Clinical Policy Bulletin:  
Distal Interphalangeal (DIP), Metacarpophalangeal (MCP) and Proximal Interphalangeal (PIP) Joint Implants

Number: 0798

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers the following metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint implants medically necessary for members with symptomatic rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis when conservative medical management fails to relieve pain or when digit deformity is interfering with hand function and activities of daily living:

- Ascension MCP joint implants of the index, long, ring, and small finger when soft tissue reconstruction can provide adequate stabilization; or
- Ascension PIP joint implants when soft tissue and bone can provide adequate stabilization and fixation, and the member expects to place his/her hands under high-loading situations after reconstruction; or
- Avanta MCP and PIP joint implants when soft tissue and bone can provide adequate stabilization and fixation, and the member expects to place his/her hands under high-loading situations after reconstruction; or
- Silicone-elastomer MCP and PIP total joint implants.

Aetna considers MCP and PIP joint implants for all other indications experimental and investigational because their value is unproven for all other indications.

Aetna considers distal interphalangeal (DIP) joint implants/splints experimental and investigational for members with symptomatic rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis because their value is unproven for these and all other indications.

Aetna considers resurfacing arthroplasty of the PIP joint experimental and investigational in the treatment of osteoarthritis and all other indications.

Aetna considers carpometacarpal (CMC) joint/trapeziometacarpal (TMC) joint implants experimental and investigational for members with symptomatic rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis because their value is unproven for these and all other indications.

See also CPB 0708 - Metatarsal Phalangeal Joint Replacement.

Background

Arthritis of the hand joints is a common disorder that frequently deteriorates over time, although its severity of symptoms, rate of deterioration and functional effects vary. When conservative medical management fails to relieve pain or when digit deformity is interfering with hand function and activities of daily living, surgical interventions are considered. For individuals with metacarpophalangeal (MCP) deformities, surgical options include synovectomy, intrinsic release/transfer, extensor tendon relocation, arthrodesis, and implant arthroplasty. Fewer surgical options exist for the arthritic interphalangeal (PIP) joint. Currently, individuals with arthritis of the PIP joint have 2 surgical options: arthrodesis or implant arthroplasty. Arthrodesis provides good pain relief and stability, however, finger function is lost in
Proponents of artificial hand joints have suggested that these protheses reduce pain, increase mobility and improve function compared with alternative treatments. Numerous total joint devices have been developed to reconstruct the MCP and PIP joints. However, regardless of design, these devices usually fail due to difficulties in restoring the biomechanics of the joint. In 1970, Swanson developed the silicone interpositional arthroplasty implant. Although this device is a joint spacer and not a total joint replacement, it provides good pain relief. Despite its numerous shortcomings (e.g., implant fracture, bone reaction adjacent to the implant, implant dislocation, silicone synovitis, and little active range of motion), the silicone spacer remains the preferred choice for the prosthetic reconstruction of the MCP and PIP joints (Hilker et al., 2007; Garcia-Moral, 2009).

Takigawa et al (2004) evaluated the Swanson silicone implant arthroplasty of the PIP joint, specifically evaluating clinical results with long-term assessment. A retrospective review of 70 silicone implants of the PIP joint in 48 patients was performed with an average follow-up period of 6.5 years (range of 3 to 20 years). Clinical assessment included motion, stability, and alignment. Radiographic assessment included implant fracture, deformity, and cystic bone resorption. The pathology consisted of degenerative joint disease in 14, post-traumatic arthritis in 11, rheumatoid arthritis in 13, and idiopathic arthritis associated with collagen disease in 12 patients. Swan neck and boutonniere deformities were assessed separately. Statistical analysis of pre-operative risk factors was compared with the post-operative assessment of pain, motion, and function (return to work). There was no significant change in the active range-of-motion (ROM) before and after PIP arthroplasty (26 degrees versus 30 degrees). Correction of swan neck and boutonniere deformities was difficult, usually leading to poor results. There was improvement in maximum active extension before surgery lacking 32 degrees to after surgery lacking 18 degrees. From a statistical standpoint rheumatoid joint involvement with PIP arthroplasty had poorer results than degenerative or post-traumatic arthritis with respect to pain relief and ROM. Pain relief was present in 70% of replaced PIP joints with residual pain and loss of strength in 30%. Radiographic analysis showed abnormal bone formation (cystic changes) in 45%. There were 11 implant fractures and 9 joints that required revision surgery. The authors concluded that silicone replacement of the PIP joint is effective in providing pain relief from arthritis but does not provide improvement in motion or correction of deformity. It provided a poorer outcome in rheumatoid disease in comparison with degenerative, post-traumatic, or idiopathic arthritis.

Individuals who are very active and use their hands for heavy labor may not be good candidates for the silicone rubber spacer. Due to the shortcomings of the silicone implant, other materials have been investigated in the hopes of improving long-term outcomes of finger joint implants. Pyrocarbon, a form of pyrolytic carbon, is a strong, durable, ceramic-like material that has proven its biocompatibility and durability in artificial heart valves and is being used in artificial hand joints as an alternative to silicone implants for end-stage arthritis.

The Ascension MCP (Ascension Orthopedics, Inc., Austin, TX) received pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA) in 2001. It is indicated for use as a total joint replacement of the index, long, ring, and small finger MCP joints that exhibit symptoms of pain, limited motion, or inadequate body alignment (i.e., subluxation/dislocation) secondary to articular destruction or degenerative disease related to rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis where soft tissue reconstruction can provide adequate stabilization. In the approval letter, the FDA stated that Ascension Orthopedics, Inc. is required to conduct a post-approval study to obtain 12 months of post-operative data on each Ascension MCP device implanted in a minimum of 100 patients at 4 sites.

The Ascension PIP (Ascension Orthopedics, Inc., Austin, TX) pyrocarbon total joint is a bicondylar, anatomically shaped, articulating implant that allows joint flexion-extension, while providing some restriction of adduction-abduction motion. The FDA granted a humanitarian use device approval for the Ascension PIP joint implant on March 22, 2002 for use in arthroplasty of the PIP joint when the patient has soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction and needs a revision of a failed PIP prosthesis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or destruction of the articular cartilage. The FDA noted that compared to current treatment alternatives, such as arthrodesis or resection arthroplasty with a silicone spacer, the Ascension PIP may provide the potential benefits of increased motion and function, and may be used on patients whose strength and motion demands would exceed the capabilities of the currently available 1-piece silicone spacers. The FDA concluded that pre-clinical testing of the Ascension PIP device demonstrated that the wear resistance, fracture strength, fatigue resistance, and resistance to articulating surface contact damage is acceptable for its intended use.

The Ontario Ministry of Health (2004) conducted a systematic review to identify the subset of patients who might benefit from pyrocarbon finger joint implants and to compare the safety and effectiveness of the pyrocarbon finger joint implants with the most commonly used implants for MCP and PIP joint arthroplasty. The authors identified the following important considerations in patient selection: (i) the condition of associated soft tissues and ligaments, (ii) the activity level of the patient, and (iii) the age of the patient. The authors stated that “pyrocarbon can be considered for patients in whom soft
tissues, capsules, and the collateral ligaments as the primary movers of the finger joints are better preserved. Therefore, it is indicated for young patients with post-traumatic arthritis or osteoarthritis. Patients with severe rheumatoid arthritis, in which adjacent ligaments and soft tissues are badly damaged, are not good candidates for pyrocarbon finger joint implants for the restoration of function. Silicone finger joint implants are not suitable for patients who are at risk of implant fracture due to high-demand loading conditions and frequent hand movements. For young patients, an implant made of a highly durable and resistant material such as pyrocarbon is expected to reduce the rate of implant fracture. The current evidence does not support the use of pyrocarbon finger joint implants for older patients and patients with severe rheumatoid arthritis. In these patients, silicone arthroplasty can be a final salvage procedure."

Based upon a systematic evidence review on artificial MCP and PIP joint replacement for end-stage arthritis, the National Institute for Health and Clinical Excellence (NICE, 2005) concluded that "[c]urrent evidence on the safety and efficacy of artificial MCP and interphalangeal (IP) joint replacement of the hand for end-stage arthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint-replacement registry for the evaluation of long-term outcomes of different types of prosthesis." The specialist advisors to the Institute's Interventional Procedures Advisory Committee noted the following potential adverse effects: stiffness, loosening of the prosthesis, generation of wear debris, bone resorption, nerve injury, wound hematoma, silicone synovitis, infection and prosthesis fatigue.

Stutz et al (2005) evaluated the pyrocarbon Ascension PIP implant for replacing the PIP joint in 13 patients and reported that at 1 year the ROM of the PIP joint improved from 0-28-51 pre-operatively to 0-22-77 post-operatively (average value), pain relief was achieved at rest and in motion of 80 % on the visual analog scale (VAS) (0: no pain, 10: incapacitating pain) and on the verbal analog scale an improvement of 62 % was achieved. The authors concluded that pyrolytic carbon implants reduce pain and are functionally superior to arthrodesis, however, a precise and individual post-operative protocol is necessary for beneficial results.

Schulz et al (2005) retrospectively reviewed the results of 20 out of 29 patients with idiopathic or post-traumatic arthritis who had been treated with the Ascension pyrolytic carbon PIP joint prosthesis from April 2002 to April 2004. Clinical, subjective and radiologic parameters were studied. On follow-up after 0.5 to 2.5 years the patients were satisfied with the pain relief; ROM varied. However, with an average ROM of 50 degrees it was equivalent to the results in the literature. Signs of periprosthetic cysts, osteophytes and loosening of the proximal as well as of the distal component could be seen in the radiograms of some patients. There was no correlation between these radiologic observations and ROM, pain or grip strength. In 3 cases the joint prosthesis had to be converted to an arthrodesis of the PIP joint. Bearing in mind the correct indications (intact collateral ligaments, stable bone stock and sufficient extensor and flexor tendons), pyrocarbon prostheses are a treatment option for idiopathic and post-traumatic arthritis preserving motion and reducing pain. Radiologic results seem to indicate an absence of osteointegration and tension forces at the prosthesis/bone interface. Further investigation will be necessary to improve surface and design to increase radiologic results in long-term follow-up. Additional surveys are required to improve indications, surgical approach and intra-operative control of correct component positioning.

Herren et al (2006) reported problematic bone fixation with the use of pyrocarbon implants in PIP joints. Seventeen pyrocarbon PIP prostheses were implanted into 14 patients, followed prospectively and reviewed clinically. The patients were assessed after a mean follow-up of 20.5 months subjectively by a VAS and radiographically. Significant pain relief was noted in all patients from a mean of 7.6 pre-operatively to 1.3 at final follow-up. Migration of one, or both, components was observed radiographically in 8 joints and radiolucent lines were evident in 3 more cases. The clinical results of the implants that had migrated were less favorable for ROM and grip strength than the stable joints of this series, although statistically the results were not significant. The number of possibly unstable prostheses in this series raises the question as to whether pyrocarbon is suitable for uncemented pressfit fixation in combination with early functional rehabilitation.

Nunley et al (2006) prospectively evaluated the subjective and objective functional outcome of patients treated with a pyrolytic carbon PIP joint arthroplasty for post-traumatic arthritis. Five patients (7 joints) with traumatic injuries to the PIP joint were followed-up for more than 1 year after pyrolytic carbon arthroplasty. All patients were treated with surgical reduction and stabilization at the time of the initial injury, but at a minimum of 6 months after the initial injury they had persistent pain, loss of motion, and functional limitations. All patients had a stable PIP joint with a satisfactory extensor mechanism but had radiographic evidence of post-traumatic arthritis. Patients were evaluated before and after arthroplasty with the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire and VAS and by radiographic and physical examination. At an average of 17 months, the mean DASH questionnaire score was unchanged. The pain rating on the VAS was 6 out of 10 before surgery and 4 out of 10 after surgery; this change was not statistically significant. The average ROM of the PIP joint decreased by 10 degrees at the last evaluation. Grip strength improved from an average of 47 lb to 63 lb after surgery. The authors concluded that the subjective and objective functional
outcomes in 5 patients more than 1 year after pyrolytic carbon PIP joint arthroplasty for PIP joint trauma were disappointing and for post-traumatic patients, they no longer use pyrolytic carbon PIP joint arthroplasty.

In a prospective study, Hilker et al (2007) evaluated 28 Ascension pyrocarbon prostheses with a mean follow-up of 4 years and reported that stability was not a problem, subjective results were satisfactory, and the ROM remained unchanged; however 46 % of prosthesis stems exhibited radiolucent seams, 7 prostheses (25 %) were rated as loose and 5 of those had to be replaced by a silicone implant. Use of the implant was abandoned as it was unreliable regarding bony fixation.

Bravo et al (2007) retrospectively reviewed the surgical technique, post-operative therapy/splinting protocols, and clinical and radiographic outcomes of patients who had pyrolytic carbon PIP joint arthroplasty. A total of 50 PIP joint replacements in 35 patients were performed with a minimum follow-up period of 27 months. Indications for surgery included pain, decreased ROM, instability, and/or deformity. The pre-operative diagnosis was osteoarthritis in 14, rheumatoid arthritis in 11, and post-traumatic arthritis in 10. There were 20 women and 15 men affected. The average age at the time of surgery was 53 years. The fingers replaced included the index (n = 15), middle (n = 18), ring (n = 10), and small (n = 7). The pre-operative arc of motion averaged 40 degrees (0 degrees to 60 degrees), and the pinch and grip measurements averaged 3 and 19 kg, respectively. The pre-operative pain scores averaged 6 (scale 0 to 10) on a VAS. The arc of motion was 47 degrees after surgery, and the average pinch and grip measurements were 4 and 25 kg, respectively. Pain scores improved to 1. At the final follow-up evaluation the overall patient satisfaction was nearly 80 %. The results of index finger PIP replacements are compatible with other digits. Fourteen joints (in 14 patients) to date have required additional procedures to improve or maintain joint motion/function or pain; 5 for minor reasons and 9 for major complications. No infections were noted. Although not medically necessary, 2 patients requested and had an amputation. Radiographic subsidence and subsequent settling (in accordance with Wolff's law) without apparent loosening occurred in 20 joints. Twenty-eight percent of patients required a second procedure and 8 % required a revision arthroplasty. Radiographs showed gross changes in implant and eventual settling to a stable position in 40 % of the joints. The authors concluded that the pyrolytic carbon implant arthroplasty showed improved pain relief and good overall patient satisfaction at the 2-year minimum follow-up evaluation, however, a longer follow-up period will help to better determine the efficacy of this implant.

Meier et al (2007) reported outcomes of PIP replacement with the pyrolytic carbon prostheses. Indications included symptomatic arthritis of the proximal interphalangeal joint with preservation of the collateral ligaments, sufficient bone support, and intact or at least reconstructable extensor tendons. Contraindications included: lack of stability (e.g., as a result of rheumatoid arthritis or destruction of the ligaments caused by an accident), non-reconstructable extensor tendons, florid or chronic infection, and lack of patient compliance. Twenty patients were treated for post-traumatic or idiopathic arthritis with 24 pyrolytic carbon PIP prostheses, and a follow-up examination was carried out after an average of 15 months (6-30 months). Surgical management was changed from arthroplasty to arthrodesis in 3 cases. For the remaining prostheses, an average ROM of 50 degrees was achieved for the PIP joint. On the VAS (0: no pain, 10: incapacitating pain), the patients suffered few symptoms (0 to 3). Eighty percent of patients said they were satisfied with the outcome of the operation. In 3 cases (1 infection, 2 dislocations) the prostheses had to be removed and arthrodesis performed. Migration of the distal components was observed on the radiographs in 5 cases, and of the proximal components in 4 cases, although this did not have any effect on the functional parameters. The development of a painless noise ("squeaking") was noticed in 9 out of 21 prostheses. However, as with prosthetic migration, this did not cause any functional deficits.

Branam et al (2007) compared the outcomes of silicone PIP arthroplasties to pyrolytic carbon implants in patients with osteoarthritis in a retrospective review of 41 arthroplasties in 22 patients with severe PIP joint osteoarthritis performed by a single surgeon. There were 13 patients and 22 joints in the silicone group with an average follow-up of 45 months. There were 9 patients and 19 joints in the pyrolytic carbon group with an average follow-up of 19 months. Clinical assessment included ROM, grip strength, and deformity. Radiographs were evaluated for alignment, subsidence, and implant fracture. Patients filled out a subjective questionnaire with respect to pain, appearance of the finger, and satisfaction. Complications were recorded. In the silicone group, the average pre-operative PIP joint ROM was 11 degrees/64 degrees (extension/flexion) and the average post-operative ROM was 13 degrees/62 degrees. In the pyrolytic carbon group, the average pre-operative PIP joint ROM was 11 degrees/63 degrees and the average post-operative ROM was 13 degrees/66 degrees. Eleven of 20 joints in the silicone group and 4 of 19 joints in the pyrolytic carbon group had a coronal plane deformity as defined by angulation of the PIP joint greater than or equal to 10 degrees. The average coronal plane deformity was 12 degrees in the silicone group and 2 degrees in the pyrolytic carbon group. The difference was statistically significant. In the silicone group, 3 of 22 joints required additional surgery. Two implants in 1 patient were removed and the PIP joint fused, and 1 implant was permanently removed for sepsis. In the pyrolytic carbon group, 8 of 19 joints squeaked, and there were 2 early post-operative dislocations and 2 implants with radiographic loosening. To date, there has been no revision surgery. Both groups had good pain relief. Patients were generally satisfied with the appearance of their joints in the pyrolytic carbon arm; however, satisfaction with appearance was variable in the silicone group. Nine of 13 patients in the silicone group and 6 of 7 patients in the
pyrolytic carbon group would have the procedure again. The authors reported that both implants provide excellent pain relief and comparable post-operative ROM. Complications were implant specific. The authors concluded that the results of this series show promise for the pyrolytic carbon PIP joint resurfacing arthroplasty but did not clearly demonstrate superiority compared with the silicone implant.

The Avanta MCP and PIP joint finger implants (Avanta Orthopaedics, Inc., San Diego, CA) received humanitarian use device approval from the FDA for use in arthroplasty of the MCP or PIP joints when the patient is in need of a revision of failed MCP or PIP prosthesis(es); or the patient expects to place his/her hands under loading situations which preclude the use of an alternative implant in the painful osteo-arthritis and post-traumatic MCP or PIP joint. The distal components are made of an ultra-high molecular weight polyethylene and the proximal components consists of a cobalt chromium-molybdenum articulating surface.

Moller and colleagues (2005) compared the results of the Avanta versus Swanson silicone implants in the MCP joint in a prospective, randomized comparison of 30 patients (120 implants). At 2-year follow-up, grip strength was measured, hand function was assessed with the Sollerman test and the subjective outcome was determined with VAS. With both implants ulnar deviation and flexion deformities decreased, and there was no difference between the groups. The increase in ROM was 7 degrees greater with Avanta implants than with Swanson implants. Grip strength and hand function were unaltered but the VAS showed decreased pain levels and subjective improvements in hand function, grip strength and cosmesis. Twenty-four of 30 patients were satisfied. Fracture of the silicone spacer occurred with 12 Avanta (20 %) and 8 Swanson implants (13 %), with a higher fracture frequency in men.

In a randomized prospective trial, Escott et al (2010) compared post-operative ROM and function of Swanson and NeuFlex MCP joint implants. A total of 33 patients who had rheumatoid arthritis underwent primary MCP arthroplasty of all 4 fingers in 40 hands; 20 received Swanson implants and 20 received NeuFlex implants. Exclusion criteria included diagnosis of other connective tissue disorders and previous MCP joint surgery. All participants followed the same post-operative rehabilitation protocol. The primary outcome measure was active MCP flexion. Secondary outcomes included active MCP extension, arc of motion, ulnar drift, function (Jamar grip strength and Sollerman hand function test), and the Michigan Hand Questionnaire. Patients were assessed pre-operatively and 12 months post-operatively. Patients’ mean age was 62.5 years (Swanson) and 58.1 years (NeuFlex) (p = 0.03). A total of 19 of 20 hands (Swanson) and 14 of 20 hands (NeuFlex) were from female patients. Pre-operative active ROM was not significantly different. At follow-up, both groups demonstrated increased active extension and arc of motion (p < 0.001), reduced active flexion and improved ulnar deviation (p < 0.001), increased mean Sollerman and Michigan Hand Questionnaire domain scores (p < 0.001), and improved grip strength (p = 0.03). Active MCP flexion was significantly greater in all 4 digits of hands with NeuFlex implants compared with Swanson implants. The NeuFlex group demonstrated a greater total arc of motion in the little finger. Implant groups were not significantly different by individual digit for active MCP extension, ulnar drift, and composite flexion. Functional outcomes did not differ between groups. Patients with Swanson implants reported higher Michigan Hand Questionnaire scores in the function and aesthetics domains. The authors concluded that both implant groups obtained satisfactory clinical improvement after MCP reconstruction of the hand. The NeuFlex group demonstrated superior ROM, whereas the Swanson group had better self-reported function and aesthetics, but not objectively measured function.

Distal InterPhalangeal (DIP) Joint:

Rehart and Kerschbaumer (2003) noted that finger joints were first replaced with endo-prostheses in 1940 by Burman. Indications for the procedure are degenerative, post-traumatic or arthritis related destruction of the joints of the hand. Nowadays, several more or less comparable prosthetic designs are available. The replacement of single bones of the wrist has not been of lasting success. Occasionally, an indication for arthroplasty of the trapezium-metacarpal joint of the thumb may exist. The MCP joint of the thumb should, in the authors' experience, be fused when the need arises. Up until the present, the silastic spacer of Swanson for the MCP and PIP joints has not shown any substantial development, although a variety of designs have been introduced. Questions related to the complicated biomechanics of these articulations in combination with problems concerning the material to be used, intra-osseous fixation, the articulation of the prosthesis components and the design of the stems have not yet been solved convincingly. The Swanson spacers in mid-term to long-term follow-ups show little active ROM, although the subjective patient satisfaction is very high and the potential for removal at its best. The authors stated that they do not see an indication for arthroplasty in the distal interphalangeal (DIP) finger joints.

Drake and Segalman (2010) noted that arthritis in the small joints of the hand can be treated with arthrodesis or arthroplasty. Arthrodesis has known risks of infection, pain, and nonunion. Distal interphalangeal arthroplasty has been successful in preserving motion and alleviating pain for distal DIP, PIP, and MCP joints. Unfortunately, complications arise that limit the success of surgery. Silicone implants have been reliable for many years but still present with the risks of infection, implant breakage, stiffness, and pain. Newer implant designs may limit some of these complications, but present with unique problems such as dislocations and loosening. It is not yet clear as to which type of implant provides
the most reliable results, although implant arthroplasty appears to give better function than arthrodesis. Silicone arthroplasty does not lead to silicone synovitis and is a reliable procedure. Pyrocarbon implants are showing some promise, particularly in the osteoarthritic patient.

Ikeda et al (2010) examined the usefulness of a custom-made splint for treatment of painful osteoarthritis of the DIP joints. The splint was designed to be easily detachable so as not to diminish finger pad sensation or interfere with PIP joint motion. These researchers enrolled 25 patients (24 women and 1 man, mean age of 58 years) with painful osteoarthritis of the DIP joints of the fingers and thumbs in this cohort study. Nineteen patients had multiple affected digits in one or both hands. Splints were applied to protect and immobilize the DIP joints. These investigators assessed the outcome of this treatment using the VAS pain score and the Quick Disabilities of the Arm, Shoulder, and Hand score for subjective assessment of symptoms. The mean follow-up period after wearing the splint until assessment was 6 months. Subjects were assessed 6 months after they started wearing the splint. Pain decreased from 100 % at pre-treatment to 34 % at final follow-up. So, the average improvement ratio was 66 %. The Quick Disabilities of the Arm, Shoulder, and Hand disability/symptom score changes were not statistically significant (28 points pre-treatment and 17 points at final follow-up). The authors concluded that this splint reduced pain from DIP osteoarthritis according to the VAS; however, this does not enable the patient to obtain completely satisfactory function of the upper extremities.

Dickson and colleagues (2014) performed a systematic review of all studies on DIP joint arthrodesis published within the English literature to provide a comparison of the different techniques. The published studies were predominantly of Level IV evidence. The most commonly employed techniques were Kirschner wire, headless compression screw and cerclage wires. There was no difference in infection rates. Headless compression screws appeared to have increased union rates but are associated with complications not seen with other well-established and cheaper techniques. The screw diameter is often similar to or larger than the joint itself, which can result in penetration. Furthermore, they limit the available angle for achieving fusion. Other than in terms of union, there is insufficient evidence to show the headless compression screw is superior to other techniques.

**Carpometacarpal (CMC) Joint/Trapeziometacarpal (TMC) Joint:**

Bozentka (2010) noted that resection arthroplasty with or without ligament reconstruction for thumb trapeziometacarpal (TMC) arthritis can be complicated by thumb shortening and pinch-strength weakness. Implant arthroplasties have been developed to limit loss of thumb length, improve strength, and limit post-operative convalescence. The ideal thumb carpometacarpal (CMC) implant should be strong and stable, provide full ROM, and prevent loosening. Unfortunately, no current prosthesis accomplishes all of these goals. The author concluded that until the ideal implant is developed, clinical acumen must be used to determine appropriate patients and implants.

Vermeulen et al (2011) provided an updated systematic review on the 8 most commonly used surgical procedures to treat TMC osteoarthritis. A thorough literature search was performed using pre-determined criteria. A total of 35 articles fulfilled the inclusion criteria; 9 of these 35 articles were not included in previous systematic reviews. Systematic evaluation demonstrated the following: (i) There is no evidence that trapeziectomy or trapeziectomy with tendon interposition is superior to any of the other techniques. However, when interposition is performed, autologous tissue interposition seems to be preferable; (ii) Trapeziectomy with ligament reconstruction or trapeziectomy with ligament reconstruction and tendon interposition (LRTI) is not superior to any of the other techniques. However, follow-up in the studies with a higher level of evidence was relatively short (12 months); therefore, long-term benefits could not be assessed. In addition, trapeziectomy with LRTI seems associated with a higher complication rate; (iii) Because the studies on thumb CMC arthrodesis were of less methodological quality and had inconsistent outcomes, we are not able to conclude whether CMC arthrodesis is superior to any other technique. Therefore, high-level randomized trials comparing CMC arthrodesis with other procedures are needed. Nevertheless, findings in the newly included studies did show that nonunion rates in the literature are on average 8 % to 21 % and, complications and repeat surgeries are more frequent following CMC arthrodesis; and (iv) A study on joint replacement showed that total joint prosthesis might have better short-term results compared to trapeziectomy with LRTI. However, high-level randomized trials comparing total joint prosthesis with other procedures are needed. In addition, there is no evidence that the Artelon spacer is superior to trapeziectomy with LRTI. The authors concluded that, at this time, no surgical procedure is proven to be superior to another. However, based on good results of CMC arthrodesis and total joint prostheses, these researchers postulated that there could be differences between the various surgical procedures. Therefore randomized clinical trials of CMC arthrodesis and total joint prostheses compared to trapeziectomy with long follow-up (greater than 1 year) are needed.

Jager et al (2013) noted that trapeziectomy has been the basis of basal thumb arthritis surgical treatment since the 1950s. This resection arthroplasty has been continuously refined (soft-tissue interposition, ligament reconstruction, spacer implantation, etc.) without leading to a dramatic outcome improvement. Pain decrease is often satisfying in the long-term, but comfort during the early post-operative period may vary. Those disadvantages of trapeziectomy led to the emergence of total TMC prostheses in the 1970s, with a constant improvement of implant design. Few series have compared those 2 surgical techniques side-by-side, and prospective ones are even rarer. These investigators compared
total TMC prosthesis and trapeziectomy-interposition in the very short-term in 2 similar groups of female patients, to
determine whether prosthesis led to faster recovery or not. These researchers compared a total TMC prosthesis (MAIA)
and trapeziectomy-interposition in the immediate and short-term (6 months), for objective, subjective, functional criteria,
as well as short-term comfort or discomfort. They prospectively followed 2 comparable cohorts of 47 and 27 female
patients above 50 years of age, treated for basal joint arthritis with a constrained TMC joint prosthesis or trapeziectomy-
interposition, respectively. The patients were followed post-operatively for 6 months. Mobility, pain reduction,
satisfaction, strength and functional scores were better in the prosthesis group. The pinch strength improved by 30 %,
the length of the thumb column was maintained, and better correction of the subluxation was obtained in this group.

There were 6 cases of De Quervain's tenosynovitis and 1 case of loosening due to trauma. The authors concluded that
in the short-term, the MAIA TMC prosthesis gave better outcome than trapeziectomy with interposition. Moreover, they
stated that this has to be confirmed in the long-term and after revision surgery that will be likely to occur.

Hentz (2014) stated that the TMC joint's unique anatomy and biomechanics render it susceptible to degeneration. For 60
years, treatment of the painful joint has been surgical when non-operative modalities have failed. Dozens of different
operations have been proposed, including total or subtotal resection of the trapezium or resection and implant
arthroplasty. Proponents initially reported high levels of patient satisfaction, but longer-term reports sometimes failed to
support initial good results. To-date, no one procedure has been shown to be superior to another. The author identified
factors responsible for the development of many different procedures to treat the same pathology and factors influencing
whether procedures remained in the armamentarium or were abandoned. A non-systematic historical review of English-
language surgical journals using the key words "carpometacarpal arthritis", or "trapeziometacarpal arthritis", and
"surgery" in combination with "history" using the PubMed database was carried out. In addition, bibliographies of
pertinent articles were reviewed. The factors that led to many surgical innovations appeared to be primarily theoretical
concerns about the shortcomings of previously described procedures, especially about proximal migration of the thumb
metacarpal after trapezial resection. Longevity of a particular procedure seems to be related to simplicity of design,
especially for prosthetic arthroplasty. The evolution of surgery for TMC joint arthritis both paralleled and diverged from
that in other joints. For example, for most degenerated joints (even many in the hand), treatment evolved from resection
arthroplasty to implant arthroplasty. In contrast, for the TMC joint, the 60-yearold procedure of trapezial resection
continues to be performed by a majority of surgeons; many modifications of that procedure have been offered, but none
have shown better pain reduction or increased function over the original procedure. In parallel, many differently designed
prosthetic total or hemi-joint arthroplasties have been proposed and performed, again with as yet unconvinced evidence
that this technology improved results over those obtained by simple resection arthroplasty. The author concluded that
many procedures have been described to treat TMC joint arthritis, from simple trapezial resection to complex soft tissue
arthroplasty to prosthetic arthroplasty. In the absence of evidence for the superiority of any one procedure, surgeons
should consider using established procedures rather than adopting novel ones, though novel procedures can and should
be tested in properly designed clinical trials.

In a Cochrane review, Wajon and colleagues (2015) examined the effects of different surgical techniques for TMC
(thumb) osteoarthritis. These investigators searched the following sources up to August 8, 2013: CENTRAL (The
Cochrane Library 2013, Issue 8), MEDLINE (1966 to August 2013), EMBASE (1972 to August 2013), CINAHL (1982 to
August 2013), Clinicaltrials.gov (to August 2013) and World Health Organization (WHO) Clinical Trials Portal (to August
2013). Randomized controlled trials (RCTs) or quasi-RCTs where the intervention was surgery for people with thumb
osteoarthritis were selected for analysis. Outcomes were pain, physical function, quality of life, patient global
assessment, adverse events, treatment failure or TMC joint imaging. These researchers excluded trials that compared
non-surgical interventions with surgery. They used standard methodological procedures expected by the Cochrane
Collaboration. Two review authors independently screened and included studies according to the inclusion criteria,
assessed the risk of bias and extracted data, including adverse events. The authors included 11 studies with 670
participants; 7 surgical procedures were identified: (i) trapeziectomy with LRTI, (ii) trapeziectomy, (iii) trapeziectomy with
ligament reconstruction, (iv) trapeziectomy with interpositional arthroplasty (IA), (v) Artelon joint resurfacing, (vi)
arthrodesis and (vii) Swanson joint replacement. Most included studies had an unclear risk of most biases which raised
doubt about the results. No procedure demonstrated any superiority over another in terms of pain, physical function,
quality of life, patient global assessment, adverse events, treatment failure (re-operation) or TMC joint imaging. One
study demonstrated a difference in adverse events (mild-moderate swelling) between Artelon joint replacement and
trapeziectomy with tendon interposition. However, the quality of evidence was very low due to a high risk of bias and
imprecision of results. Low quality evidence suggested trapeziectomy with LRTI may not provide additional benefits or
result in more adverse events over trapeziectomy alone. Mean pain (3 studies, 162 participants) was 26 mm on a 0 to
100 mm VAS (0 is no pain) for trapeziectomy alone, trapeziectomy with LRTI reduced pain by a mean of 2.8 mm (95 %
confidence interval [Cl]: -9.8 to 4.2) or an absolute reduction of 3 % (-10 % to 4 %). Mean physical function (3 studies,
211 participants) was 31.1 points on a 0 to 100 point scale (0 is best physical function, or no disability) with
trapeziectomy alone, trapeziectomy with LRTI resulted in slightly lower function scores (standardized mean difference
0.1, 95 % Cl: -0.30 to 0.32), an equivalent to a worsening of 0.2 points (95 % CI: -5.8 to 6.1) on a 0 to 100 point scale
(absolute decrease in function 0.03 % (-0.83 % to 0.88 %)). Low quality evidence from 4 studies (328 participants)
indicated that the mean number of adverse events was 10 per 100 participants for trapeziectomy alone, and 19 events per 100 participants for trapeziectomy with LRTI (risk ratio [RR] 1.89, 95 % CI: 0.96 to 3.73) or an absolute risk increase of 9 % (95 % CI: 0 % to 28 %). Low quality evidence from 1 study (42 participants) indicated that the mean scaphometacarpal distance was 2.3 mm for the trapeziectomy alone group, trapeziectomy with LRTI resulted in a mean of 0.1 mm less distance (95 % CI: -0.81 to 0.61). None of the included trials reported global assessment, quality of life, and revision or re-operation rates. Low-quality evidence from 2 small studies (51 participants) indicated that trapeziectomy with LRTI may not improve function or slow joint degeneration, or produce additional adverse events over trapeziectomy and ligament reconstruction. These investigators were uncertain of the benefits or harms of other surgical techniques due to the mostly low quality evidence from single studies and the low reporting rates of key outcomes. There was insufficient evidence to assess if trapeziectomy with LRTI had additional benefit over arthrodesis or trapeziectomy with IA. There was also insufficient evidence to assess if trapeziectomy with IA had any additional benefit over the Artelon joint implant, the Swanson joint replacement or trapeziectomy alone. The authors did not find any studies that compared any other combination of the other techniques mentioned above or any other techniques including a sham procedure. They did not identify any studies that compared surgery to sham surgery; they excluded studies that compared surgery to non-operative treatments. The authors were unable to demonstrate that any technique confers a benefit over another technique in terms of pain and physical function. Furthermore, the included studies were not of high enough quality to provide conclusive evidence that the compared techniques provided equivalent outcomes.

Huang et al (2015) stated that thumb CMC joint total arthroplasty has been undertaken for many years. The proponents believed the short-term outcomes are better than trapeziectomy and its variants, but the longer term complications are often higher. This systematic review of all peer-reviewed articles on thumb CMC joint arthroplasty for osteoarthritis showed that there are reports of many implants. Some are no longer available. The reported outcomes are very variable: for some there are good long-term outcomes to beyond 10 years; for others there are unacceptably high early rates of failure. Overall, the published evidence does not show that total arthroplasty is better than trapeziectomy and its variants yet there is a higher complication rate and significant extra cost of using an implant. The authors concluded that future research needs to compare total arthroplasty with trapeziectomy to assess short-term results where the arthroplasties may be better, as well as the long-term outcomes and the healthcare and personal costs so that surgeons and patients can make fully informed choices about the treatment of symptomatic thumb CMC joint osteoarthritis.

Papalia et al (2015) performed an online search using Medline, Cochrane and Google scholar online databases, searching for studies on small joints replacement in hand surgery. Good functional and clinical outcomes can be achieved with silicone and pyrolytic carbon implants, either for TMC and MCP joints. In particular, the silicone spacer seems to be very effective for TMC osteoarthritis, while the pyrolytic carbon total joint prosthesis produces excellent outcomes if used for MCP replacement. Major complications, such as persistent pain and implant loosening, have still a variable rate of occurrence. Heterogeneity in the methodology of the assessments in the studies reviewed and the implants and techniques involved made it difficult to carry out a complete and effective comparative analysis of the data collected. Larger cohorts treated with the same implant should be investigated in better designed trials, to draw more clinically relevant conclusions from the evidences presented. Better methodology is also a goal to achieve, since the average Coleman Methodology Score measured for the articles included was 54.9 out of 100. The authors concluded that more and better designed studies are needed to produce clear guidelines to define the better implant in terms of clinical outcomes, function and complications for TMC and MCP joints.

Semere and associates (2015) stated that the Roseland hydroxyapatite-coated (HAC) prosthesis is a total TMC joint prosthesis used for the surgical treatment of thumb basal joint arthritis. In a retrospective study, these researchers evaluated the long-term outcomes of the Roseland HAC prosthesis. A total of 51 patients (64 thumbs) underwent TMC joint replacement with this prosthesis. The mean follow-up was 12.5 years. Survival rate of the prosthesis was 91 %. There was either no pain or only occasional pain in 91 % of cases. The mean QuickDASH score was 27.6. Abnormal radiographic findings were present in 70 % of cases. Since they were often asymptomatic, no further treatment was carried out. Complications were common (25 %) and occurred early on but could often be treated without surgery. The authors concluded that the long-term results with the Roseland HAC prosthesis were satisfactory in terms of pain relief and function. However, the high complication rate was a major concern.

In a retrospective study, Zschock-Holle et al (2015) evaluated the clinical and radiological results after treatment of the first CMC joint by trapeziectomy resection and implantation of a Swanson silicone prosthesis. The results of 100 trapeziometatarsal resections in 72 patients with subsequent joint replacement by a Swanson silicone prosthesis have been followed-up over 8.6 years on average. Besides the ROM, the strength in grip, tip pinch and key pinch were measured. The quality of pain was determined using a VAS from 1 to 10. The post-operative subjective satisfaction of patients was recorded as well as the DASH, Mayo, modified Wrist and Krimmer scores. In follow-up X-ray controls, subluxations of the silicone implants as well as bony abnormalities were evaluated. The post-operative ROM of the TMC joint in radial abduction was measured with 52° and at palmar abduction with 39°. The average grip strength amounted to 16.5 kg. This represented 80 % of the value of the contralateral side. In tip pinch the force value was 3.3 kg, corresponding to 70 % of that of the opposite side and in key pinch, it was 3.5 kg, corresponding to 71 % of the healthy contralateral side. The
DASH score was recorded with 22.5 points. Post-operative pain symptoms on the VAS were recorded at 2.4 points. The majority of the patients were satisfied or very satisfied after the surgical treatment. In X-ray controls, subluxations of the silicone implants could be detected in 54 cases (61.4%) as well as bony abnormalities in 41 cases (46.6%). However, there was no correlation between the radiological findings and patient satisfaction. The authors concluded that trapezium resection and joint replacement with a silicone prosthesis achieved good results. However, the high number of radiographic subluxations of the prosthesis and bone abnormalities as a cause of foreign body reactions limited these results. These investigators noted that despite the good clinical findings, this method will not be used any more in their patient population.

Thillemann and colleagues (2016) retrospectively evaluated a consecutive series of 42 Motec thumb CMC total joint arthroplasties. The primary end-point was revision with implant removal and trapeziectomy. At follow-up the DASH score, pain on numerical rating scale at rest and with activity and serum chrome and cobalt concentrations were assessed for both unrevised and revised patients. At a mean follow-up of 26 months, 17 patients had been revised. The 2-year cumulative revision rate was 42 % (95 % CI: 28 to 60 %). The DASH score and pain scores at rest and with activity were comparable between the patients whose thumbs remained unrevised and those revised. Patients with elevated serum chrome and cobalt levels had significantly higher DASH and pain scores, but elevated levels were not associated with revision. The authors concluded that the revision rate in this study was unacceptably high. However, pain and DASH scores after revision were acceptable and comparable with patients with non-revised implants.

Mattila and Waris (2016) noted that the bioabsorbable poly-L-D-lactide joint scaffold arthroplasty is a recent attempt in the reconstruction of small joints in rheumatoid patients. These researchers analyzed the 1-year clinical, functional and radiologic results of partial trapeziectomy with the poly-L-D-lactide (96/4) joint scaffold in 23 patients with isolated TMC osteoarthritis. The results showed that the procedure provided pain relief and improvement in overall function according to the QuickDASH score in most patients. However, radiographs demonstrated a high frequency of osteolysis around the implant; 7 patients developed clinically manifested foreign-body reactions 6 months to 1 year after surgery. The reason for the unexpected tissue reactions may relate to excessive mechanical cyclic loading of the implant. The authors concluded that the outcomes of this implant in their patients have not been sufficiently beneficial and they have discontinued use of this implant in isolated TMC osteoarthritis.

Van Aaken et al (2016) stated that the PI2 spacer is designed for treatment of TMC osteoarthritis. However, the shape of this implant has raised concerns about its stability. These investigators retrospectively investigated 45 implants in 41 patients (treated for TMC osteoarthritis between 2004 and 2009) who underwent trapeziectomy and insertion of a PI2 spacer. Outcome parameters included revision rates and clinical outcomes correlated with implant position and scapho-metacarpal distance, assessed using standard radiographs. A total of 12 implants (27 %) were removed at a median time of 10 months (interquartile range (IQR), 7 to 22). These included 5 dislocations, 1 early infection, 6 patients underwent revision due to persistent pain, and 3 of these had scapho-trapezoid osteoarthritis, 2 had developed subluxation of the implant, and 1 did not show any radiographic abnormalities. A review of patient records revealed that 33 implants remained in place at a median time of 29 months (IQR, 20 to 57). However, of those, only 21 implants (64 %) in 17 patients were available for clinical evaluation at a median follow-up of 29 months (IQR, 19 to 62). No significant differences in clinical outcomes including functional results were observed between in-place (n = 8) and subluxated (n = 13) implants. The authors concluded that due to the high revision rate (12/45), consistent with other reports in the literature, they have abandoned the use of the PI2 spacer.; and have recommended the establishment of a registry for evaluation of future implants.

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**CPT Codes / HCPCS Codes / ICD-10 Codes**

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "*". Epiphora due to excess lacrimation:

**ICD-10 codes will become effective as of October 1, 2015:**

**CPT codes covered if selection criteria are met:**

- 26531 Arthroplasty, metacarpophalangeal joint; with prosthetic implant
- 26536 Arthroplasty, interphalangeal joint; with prosthetic implant [covered for proximal interphalangeal (PIP) joint (see criteria) [not covered for distal interphalangeal (DIP)]

**HCPCS codes covered if selection criteria are met:**

- L8630 Metacarpophalangeal joint implant
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8631</td>
<td>Metacarpal phalangeal joint replacement, two or more pieces, metal (e.g. stainless steel or cobalt chrome), ceramic-like material (e.g. pyrocarbon), for surgical implantation (all sizes, including entire system)</td>
</tr>
<tr>
<td>L8658</td>
<td>Interphalangeal joint spacer, silicone or equal</td>
</tr>
<tr>
<td>L8659</td>
<td>Interphalangeal finger joint replacement, 2 or more pieces, metal (e.g. stainless steel or cobalt chrome), ceramic-like (pyrocarbon) for surgical implantation, any size</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9743</td>
<td>Injection/implantation of bulking or spacer material (any type) with or without image guidance (not to be used if a more specific code applies)</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met [covered for metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint, not distal interphalangeal joint (DIP)]:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M05.00 - M08.99</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>M12.541 - M12.549</td>
<td>Traumatic arthropathy, hand</td>
</tr>
<tr>
<td>M15.1 - M15.2, M18.0</td>
<td>Osteoarthritis and allied disorders, hand</td>
</tr>
<tr>
<td>M32.0 - M32.9</td>
<td>Systemic lupus erythematosus</td>
</tr>
</tbody>
</table>

**Resurfacing Arthroplasty of the proximal interphalangeal (PIP) joint:**

**ICD-10 codes not covered for indications listed in the CPB (not all inclusive):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M05.6 - M08.99</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>M15.1 - M15.2, M18.0</td>
<td>Osteoarthritis and allied disorders, hand</td>
</tr>
</tbody>
</table>

**Carpometacarpal (CMC) joint/trapeziometacarpal (TMC) joint implants:**

**HCPCS codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1776</td>
<td>Joint device (implantable) [carpometacarpal (CMC) joint/trapeziometacarpal (TMC)]</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
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</tr>
<tr>
<td>M15.1 - M15.2, M18.0</td>
<td>Osteoarthritis and allied disorders, hand</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


25. Escott BG, Ronald K, Judd MG, Bogoch ER. NeuFlex and Swanson metacarpophalangeal implants for...


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: Distal Interphalangeal (DIP), Metacarpophalangeal (MCP) and Proximal Interphalangeal (PIP) Joint Implants

There are no amendments for Medicaid.