

Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder

Policy # 00930

Original Effective Date: 07/01/2025

Current Effective Date: 07/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers subacromial balloon spacer implantation as a treatment for massive, irreparable, full-thickness rotator cuff tears to be **investigational**.*

Background/Overview

Massive, Irreparable Full-Thickness Rotator Cuff Tears

Rotator cuff tears represent a common shoulder injury affecting a significant portion of the population, with overall incidence rates ranging from 5% to 40%, and approximately 54% of individuals over the age of 60 experiencing partial or complete tears. Massive tears, commonly defined as full-thickness tears involving at least 2 tendons or measuring greater than 5 cm in the coronal plane, constitute about 20% of all rotator cuff tears and 80% of recurrent tears. However, multiple definitions exist for what constitutes a massive tear, and a recent Delphi consensus of expert orthopedic shoulder specialists suggested that the most agreed upon definition would be tears with retraction of tendons to the glenoid rim in either the coronal or axial plane and/or a tear with at least 67% of the greater tuberosity exposed in the sagittal plane. Rotator cuff tears are considered irreparable when they cannot be restored to their original insertion on the tuberosities using standard surgical release and mobilization techniques due to excessive size, tendon retraction, and muscle degeneration, including atrophy and fatty infiltration. Without intervention, the natural progression of untreated massive tears can lead to muscle atrophy, fatty infiltration, and further tendon retraction, rendering potentially repairable tears irreparable over time.

Treatment

Management of massive, irreparable full-thickness rotator cuff tears (MIRCTs) encompasses both nonoperative and surgical approaches. Nonoperative treatments primarily focus on alleviating pain and enhancing shoulder function. These include physical therapy, activity modification to reduce strain on the shoulder, and pharmacological interventions such as nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections to manage inflammation and discomfort. Surgical

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interventions are considered when nonoperative treatments fail to provide adequate relief or in patients with higher functional requirements. Options include partial rotator cuff repair, which may restore some function depending on the tear's extent and tissue quality. For patients with significant deficits, tendon transfer procedures, such as latissimus dorsi or lower trapezius transfers, can compensate for lost rotator cuff function. Additionally, reverse total shoulder arthroplasty is a treatment option, particularly in individuals with pseudoparalytic shoulder, irreparable rotator cuff tears, and glenohumeral osteoarthritis who are not candidates for tendon transfers. Arthroscopic debridement with subacromial balloon spacer implantation (SBSI) is being investigated as a potential alternative treatment for managing MIRCTs.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In July 2021, the InSpace^{TM†} Subacromial Tissue Spacer System (Stryker; previously Ortho-Space Ltd.) was granted De Novo classification by the FDA ([DEN200039](#); Product Code: QPQ). The device is a biodegradable subacromial balloon spacer indicated for the treatment of MIRCTs in patients at least 65 years of age with mild to moderate glenohumeral osteoarthritis who may benefit from a shorter surgical time compared to partial rotator cuff repair. The InSpace system consists of a resorbable polymer implant pre-loaded on a deployer, which is inflated with sterile saline after being positioned within the subacromial space. The inflated balloon aims to reduce acromiohumeral contact pressure and restore shoulder biomechanics while it remains inflated for 3 to 4 months and the device is designed to biodegrade over approximately 1 year. The device purports to result in shorter operative times as well as earlier functional and pain relief when compared to partial repair.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Subacromial balloon spacer implantation represents a minimally invasive treatment modality for massive irreparable rotator cuff tears. The biodegradable spacer is introduced arthroscopically into the subacromial region where it functions to depress the humeral head, successfully reestablishing normal shoulder mechanics by blocking upward displacement of the humeral head toward the acromion. This technique addresses pain and functional limitations by creating a temporary articulating interface between the humeral head and acromion by reducing subacromial impingement. The biodegradable spacer gradually deflates over several months, potentially allowing time for adaptation of surrounding tissues and pain reduction without the complexity of tendon transfers or reverse shoulder arthroplasty.

Summary of Evidence

For individuals with massive irreparable rotator cuff tears (MIRCTs) who receive subacromial balloon spacer implantation (SBSI) as an adjunct to routine care, including surgery, the evidence

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includes meta-analyses, RCTs, non-randomized comparative studies, and uncontrolled studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Two RCTs provided conflicting evidence regarding the efficacy of SBSI. The non-inferiority trial comparing SBSI to partial repair found comparable improvements in American Shoulder and Elbow Surgeons (ASES) scores at 24 months, with SBSI demonstrating better forward elevation and shorter operative times. However, an FDA analysis recommended using a composite primary efficacy endpoint instead of ASES alone and found non-inferiority only in the subset of patients aged 65 years or older. Another RCT that compared arthroscopic debridement with and without SBSI was terminated early due to futility, with results favoring debridement alone over SBSI. This was supported by a 2024 meta-analysis comparing SBSI to arthroscopic debridement, which found that debridement alone demonstrated superior outcomes in pain reduction and Constant-Murley scores. A second review showed significant improvements in pooled patient-reported outcomes following SBSI from baseline through 2 years follow-up on Constant-Murley, ASES scores, and pain reduction, but a meta-analysis of comparative trials revealed no benefits over alternative therapies. Nonrandomized comparative studies typically reported improvements in functional outcomes and pain scores following SBSI compared to baseline; however, none showed it to be superior to other surgical reconstruction techniques. Case series have reported long-term follow-up of up to 8 years, with most showing a sustained benefit in functional and pain outcomes. Device-related complications were uncommon, with one review reporting that most studies (52%) did not observe any complications related to SBSI. Complications reported included implant migration, implant removal due to pain, early deflation of the implant resulting in temporary functional impairment, worsening of glenohumeral osteoarthritis, revision to other surgical procedures, and infection. Multiple studies emphasized the importance of proper patient selection and noted that while SBSI may provide short-term benefits, its long-term effectiveness compared to alternative treatments remains uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Orthopedic Surgeons

The 2025 American Society of Orthopedic Surgeons (AAOS) guidelines for the management of rotator cuff injuries includes the following summary of options for patients with unrepairable tears without arthropathy: "In the absence of reliable evidence, it is the opinion of the workgroup that physical therapy, biceps tenotomy/tenodesis, partial repair, tendon transfer, superior capsular reconstruction, arthroscopic debridement, balloon spacers, graft interposition, or graft augmentation (nonporcine) can improve patient-reported outcomes (strength of evidence: moderate, low; strength of option: consensus)."

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National Institute for Health and Care Excellence

In 2023, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on the use of biodegradable subacromial spacer insertion for rotator cuff tears. For individuals where debridement is suitable, NICE recommends that subacromial spacers should not be used. When debridement is not a suitable option, NICE recommends that the procedure be only used in a research setting with patient selection done by a multidisciplinary team, including clinicians with specific training in the procedure due to limited evidence.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05329584 ^a	An Assessment of Two Accelerated Rehabilitation Programs for Use With the InSpace ^{TM‡} Subacromial Tissue Spacer System in the Treatment of Full-thickness Massive, Irreparable Rotator Cuff Tears	160	Apr 2026
<i>Completed</i>			
NCT04704700	Evaluate the Rotator Cuff Repair With "InSpace" VS Without "InSpace"	48	Jul 2025

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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06/05/2025 Medical Policy Committee review

06/11/2025 Medical Policy Implementation Committee approval. New policy.

06/04/2026 Medical Policy Committee review

06/10/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. Coverage eligibility unchanged.

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Next Scheduled Review Date: 06/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	29999
HCPCS	C9781
ICD-10 Diagnosis	M75.100-M75.122

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.