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MEDICAL POLICY – 7.01.180

Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder

BCBSA Ref. Policy:	7.01.180	
Effective Date:	**Oct. 3, 2025**	RELATED MEDICAL POLICIES:
Last Revised:	Jun. 10, 2025	N/A
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Rotator cuff tears are a common cause of shoulder pain and can make it hard to do everyday activities. Surgery is often used to fix these tears, but some tears can't be repaired because the tendon is too damaged. These irreparable tears cause more pain and have fewer treatment options. A new technique called balloon spacers involves inserting a small balloon between the arm bone and shoulder bone. The goal of these balloon spacers is to reduce friction, improve shoulder movement and help with recovery. Balloon spacers are considered investigational (unproven). There's not enough evidence to show they are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Investigational
Subacromial balloon spacer implantation	**Subacromial balloon spacer implantation is considered investigational as a treatment for massive, irreparable, full-thickness rotator cuff tears.**

Coding

Code	Description
CPT	
29999	Unlisted procedure, arthroscopy
HCPCS	
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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.

Background

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.[1] 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.[2,3] 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.[3] Without intervention, the natural progression of untreated massive tears can lead to muscle atrophy, fatty infiltration, and further tendon retraction, rendering potentially reparable 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.[4] Surgical interventions are considered when nonoperative treatments fail to provide adequate relief or in individuals with higher functional requirements. Options include partial rotator cuff repair, which may restore some function depending on the tear's extent and tissue

quality.[3] For individuals 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.[3] Arthroscopic debridement with subacromial balloon spacer implantation (SBSI) is being investigated as a potential alternative treatment for managing MIRCTs.

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 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 individuals 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 individual-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 individual 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing 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
Ongoing			
NCT05329584[a]	An Assessment of Two Accelerated Rehabilitation Programs for Use With the InSpaceTM Subacromial Tissue Spacer System in the Treatment of Full-thickness Massive, Irreparable Rotator Cuff Tears	160	Apr 2026
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.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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 most recent American Society of Orthopedic Surgeons (AAOS) guidelines for the management of rotator cuff injuries do not provide guidance regarding the use of subacromial balloon spacer implantation for the treatment of rotator cuff tears or shoulder conditions.[53,]

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.[54] 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 individual selection done by a multidisciplinary team, including clinicians with specific training in the procedure due to limited evidence.

Medicare National Coverage

There is no national coverage determination

Regulatory Status

In July 2021, the InSpace 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 individuals 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.[5]

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History

Date	Comments
07/01/25	New policy, approved June 10, 2025, effective for dates of service on or after October 3, 2025, following 90-day provider notification. Policy created with literature review through February 3, 2025. Subacromial balloon spacer implantation is considered investigational as a treatment for massive, irreparable, full-thickness rotator cuff tears.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.