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Surgery of the Shoulder (for Louisiana Only)

Policy Number: CS109LA.0R
Effective Date: ~~March 1~~TBD, 2023

[Instructions for Use](#)

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Application

This Medical Policy only applies to the state of Louisiana.

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.

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 federal, state, or contractual

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requirements 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
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 claviclectomy 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

CPT® is a registered trademark of the American Medical Association

Clinical Evidence

Subacromial Balloon Spacers (SABS)

The INSpace™ Subacromial Tissue Spacer System (Stryker) is a new, minimally invasive, biodegradable balloon spacer for the ~~treatment of massive~~ 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 ~~patients~~ 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)

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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 ~~included in ECRI report below~~) 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 ~~184 patients~~ met the inclusion criteria: \geq age 40, magnetic resonance imaging (MRI) imaging showing a full-thickness massive rotator cuff tear measuring \geq 5-cm and involving \geq 2 tendons within 9-nine months of study enrollment, functional deltoid muscle and preserved passive range of motion (ROM) on physical examination, visual analog scale (VAS) score greater than 30 mm and who underwent failed conservative therapy for at least 4-four months. Patients-Participants randomized to receive partial repair, underwent suture anchor repair of the posterosuperior ~~posteriosuperior~~ rotator cuff, and concomitant procedures were done on both groups. Follow-up was completed at day 10 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, visual analog scale (VAS) score, EuroQol-5 Dimensions-5 Level (EQ-5D-5L) quality-of-life (QOL) score, and active range of motion (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-INSpace group showed earlier recovery at week 6-six as shown by improvements in the 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 impacted 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 as well as longer term follow-up are warranted (included in the 2022 ECRI report below and Kunze et al. [2023] above).

~~Metcalf et al. (2022 - included in ECRI report below) conducted a multicenter double-blind, group sequential, adaptive randomized controlled trial on the effectiveness of the InSpace subacromial balloon spacer in patients with irreparable rotator cuff tears (the majority of which were \geq 3 cm) who underwent arthroscopic debridement of the subacromial space and biceps tenotomy plus insertion of INSpace balloon, compared to the same procedure without insertion of the INSpace device. 117 patients met the inclusion criteria that included adults with a rotator cuff tear with pain and loss of function that had failed conservative treatment and surgery was warranted. During standard shoulder arthroscopy, eligibility was verified, and participants were equally randomized to each group. The control group received surgery only by shoulder surgeons following a standardized technique. The intervention group received the same procedure followed by insertion of the INSpace balloon following the manufacturer's recommended technique. The primary outcome was improvement in the Oxford Shoulder Score which is a 12 item patient reported measure of pain and function at 12 months. Secondary outcomes included the Constant Score, range of pain free ROM, the WORC index, EQ-5D-5L, change in symptoms, Participant Global Impression of Change, resource use, and adverse events. The results showed at 12 months, the primary outcome data were obtained from 114 of the original 117 participants and showed improvement in both groups compared to baseline; however, the~~

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~~improvement was slightly greater in the control group. Secondary outcome results showed similar results. The authors concluded that this study demonstrates no meaningful benefit for the use of the INSpace device in addition to arthroscopic debridement. Limitations of this study include the fact that it did not address the use of the INSpace device alone, and COVID-19 restrictions limited the authors' ability to complete data collection for objective measures, although the objective measures taken in the study correlated well with the primary outcome measures.~~

In a 2022 Hayes evolving evidence review, it was concluded that there are minimal levels of support for the use of the InSpace Biodegradable Subacromial 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 ~~randomized controlled trials~~ RCTs and four nonrandomized comparison studies, the InSpace is safe and improves function and quality of life (QOL) in for individuals with patients with large to massive, ~~irreparable rotator cuff tears (MRCT)~~. However, rotator cuff tear ~~RCTs~~ included too few participants ~~patients~~ to form conclusions about its comparative effectiveness to arthroscopic repair or debridement, and none of the studies reported ~~on~~ outcomes longer than 2-two years. Larger RCTs comparing InSpace as a standalone treatment and as an adjunct treatment with other ~~irreparable~~ MRCT treatments and reporting on long-term patient-oriented outcomes are needed to ~~validate~~ 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 ~~August 15, 2022~~ July 31, 2023)

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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 in ~~patients~~ 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. ~~September 2021.~~ Updated July 2022.

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

Kunze KN, Moran J, Cecere R, et al. High rate of clinically meaningful achievement in outcomes after subacromial balloon spacer implantation for massive irreparable rotator cuff tears: a systematic review and meta-analysis. Am J Sports Med. 2023 Mar 22;3635465231155916.

~~Metcalf A, Parsons H, Parsons N, et al; START:REACTS team. Subacromial balloon spacer for irreparable rotator cuff tears of the shoulder (START:REACTS): a group sequential, double-blind, multicentre randomised controlled trial. Lancet. 2022 May 21;399(10339):1954-1963.~~

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.

Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	<u>Supporting Information</u> <ul style="list-style-type: none"><u>Updated Clinical Evidence, FDA, and References sections to reflect the most current information</u> <u>Archived previous policy version CS109LA.Q</u>

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