Medical Coverage Policy | Balloon Spacers for Treatment of Irreparable Rotator Cuffs of the Shoulder

EFFECTIVE DATE: 12|01|2025
POLICY LAST REVIEWED: 07|15|2026

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Subacromial balloon spacer implantation is considered not covered as a treatment for massive, irreparable, full-thickness rotator cuff tears as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Subacromial balloon spacer implantation is considered not medically necessary as a treatment for massive, irreparable, full-thickness rotator cuff tears, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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 reparable tears irreparable over time.

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 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.3, 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.3,. Arthroscopic debridement with subacromial balloon spacer implantation (SBSI) is being investigated as a potential alternative treatment for managing MIRCTs.

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 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.

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 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.

CODING

Medicare Advantage Plans and Commercial Products

The following code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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

There is no specific CPT code for this procedure. The following Unlisted code can be used:

29999 Unlisted procedures, arthroscopy

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, September 2026
Provider Update, October 2025

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