Medica Coverage Policy

Policy Name:	**Subacromial Tissue Spacer for Treatment of Rotator Cuff**
Effective Date:	**2/20/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Subacromial tissue spacer insertion systems (e.g., InSpace™ biodegradable spacer) for the treatment of rotator cuff tears are considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Surgical repair of a massive or irreparable rotator cuff tear is a technically challenging procedure and associated with high rates of failure, and there is no consensus regarding optimal management. Conventional treatment options, some less complex, include arthroscopic debridement, subacromial decompression, partial cuff repair, tendon transfers, superior capsular reconstruction, biceps tenotomy, and reverse shoulder arthroplasty. An emerging treatment modality is the use of a biodegradable balloon system arthroscopically inserted by an orthopedic surgeon through a lateral portal. The device theoretically acts as a physical barrier, decreases subacromial friction, restores proper shoulder biomechanics and function during dynamic movements, and purportedly reduce pain.

One device that is currently available is the InSpace™ Subacromial Tissue Spacer System (Stryker Corporation). According to its regulatory summary, this device is indicated for the treatment of patients with massive, irreparable full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age. The implant is filled with sterile saline solution to a predefined volume, sealed, and released once positioned in the tissue space between the acromion and the humeral head. It self deflates after approximately 10 weeks and resorbed after 12 to 15 months.

FDA Approval

The InSpace biodegradable subacromial spacer by Stryker received de novo clearance as a class II device under regulation number 21 CFR 888.3630 from the U.S. Food and Drug Administration (FDA) on July 12, 2021, under product code QPQ (reabsorbable shoulder spacer).

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **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

Original Effective Date: 2/20/2023