7.01.176	Suture Button Suspensionplasty Fixation System for Thumb Carpometacarpal Osteoarthritis		
Original Policy Date:	December 1, 2023	**Effective Date:**	December 1, 2024
Section:	7.0 Surgery	**Page:**	Page 1 of 14

Policy Statement

I. Suture button suspensionplasty for thumb carpometacarpal joint osteoarthritis is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
See the Codes table for details.

Description

In the thumb, the most common site for arthritis to develop is in the joint at the base of the thumb, also known as the carpometacarpal (CMC) joint. Pain and functional limitations associated with symptomatic thumb CMC joint osteoarthritis, especially when pinching or gripping objects, can significantly interfere with quality of life. Surgery is indicated when conservative measures fail to provide sufficient relief and functional improvement. There is currently no consensus on the optimal surgical approach, but the most frequently used procedure is trapeziectomy with ligament reconstruction and tendon interposition (LRTI). Trapeziectomy using suture button suspensionplasty (SBS) is proposed as a less invasive alternative to trapeziectomy with LRTI.

Related Policies

- Synthetic Cartilage Implants for Joint Pain

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2014, the CMC Mini TightRope System (Arthrex, Inc) was FDA cleared through the 510K process.[6,] Clearance was based on a determination that the device is substantially equivalent to the predicate device Arthrex Implant System (Mini TightRope). The CMC MiniTightRope system is indicated for CMC joint arthroplasty as an adjunct in the suspension of the thumb metacarpal by

providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Product code: HTN

Rationale

Background

Thumb Carpometacarpal Joint Osteoarthritis

In the thumb, the most common site for arthritis to develop is in the joint at the base of the thumb, also known as the carpometacarpal (CMC) joint. The incidence of CMC joint osteoarthritis is estimated to be 5% to 33% among adults in their 50s and 60s, and rises with age. It is more common in postmenopausal women. Pain and functional limitations, especially when pinching or gripping objects, can significantly interfere with quality of life.[1,]

First-line treatment of CMC joint osteoarthritis includes non-surgical measures such as activity modifications, rest, hand orthosis, anti-inflammatory medications, physical therapy, and corticosteroid injections.[2,] Surgery is indicated when conservative treatment fails to provide sufficient relief and functional improvement. Although thumb CMC joint osteoarthritis is often staged using radiological classification systems (e.g., the Eaton-Littler classification), the severity of symptoms does not necessarily correspond to radiographic findings; therefore a decision to proceed to surgery is based on symptoms and degree of disability.[3,]

Multiple surgical techniques to treat thumb CMC osteoarthritis have been developed but there is currently no consensus on the optimal approach.[3,4,5,] The most common surgical technique is removal of the trapezium bone at the base of the thumb (trapeziectomy). Trapeziectomy can be performed alone but is most commonly performed in conjunction with reconstruction of the ligament that holds the bones between the thumb and index finger together, and filling the space left behind by the removed trapezium with tendon harvested from the forearm to support the thumb. This procedure is known as trapeziectomy with ligament reconstruction and tendon interposition (LRTI). Either the flexor carpi radialis (FCR) tendon or abductor pollicis longus (APL) tendon is used in this procedure.

Trapeziectomy using suture button suspensionplasty is proposed as a less invasive alternative to trapeziectomy with LRTI. Instead of using tendon to support the thumb, the procedure suspends the first metacarpal to the second using a strong suture material (fiberwire) passed through both bones. A button on each of the metacarpals is attached to either end of the suture to secure the bones in the correct position.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some

circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Suture Button Suspensionplasty Fixation System for Thumb Carpometacarpal Joint Osteoarthritis

Clinical Context and Therapy Purpose

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with thumb carpometacarpal (CMC) joint osteoarthritis who have not responded to conservative treatment.

Interventions

The therapy being considered is suture button suspensionplasty with the CMC Mini TightRope System. Suture button suspensionplasty is intended to provide stabilization at the base of the first and second metacarpal following trapeziectomy for CMC joint osteoarthritis. The system suspends the first metacarpal to the second using suture material (fiberwire) passed through both bones. A button on each of the metacarpals is attached to either end of the suture to secure the bones in the correct position. This procedure may also be an option in the salvage or revision setting, as it avoids sacrifice of a donor tendon. In a cross-sectional survey of active members of the American Society for Surgery of the Hand published in 2024, surgeons preferring suture button suspensionplasty (5.9%) cited avoidance of autogenous tissue harvest, shorter immobilization time, and quicker recovery time as the main factors impacting their choice.[7,]

Comparators

Multiple surgical techniques to treat thumb CMC osteoarthritis have been developed but there is currently no consensus on the optimal approach.[3,5,] The most common surgical technique is removal of the trapezium bone at the base of the thumb (trapeziectomy). Trapeziectomy can be performed alone but is most commonly performed in conjunction with reconstruction of the ligament that holds the bones between the thumb and index finger together and filling the space left behind by the removed trapezium with tendon harvested from the forearm to support the thumb. This procedure is known as trapeziectomy with ligament reconstruction and tendon interposition (LRTI). While no current surgical technique has established superiority - classical LRTI is considered the "gold standard" approach.[1,]

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and treatment-related morbidity.

The Disabilities of the Arm, Shoulder and Hand (DASH) and QuickDASH Questionnaires and the Visual Analog Scale for pain are patient-reported outcome measures commonly used to assess surgical treatment of thumb CRC osteoarthritis (Table 1).

There are no guidelines specific to the duration of follow-up to assess outcomes of thumb CMC joint surgery. Long-term follow-up over years would be of interest to assess pain, function, and procedure-related adverse events. The only published RCT of SBS specified at least 2 years of follow-up for inclusion in the analysis.[8,] Both immediate operative complications and longer-term adverse events would be of interest.

One proposed advantage of SBS over LRTI is a reduction in the occurrence of subsidence (the collapse or settling of bone located immediately next to an implantable device). However, there is no consensus on how to measure subsidence and its correlation to symptoms is not clear.

Table 1. Outcome Measures

Outcome	Measure	Scale Description and Administration	Minimal Clinically Important Difference
Pain	Visual analog scale	0-10, Lower score means reduced pain	1.4, 1.6-1.9 points[9,]
Pain and function	Disabilities of the Arm, Shoulder and Hand (DASH)	A 30 Item self-reported questionnaire that measures an individuals' ability to complete tasks, absorb forces and severity of symptoms. Lower scores indicate better functional outcomes.	11-15 points[10,]
Pain and function	Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH)	Abbreviated version of DASH (11 items)	16-20 points[10,]
Revision Surgery rates	Frequency, percent	NA	NA
Surgical Complications	Frequency, percent	NA	NA

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Wininger et al (2022) published a systematic review of LRTI compared to SBS for carpometacarpal joint osteoarthritis, with searches conducted through November 2020.[1,] Study eligibility criteria included reporting of postoperative DASH or QuickDASH scores. The quality of the overall body of evidence for each intervention was rated for quality, quantity, and consistency using Strength of Recommendation Taxonomy (SORT) criteria.

The analysis included 31 studies (LRTI: 25 studies [1289 thumbs]; SBS: 6 studies [113 thumbs]). At the time the review was conducted, no studies directly comparing SBS to LRTI had been published. The body of evidence for SBS was rated SORT C (based on case series) and for LRTI was rated SORT B (based on inconsistent or limited-quality patient-oriented evidence). In studies that reported both pre-operative and post-operative data, DASH or QuickDash scores improved following either LRTI

and SBS. Grip strength and key pinch were similarly improved but inconsistently reported across studies. Overall, complications occurred in 12.3% of 740 individuals who underwent LRTI and 13.3% of 113 who underwent SBS. There were 6 re-operations in the LRTI studies (of which 4 came from RCTs) and 2 re-operations in the SBS studies. Complete reporting of complications varied greatly between studies and follow-up times were generally short, precluding any conclusions on long-term complications associated with each procedure.

The authors noted multiple limitations of the body of the evidence, including increased risk of bias especially for SBS studies, short follow-up times, and lack of reporting of the time period of postoperative outcome measurements. They concluded that, although both LRTI and SBS seemed to provide improved short-term patient-reported functional improvement and objective strength, larger prospectively designed studies of high-quality evidence are needed to compare outcomes between the 2 techniques.

Randomized Controlled Trial

Morais et al (2022) reported on an RCT, conducted at a single center in Portugal that evaluated SBS for thumb CRC joint osteoarthritis (Table 2).[8,] The trial compared trapeziectomy with SBS to trapeziectomy with LRTI in 76 individuals. Mean follow-up was 37.3 (standard deviation [SD], 12.6) months in the SBS group and 40.5 (SD, 14.8) months in the SBS group. Pain and function as assessed by visual analogue scale (VAS) and QuickDash scores at follow-up improved from baseline in both intervention groups but did not differ between groups (Table 3). The incidence of postoperative complications was also similar in each group. One individual in the SBS and 2 in the LRTI group required reoperation. Of note, 2 individuals in the SBS group and 1 in the LRTI group developed a complex regional pain syndrome requiring physical therapy.

The trial had several important limitations (Tables 4 and 5). Lack of blinding combined with subjective outcome measures poses a serious risk of bias. Outcomes were not prespecified and the trial was not registered. Although the methods section mentions that a power calculation was conducted, no details are given and there is no reporting of pre-specified thresholds for minimally clinically important differences. Generalizability is limited because the trial was conducted at a single center, with all surgeries performed by the same individual. Additionally, 20% of individuals who received surgery were excluded from the analysis. Individuals who were lost to follow-up (n=5), those who underwent revision surgery (n=7), and those who received associated procedures (n=7) were all classified as ineligible and were not included in the analysis. There was no analysis to account for missing data. Study authors concluded that "further prospective randomized controlled studies with longer follow-up are recommended."

Table 2. Randomized Controlled Trial of Suture Button Suspensionplasty for Thumb Carpometacarpal Joint Osteoarthritis: Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Trapeziectomy with SBS	Trapezeictomy with LRTI
Morais et al (2022)[8,]	Portugal	1	2015-2019	Individuals with thumb carpometacarpal osteoarthritis 9.2% stage II; 64.5% stage III; 26.3% stage IV 88.2% female Race not reported	39	37

LRTI: ligament reconstruction and tendon interposition; SBS: suture button suspensionplasty.

Table 3. Randomized Controlled Trial of Suture Button Suspensionplasty for Thumb Carpometacarpal Joint Osteoarthritis: Results

Study	Percent of Patients Reporting Pain Relief (SD)	Patient-Reported VAS score at discharge (SD)	Quick DASH score at discharge (SD)	Complications
Morais et al (2022)[8,]				
N	76	76	76	76
SBS	94.6%	1.5 (1.4)	31.6 (20.3)	Postoperative complications (all): 4/37 (11%) Reoperation rate: 1/37 (2.7%)
LRTI	92.3%	1.3 (1.2)	30.1 (17.8)	Postoperative complications (all): 3/39 (8%) Reoperation rate: 2/39 (5.1%)
P-value	.6877	.9658	.7336	Postoperative complications (all):.3585 Reoperation rate:.5873

LRTI: ligament reconstruction and tendon interposition; SBS: suture button suspensionplasty; SD: standard deviation; VAS: visual analog scale.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Morais et al (2022)[8,]	3. 9.2% of participants had stage 2 osteoarthritis 4. Participants were treated at a single center in Portugal; subpopulations not reported			5. Clinically significant differences not specified	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Morais et al (2022)[8,]	3. Not described	1. Participants and surgeon not blinded; 1 surgeon performed all	1. Trial not registered; outcomes not pre-specified;	1. 19/95 individuals who received surgery (20%)	1. Methods section states that a power analysis was	3. Methods section notes that confidence

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		procedures 2. Outcome assessor described as independent, but not clear if blinded	clinically important differences on outcomes not pre-specified.	were excluded: Participants who were lost to follow-up (n = 5), had associated procedures (n=7), underwent revision surgeries (n =4), or refused to participate (n =3) were all defined as not meeting inclusion criteria; no analysis to account for missing data	performed but no details are given	intervals were calculated, but none reported in results 4. No calculation of comparative treatment effects for non-inferiority

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Prospective Cohort Study

Shonuga et al (2023) conducted a prospective cohort study of 112 consecutive individuals who underwent SBS or LRTI (Table 6).[11,] Individuals who underwent SBS had significantly lower QuickDASH scores at 1 year postoperatively compared with those who underwent LRTI (Table 7). The 14-point difference between groups exceeded the minimum clinically important difference (MCID) prespecified by the study investigators; however there was no rationale provided for this threshold, and other researchers have recommended a MCID of 16 to 20 points on the QuickDash.[10,] No fractures or reoperations occurred in either group. No details on other complications or adverse events are reported. Study limitations are shown in Tables 8 and 9. Lack of blinding and randomization pose a serious risk of bias. Additional limitations are the relatively short-term follow-up period and variation in the surgical procedures used in the LRTI group.

Table 6. Prospective Cohort Study of Suture Button Suspensionplasty for Thumb Carpometacarpal Joint Osteoarthritis: Characteristics

Study	Study Type	Country	Dates	Participants	Trapeziectomy with SBS	Trapeziectomy with LRTI	Follow-Up
Shonuga et al (2023)[11],	Prospective Cohort	US	2015-2017	112 consecutive individuals with Eaton stage 3-4 thumb CMC arthritis who underwent open trapeziectomy and suspensionplasty. Exclusions: history of rheumatoid arthritis, previous thumb surgery, traumatic arthritis, or incomplete radiographic records 71.4% female Mean age 63 years (range 44-80) Race not reported	n = 59	n = 53	1 year

LRTI: ligament reconstruction and tendon interposition; SBS: suture button suspensionplasty

Table 7. Prospective Cohort Study of Suture Button Suspensionplasty for Thumb Carpometacarpal Joint Osteoarthritis: Results

Study	QuickDASH Questionnaire Score at 12 months	VAS for pain Score at 12 months	Lateral Pinch Strength	Post-Operative Complications
Shonuga et al (2023)[11],				
SBS	7.5	0.3	5.7 kg	No fractures or reoperations in either group; no additional details
LRTI	21.5	0.6	5.2 kg	
P-value	<.05	<.05	<.99	

LRTI: ligament reconstruction and tendon interposition; SBS: suture button suspensionplasty; VAS: visual analog scale.

Table 8. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Shonuga et al (2023)[11],			5. LRTI procedure used FCR or APL tendon, may be differences in outcomes based on variation in procedures	3. Limited detail on adverse events; unclear if outcomes prespecified	1.2. 1-year follow-up may be insufficient to assess outcomes

APL: abductor pollicis longus; FCR: flexor carpi radialis; LRTI: ligament reconstruction and tendon interposition. The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Shonuga et al (2023)[11],	1. Not randomized	1. Not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Retrospective Studies

Multiple retrospective, non-randomized studies have been published.[12,-20,]These studies are limited by their lack of a comparator, lack of blinded outcome assessment, outcome assessment based on medical record data, and insufficient follow-up duration to assess longer-term outcomes. Because of their methodological limitations they are not discussed further, but are cited for reference only.

In 2024, Lachnish et al published a chart review of 17 out of 50 eligible patients treated with trapeziectomy plus SBS and assessed long-term functional outcomes at 10 years.[21,] Improvements were seen in QuickDASH scores, grip strength, and pinch strength compared to historical 3 month assessments, with radial and palmar range of motion maintained within 98% and 94%, respectively. These outcomes were observed despite radiographic evidence of subsidence, with the average height of the trapezial space reduced to 69% of the previous measurement in 9/17 patients with available imaging.

Section Summary: Suture Button Suspensionplasty Fixation System for Thumb Osteoarthritis

The evidence includes a systematic review, 1 RCT, 1 prospective, comparative observational study, and multiple nonrandomized, retrospective studies. Relevant outcomes are symptoms, functional outcomes, and adverse events. A single-center RCT compared trapeziectomy with SBS to trapeziectomy with LRTI in 76 individuals. The RCT had multiple methodologic limitations, including lack of blinding, inappropriate handling of missing data, and no pre-specification of outcome measures. Pain and functional outcomes did not differ between intervention groups after 40 months

of follow-up, although operative and recovery time was shorter in the suspensionplasty group. A prospective cohort study of 112 consecutive individuals who underwent suture button suspensionplasty or LRTI found similar improvements in pain scores and function with both procedures. While these results are encouraging, well-designed randomized controlled trial data are required to support non-inferiority of trapeziectomy with SBS compared to LRTI.

Supplemental Information

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

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 College of Rheumatology/Arthritis Foundation

In 2019, the American College of Rheumatology/Arthritis Foundation published a guideline on the management of osteoarthritis of the hand, hip, and knee.[2,] The guideline included recommendations for non-surgical treatment of thumb carpometacarpal (CMC) joint osteoarthritis, but surgical approaches were not addressed.

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 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05111405	A Randomized Prospective Multicenter Study Comparing Suture Button Suspensionplasty (SBS) With Ligament Reconstruction and Tendon Interposition (LRTI)	138	May 2025
NCT04458584	Restoration of Thumb Strength and Function in Basal Joint Arthritis: A Comparative Effectiveness Trial (RESTART)	165	July 2026

NCT: national clinical trial.

References

1. Wininger AE, Orozco EI, Han A, et al. Systematic Comparison of Ligament Reconstruction With Tendon Interposition and Suture-Button Suspensionplasty for Trapeziometacarpal Osteoarthritis. Hand (N Y). Mar 10 2022: 15589447211043217. PMID 35272518
2. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care Res (Hoboken). Feb 2020; 72(2): 149-162. PMID 31908149

3. Shah ND, Yuksel S, Sasson DC, et al. A 15-Year Review of Clinical Practice Patterns and Evidence-Based Medicine in Carpometacarpal Joint Arthroplasty. Hand (N Y). Mar 2023; 18(2_suppl): 65S-73S. PMID 34969303
4. Wajon A, Vinycomb T, Carr E, et al. Surgery for thumb (trapeziometacarpal joint) osteoarthritis. Cochrane Database Syst Rev. Feb 23 2015; 2015(2): CD004631. PMID 25702783
5. Challoumas D, Murray E, Ng N, et al. A Meta-analysis of Surgical Interventions for Base of Thumb Arthritis. J Wrist Surg. Dec 2022; 11(6): 550-560. PMID 36504527
6. Food & Drug Administration. 2014. Arthrex CMC Mini Tightrope. 510K Summary of Safety and Effectiveness. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140328.pdf. Accessed October 4, 2023.
7. Wu EJ, Fossum BW, Voort WV, et al. Surgeon preferences in the treatment of thumb carpometacarpal osteoarthritis. World J Orthop. May 18 2024; 15(5): 435-443. PMID 38835687
8. Morais B, Botelho T, Marques N, et al. Trapeziectomy with suture-button suspensionplasty versus ligament reconstruction and tendon interposition: a randomized controlled trial. Hand Surg Rehabil. Feb 2022; 41(1): 59-64. PMID 34728434
9. Shinya Y, Ikeguchi R, Noguchi T, et al. Radiographic Evaluation after Arthroscopic Partial Trapeziectomy with Suture-button Suspensionplasty for Thumb Carpometacarpal Arthritis. Plast Reconstr Surg Glob Open. May 2023; 11(5): e4983. PMID 37180981
10. Franchignoni F, Vercelli S, Giordano A, et al. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther. Jan 2014; 44(1): 30-9. PMID 24175606
11. Shonuga O, Nicholson K, Abboudi J, et al. Thumb-Basal Joint Arthroplasty Outcomes and Metacarpal Subsidence: A Prospective Cohort Analysis of Trapeziectomy With Suture Button Suspensionplasty Versus Ligament Reconstruction With Tendon Interposition. Hand (N Y). Jan 2023; 18(1): 98-104. PMID 33789518
12. Walter N, Duncan E, Roskosky M, et al. Suture Button Suspensionplasty in the Treatment of Carpometacarpal Arthritis: A Retrospective Analysis of One Surgeon's Experience Over 9 Years. J Hand Surg Glob Online. Jan 2020; 2(1): 25-30. PMID 35415470
13. Yao J, Cheah AE. Mean 5-Year Follow-up for Suture Button Suspensionplasty in the Treatment of Thumb Carpometacarpal Joint Osteoarthritis. J Hand Surg Am. Jul 2017; 42(7): 569.e1-569.e11. PMID 28412189
14. Yao J, Song Y. Suture-button suspensionplasty for thumb carpometacarpal arthritis: a minimum 2-year follow-up. J Hand Surg Am. Jun 2013; 38(6): 1161-5. PMID 23647637
15. Özçelik İB, Uğurlar M, Sarı A. Arthroscopic Hemitrapeziectomy and Suture Button Suspensionplasty in the Treatment of First Carpometacarpal Joint Eaton-Littler Stage 2-3 Arthrosis. J Wrist Surg. Apr 2019; 8(2): 132-138. PMID 30941253
16. Tanaka H, Muraoka K, Tanaka Y, et al. Suspension arthroplasty using the palmaris longus tendon with a suture button for thumb trapeziometacarpal arthritis: a retrospective observational study. J Orthop Sci. Jul 2023; 28(4): 795-801. PMID 35690542
17. Maeda A, Ikeguchi R, Noguchi T, et al. Clinical Results of Arthroscopic Partial Trapeziectomy With Suture-Button Suspensionplasty for Thumb Carpometacarpal Arthritis. Hand (N Y). Jul 2023; 18(5): 740-745. PMID 35156403
18. Landes G, Gaspar MP, Goljan P, et al. Arthroscopic Trapeziectomy With Suture Button Suspensionplasty: A Retrospective Review of 153 Cases. Hand (N Y). Jun 2016; 11(2): 232-7. PMID 27390569
19. Avant KR, Nydick JA, White BD, et al. Basal joint osteoarthritis of the thumb: comparison of suture button versus abductor pollicis longus suspensionplasty. Hand (N Y). Mar 2015; 10(1): 80-4. PMID 25767424
20. Das T, Mishra J, Chawla S, et al. Trapeziectomy and Mini TightRope Suspensionplasty for First Carpometacarpal Joint Arthritis. Cureus. Aug 2024; 16(8): e67695. PMID 39318898
21. Lachnish J, Titan AL, Sen S, et al. Long-Term Results of Suture-Button Suspensionplasty in the Treatment of Thumb Carpometacarpal Arthritis: A Minimum 10-Year Follow-Up. J Hand Surg Glob Online. Mar 2024; 6(2): 206-211. PMID 38903836

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	26989	Unlisted procedure, hands or fingers
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/01/2023	New policy.
12/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and

effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Suture Button Suspensionplasty Fixation System for Thumb Carpometacarpal Osteoarthritis 7.01.176 **Policy Statement:** I. Suture button suspensionplasty for thumb carpometacarpal joint osteoarthritis is considered **investigational.**	**Suture Button Suspensionplasty Fixation System for Thumb Carpometacarpal Osteoarthritis 7.01.176** **Policy Statement:** I. Suture button suspensionplasty for thumb carpometacarpal joint osteoarthritis is considered **investigational**.