>• Prior therapies/treatments tried, failed, or contraindicated; include the dates, duration, and reason for discontinuation<br>• Member has the ability to participate in post-surgical rehabilitation<br>• For revision surgery, also include:<br>  ○ Details of complication<br>  ○ Complete (staged) surgical plan<br>• If the location is being requested as an **inpatient stay**, provide medical notes to support site of service |

# 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 guideline 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 |
| 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 |

| CPT Code | Description |
|---|---|
| 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 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. Furthermore, studies include individuals with varying rotator cuff tear sizes.

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 Visual Analog Scale (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 external rotation (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 unknown are the long-term implications of SABS use on the outcomes of further salvage procedures and how long symptomatic improvement can be expected.

In 2023, Kunze and associates performed a systematic literature review to understand the propensity for clinically meaningful improvement after individuals received subacromial balloon spacer implantation 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), Patient Acceptable Symptom State (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 subacromial balloon spacer implantation 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 range of motion (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 posterosuperiorrotator cuff, and concomitant procedures were done on both groups. Follow-up was completed at day 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 below and Kunze et al. [2023] above).

In a 2022 Hayes evolving evidence review, it was concluded that there are minimal levels of support for the use of the InSpace Biodegradable Subacromal Spacer for the treatment of 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 improvement in patient centered outcomes, the very poor quality of available studies suggest that the potential clinical benefit should be regarded with caution.

A 2021 ECRI clinical evidence assessment, updated in 2022 entitled InSpace Subacromial Tissue Spacer System 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 tear 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. 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.

In 2016 NICE developed interventional procedures guidance on biodegradable subacromial spacer insertion for rotator cuff tears. The recommendations are as follows:

- Current evidence on the efficacy and safety of biodegradable subacromial spacer insertion for rotator cuff tears is limited in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures' guidance page.

- Further research may include collaborative data collection and clinical trials. Patient selection should be clearly documented. Outcomes of interest include measures of shoulder function, pain relief, and quality of life. All complications should be reported. Follow-up should ideally be for a minimum of 2 years.

## 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 31, 2023)

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 31, 2023)

## References


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.

National Institute for Health and Care Excellence (NICE). IPG 558. Biodegradable subacromial spacer insertion for rotator cuff tears. May 2016.

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.


## Guideline History/Revision Information

| Date | Summary of Changes |
|---|---|
| 11/01/2023 | **Documentation Requirements**<br>• Updated list of required clinical information:<br>  ○ Replaced:<br>  ▪ "Severity of pain *as documented on a validated pain scale* and functional disability(ies) *as documented on a validated functional disability scale or described as* interfering with activities of daily living *(preparing meals, dressing, driving, walking)*" with "severity of pain and *details of* functional disability(ies) interfering with activities of daily living (ADLs)"<br>  ▪ "Upon request, we may require the specific diagnostic image(s) *that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) and* that shows the abnormality for which surgery is being requested" with "upon request, we may require the specific diagnostic image(s) that shows the abnormality for which surgery is being requested"<br>  ▪ "Therapies tried *(including dates) and* failed *as documented by a lack of clinically significant improvement between at least two measurements concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: nonoperative therapy (i.e., orthotics, medications/injections, physical therapy, other* |

| Date | Summary of Changes |
|---|---|
| | *pain management procedures, etc.) and/or surgery*" with "*prior* therapies/ *treatments* tried, failed, *or contraindicated; include the dates, duration, and reason for discontinuation*"<br>▪ "If the location is being requested as an inpatient stay, provide medical notes to support *at least one of the following: surgery is bilateral, member has significant co-morbidities, and/or the member does not have appropriate resources to support post-operative care after an outpatient procedure*" with "if the location is being requested as an inpatient stay, provide medical notes to support *site of service*"<br>○ Removed:<br>▪ Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis)<br>**Supporting Information**<br>• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information<br>• Archived previous policy version MMG117.T |

# Instructions for Use

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare 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 guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.