

Healthcare Operations Utilization Management Protocol Metacarpophalangeal and Proximal Interphalangeal Joint Implant

Number
SUR045

HEALTH PLAN OF NEVADA, INC.™ SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.®

For Sierra Health-Care Options products, please review plan documents prior to issuing a determination.

Description	After evaluating relevant benefit document language (exclusions or limitations), refer to Coverage sections of this document to determine coverage.
This policy describes the use of metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants for treating patients with symptomatic joint disease related to conditions such as arthritis.	

Coverage	All reviewers must first identify member eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this policy.
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Commercial, Medicare & Medicaid Coverage Rationale

- Metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants with silicone are **medically necessary** for total joint replacement in patients with pain or functional impairment.
- Metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants (pyrocarbon, stainless steel or cobalt chrome) are **not medically necessary** for total joint replacement in patients with pain or functional impairment. There is insufficient evidence to conclude that MCP or PIP joint implants are safe and effective for total joint replacement in patients with pain, limited motion, or inadequate joint alignment secondary to articular destruction or degenerative disease of the hand. Conclusions regarding the optimal clinical role of MCP and PIP implants for treating arthritis-related joint dysfunction await the performance and completion of large, prospective, well-designed clinical trials and defined patient selection criteria.
- The Ascension PIP joint implant is **not medically necessary**.

Medicare & Medicaid Coverage Rationale

For Medicare and Medicaid Service Determinations Related to States Outside of Nevada:

Please review Local Coverage Determinations that apply to other states outside of Nevada.

<http://www.cms.hhs.gov/mcd/search>

Regulatory Requirements

U.S. Food and Drug Administration (FDA): Ascension Orthopedics Inc. received FDA approval for its Ascension metacarpophalangeal (MCP) finger-joint prosthesis on November 19, 2001. This device is indicated for use as a total joint replacement of index, long, ring, and small finger metacarpophalangeal (MCP) joints that exhibit symptoms of pain, limited motion, or inadequate bony alignment, such as subluxation/dislocation, secondary to articular destruction or degenerative disease of the hand related to rheumatoid arthritis, lupus erythematosus, osteoarthritis, or posttraumatic 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 postoperative data on each Ascension MCP device implanted in a minimum of 100 patients at 4 sites. Additional information may be obtained directly from the U.S. Food and Drug Administration (FDA) [Website] - Center for Devices and Radiological Health (CDRH) at: <http://www.fda.gov/cdrh/pdf/p000057.html>. Accessed February 2, 2009.

Ascension has also received FDA approval for PyroSphere and PyroHemiSphere implants for carpometacarpal basal thumb joint replacement. Additional information may be obtained directly from the U.S. Food and Drug Administration (FDA) [Website] - Center for Devices and Radiological Health (CDRH) at: <http://www.fda.gov/cdrh/pdf6/K060560.pdf>. Accessed February 3, 2009.

Further information is also available at: <http://www.fda.gov/cdrh/pdf4/k041451.pdf>. Accessed February 2, 2009.

On March 22, 2002, a Humanitarian Device Exemption (HDE) was granted for the Ascension proximal interphalangeal (PIP) joint implant. This device is indicated 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. Additional information may be obtained directly from the U.S. Food and Drug Administration (FDA) [Website] - Center for Devices and Radiological Health (CDRH) at: <http://www.fda.gov/cdrh/pdf/h010005b.pdf>. Accessed February 2, 2009.

Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis received an HDE on August 28, 2001. This device is indicated for use in arthroplasty of the MCP joint when either the patient is in need of a revision of failed MCP 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-arthritic and post traumatic MCP joint. Additional information may be obtained directly from the U.S Food and Drug Administration (FDA) [Website] - Center for Devices and Radiological Health (CDRH) at: <http://www.fda.gov/cdrh/ode/H010001sum.html>. Accessed February 2, 2009.

Research Evidence

Background

There is insufficient evidence to conclude that the Ascension PIP joint implant is a durable alternative for metacarpophalangeal and proximal interphalangeal joint implant due to small sample size and lack of long term follow-up studies. It is approved by the U.S. Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE) 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.

Metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants are intended for use as a surgical treatment option for patients with symptomatic joint disease related to rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis where soft tissue reconstruction can provide adequate stabilization (Hayes, 2002).

Historically, the Swanson silicone-elastomer interpositional spaces have been the most commonly used implant. However, the rates of mechanical failure for this implant have been high. In an effort to improve the long-term outcomes of finger joint arthroplasty, implants, including the Ascension MCP and PIP prostheses which are made of pyrocarbon, have been developed (Hayes, 2002).

Research

There are a limited number of published, peer-reviewed clinical trials evaluating the outcomes of patients receiving metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants.

Pyrocarbon

Cook et al. evaluated the Ascension pyrocarbon MCP implant in a retrospective case series (Cook, 1999). The study included 53 patients (151 implants) who were followed for an average of 11.7 years (range 10.1 to 16 years). However, long-term data were only available for 26 (49%) patients. Patients with dislocated joints with shortening of greater than 1 cm or with advanced cortical bone loss were excluded from the study population. Outcome measures included dislocations, subluxation and reductions based on radiographic examination, range of motion, survival analysis, and complications. Actuarial analysis indicates that the 16-year survival rate of the implant was 70%, with an average annual failure rate of 2.1%. There was no evidence of implant material within the joint tissues, and none of the revised implants showed visible wear or deformity of the surfaces or stems. These results suggest that the Ascension MCP implant may be biologically compatible and wear-resistant; however, the durability of the MCP arthroplasty with this device cannot be adequately evaluated, given the small sample size, retrospective design, and extremely high drop-out rate in this study.

Nunez and Citron evaluated the use of the Ascension pyrolytic carbon implant in 7 patients (10 MCP joints) (Nunez, 2005). At a mean follow-up at 2.2 years, there were no loosening of components or implant failures. Pain scores improved from 68% to 3% after surgery.

A study by Stutz et al. retrospectively evaluated 13 patients who received pyrocarbon PIP joint

replacements (Stutz, 2005). One year after surgery, there was improved range of motion of the PIP joint from 0-28-51 preoperatively to 0-22-77 postoperatively. Pain relief at rest and in motion was also improved.

Schulz et al. reviewed the results of 20 patients who received pyrolytic carbon PIP joint prostheses (Schulz, 2005). Follow-up after 0.5 to 2.5 years indicated that patients were satisfied with pain relief. Average range of motion was 50 degrees. In 3 patients, the joint implant had to be converted to an arthrodesis. The authors concluded that improvement of implant design and long-term results are necessary.

In a retrospective review by Bravo et al., 35 patients who received PIP joint replacement were followed for 27 months (Bravo, 2007). A total of 50 PIP joint replacements were conducted. The review included replacement in the index (15), middle (18), ring (10), and small (7) fingers. Results showed an improvement of 7 degrees in the arc motion (40 degrees compared to 47 degrees postoperatively), and the pinch and grip measurements averaged 4 and 25 kg compared to 3 and 19 kg, preoperatively. Pain scores improved as well from a score of 6 preoperatively to a score of 1 postoperatively using a visual analog scale. 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. The revision arthroplasty rate was 8%. Radiographic subsidence and subsequent settling (in accordance with Wolff's law) without apparent loosening occurred in 20 joints. The authors concluded that use of pyrolytic carbon implant arthroplasty showed improved pain relief and good overall patient satisfaction. However, 28% 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. Despite these results, the authors conceded that a longer follow-up period will help to better determine the efficacy of this implant.

Silicone

In a study by Goldfarb and Stern, 36 patients (52 hands) with rheumatoid arthritis who underwent simultaneous silicone metacarpophalangeal joint arthroplasties of all four fingers by one surgeon were evaluated (Goldfarb, 2003). Patients were evaluated at an average of fourteen years postoperatively. Active metacarpophalangeal joint motion, ulnar drift, and radiographs were assessed for changes in bone length, erosions, and implant fractures. Changes in mean arc of motion, mean extension deficit, and mean ulnar drift all showed a decrease from initial improvement at time of follow-up. Implant fracture was noted in 130 implants as well as 45 deformed implants noted at final follow-up. The authors concluded that silicone metacarpophalangeal joint arthroplasty in patients with rheumatoid arthritis worsens with long-term follow-up. Given these findings, the indications for and long-term expectations of silicone metacarpophalangeal arthroplasty must be carefully examined in light of the improvements in the medical management of rheumatoid disease.

In a study by Rettig et al., 14 patients (15 arthroplasties) who had silicone MCP joint implant arthroplasty for idiopathic osteoarthritis were followed for an average of 40 months (Rettig, 2005). X-rays, range of motion and strength were recorded pre- and postoperatively. At final follow-up

evaluation, an increase in MCP joint flexion was noted as well as grip and lateral pinch strengths were below age-matched normative data. None of the silicone implants showed signs of subluxation and radiographic radioulnar alignment was maintained. One implant was revised at 35 months secondary to fracture. The authors concluded that silicone implant arthroplasty is a motion-sparing procedure that provides good pain relief and maintenance of function at intermediate follow-up evaluation in patients with idiopathic osteoarthritis of the MCP joint. Small sample size and longer follow-up to assess stability of the implant are limitations of this study.

Several studies have compared survival and fracture rates for silicone implants. In a prospective, randomized study by Moller et al., the Swanson and Avanta implants were compared in 30 patients with rheumatoid arthritis (Moller, 2005). Patients were followed for 2 years. Fracture occurred in 12 Avanta and 8 Swanson implants, with a higher fracture frequency in men. Parkkila et al. compared the Swanson and Sutter implants in a prospective series of 53 patients with rheumatoid arthritis (Parkkila, 2006). The Swanson group was made up of 25 hands and 89 implants, while the Sutter group was made up of 33 hands and 126 implants. Patients were followed for 58 months. The fracture rate was 34% (26) in the Swanson group and 26% (25) for the Sutter group. Comparison of the Swanson and Neuflex joint replacements were assessed in a prospective double blind trial by Delaney et al. (Delaney, 2005). There were 37 joints (10 patients) in the Swanson group and 40 joints (12 patients) in the Neuflex group. X-ray examination showed no evidence of implant failure. Chung et al. conducted a prospective study of 16 patients with rheumatoid arthritis to determine outcomes with the Swanson Metacarpophalangeal Joint Arthroplasty (Chung, 2004). Patients were followed for 1 year. Functional assessments by grip strength, pinch strength, and Jebsen-Taylor test did not show improvement when compared to preoperative results; however, improvement was noted in functions of activities of daily living, aesthetics, and patient satisfaction. While patient reported outcomes were favorable, the authors concluded that continued follow-up to determine if the improvements are maintained in the long term.

Stainless Steel or Cobalt Chrome

No studies that provide substantial evidence regarding the use of stainless steel or cobalt chrome for treating patients with symptomatic joint disease related to conditions such as arthritis with metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint implants were identified.

Conclusions regarding the optimal clinical role of MCP and PIP implants for treating arthritis-related joint dysfunction await the performance and completion of large, prospective, well-designed clinical trials, which include direct comparisons with other joint prostheses, and subgroup analyses for defining patient selection criteria.

References and Resources

Resources

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History/Update Approval

02/19/2009	Medical Technology Assessment Committee
07/24/2009	Corporate Medical Affairs Committee

Coding

The Current Procedural Terminology (CPT) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document.

CPT Codes

26531	Arthroplasty, metacarpophalangeal joint; with prosthetic implant, each joint
26536	Arthroplasty, interphalangeal joint; with prosthetic implant, each joint

HCPCS Codes

L8630	Metacarpophalangeal joint implant
L8631	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, includes entire system)
L8658	Interphalangeal joint spacer, silicone or equal, each
L8659	Interphalangeal finger joint replacement, 2 or more pieces, metal (e.g., stainless steel or cobalt chrome), ceramic-like material (e.g., pyrocarbon) for surgical implantation, any size

ICD-9 Procedure Codes

81.71	Arthroplasty of metacarpophalangeal and interphalangeal joint with implant
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