Clinical Policy Title: Hammer toe surgery

Clinical Policy Number: 18.03.04

Effective Date: July 1, 2016
Initial Review Date: July 15, 2016
Most Recent Review Date: June 22, 2017
Next Review Date: June 2018

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of hammer toe arthrodesis of the proximal interphalangeal (PIP) joint with Kirschner-wire (K-wire) fixation to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Disease is symptomatic or impairs function, and is refractory to conservative medical therapy.
  - Conservative medical therapy may include, but is not limited to, the following:
    - Wider, lower-heeled shoes.
    - Bunion pads.
    - Over-the-counter analgesics and nonsteroidal anti-inflammatory medications (NSAIDS).
    - Debridement.
    - Padding.
    - Anti-inflammatory injections.
    - Steroid injections.
Foot orthoses.

Limitations:

AmeriHealth Caritas Pennsylvania considers hammer toe surgery using intramedullary device options to be investigational and not medically necessary.

AmeriHealth Caritas Pennsylvania considers hammer toe surgery for the sole purpose of improving appearance of the foot to be not medically necessary.

All other uses of hammer toe surgery are not medically necessary.

Alternative covered services:

- Primary medical care evaluation and management of hammer toe.
- Podiatric medical care evaluation and management of hammer toe.

Background

Hammertoe deformity is the most common deformity of the lesser toes. It primarily comprises flexion deformity of the PIP joint of the second toe, with hyperextension of the metatarsophalangeal (MTP) joint.

Etiologies of hammertoe deformity include a foot in which the second toe is longer than the first, MTP synovitis and instability, inflammatory arthropathies, neuromuscular conditions, and ill-fitting shoe-wear. Rheumatoid arthritis causes hammertoe deformity by progressive MTP joint destruction, leading to MTP joint subluxation and dislocation.

With all of these etiologies, the extensor digitorum longus (EDL) tendon gradually loses mechanical advantage at the PIP joint, as does the flexor digitorum longus (FDL) tendon at the MTP joint. The intrinsic muscles fire and sublux dorsally, as the MTP hyperextends. They now extend the MTP joint and flex the PIP joint, as opposed to their usual function of flexing the MTP joint and extending the PIP joint.

Traditionally, K-wire fixation of the PIP joint has served as the standard operative procedure to correct hammertoe deformity. However, K-wire fixation for PIP joint fusion carries a 20 percent incidence of malalignment, traumatic break, or infection — a troubling rate of complication for a common operation. In the eyes of some practitioners, the PIP joint arthroplasty with a digital implant is a more satisfactory alternative, and represents the new standard of care in treatment of medically refractive hammertoe. These new advances for the purpose of PIP fusion include implants such as Flexible Digital Implant®, Futura Lesser Metatarsophalangeal Joint Implant®, IPP-on®, Nitinol®, Pro Toe®, Smart Toe®, Stay Fuse®, TenFUSE® PIP, and the Weil-Carver® devices.
Searches

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on May 4, 2017. Search terms were: "hammertoe" (MeSH), "PIP joint and K-wire," (MeSH) and "intramedullary devices."

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Guelfi (2015) in a narrative review published notes that PIP joint arthrodesis with K-wire fixation still represents the standard treatment for rigid and structured hammertoes. The authors note that 93 percent to 100 percent of patients who undergo the procedure report good or excellent postoperative satisfaction (as measured by the American Orthopedic Foot and Ankle Society [AOFAS] symptom score). Radiological arthrodesis is achieved in 60.5 percent to 100 percent of cases, again reflecting the relatively high incidence of malalignment and nonunion typical of the procedure. Major complications requiring a secondary surgical revision are acceptable, averaging between 0 percent and 8.6 percent. The complications of K-wire used in arthrodesis of the PIP joint (e.g., malunion, nonunion) are similar to those of arthroplasty with an implantable device. Also, the reoperation rate is close to equal (maximal difference 2 percent).

In a retrospective study, (n= 86) Scholl (2013) reported no significant difference in number of revisions utilizing K-wire with the buried technique (9 percent against 10.7 percent P = 0.754) versus a Smart Toe implant. Both K-wire and the Smart Toe implant placed in a prepared PIP joint did not violate other digital or metatarsal joints and were not exposed percutaneously. There were 58 Smart Toe implants and 28 buried K-wires in the series. No statistically significant difference was found between the rate of malunion, nonunion, fracture of internal fixation, or the need for surgical revision. The authors concluded that both the Smart Toe implant and the buried K-wire offer a viable choice for internal fixation of an arthrodesis of the digit.
Ellington (2010) and Coillard (2014) point out the type of complications reported for the new implantable devices and K-wire treatment are similar, except for the superficial infections associated with non-buried K-wire technique. Taking into consideration the major complications (i.e., reoperation) of the new devices compared to K-wire, no differences were found.

Bussewitz (2014) notes that K-wires have been demonstrated as not being inferior to digital implants, and argues that the significant cost of digital implants can only be justified by the demonstration of significantly superior outcome when compared to K-wires. Furthermore, almost all K-wire associated complications can be addressed simply by removal of the wire. Removal of failed digital implant arthrodesis is frequently complex, may entail a good deal of bone destruction, and leaves the patient with foot swelling and associated local symptoms for a variable period of time.

Fazal (2013) reported the results of PIP joint fusion carried out with a StayFuse intramedullary fusion device in 150 toes in 140 consecutive patients. The rate of postoperative radiologic fusion was 73 percent. There were implant-related complications in eight toes. Ninety-five percent of the patients were satisfied with the procedure, and 3.3 percent of the patients needed revision surgery.

Angirasa (2012) attempted to determine the effectiveness of the SmartToe intramedullary shape memory implant compared with K-wire arthrodesis for hammertoe. In a retrospective analysis of 28 cases, the authors evaluated several important parameters at baseline, postoperative at days seven, 14, 21, 28, and 56, and at six months, including pain, complications, arthrodesis achieved, and return-to-work status. There was no evidence of significant difference in rate of complications, and the authors stated a preference for the implantable device. This study was funded with a research grant by MMI-USA, now part of Stryker Foot and Ankle, the makers of the SureToe device.

Zelen (2013) found fusion of the PIP joint offers good long-term correction and predictability for correction of hammertoe. Digital implants currently being used take advantage of the latest metallurgic and polymeric innovations (with implants being composed of Nitinol, polylactic or polyglycolic acids, and polydioxanone) and offer easy insertion and good stability, with no percutaneous wires. Pin-tract infection rates from exposed K-wires may be as high as 18 percent, and newer implants help to mitigate this problem.

Roukis (2009) performed a retrospective study involving 10 patients (30 toes) with diabetes, dense peripheral neuropathy, and rigid structural toe contracture treated with a one-piece shape-memory nickel-titanium (Nitinol) intramedullary internal fixation device for arthrodesis of the PIP joint. Successful fusion was achieved in 28 of 30 toes (93 percent), with a stable nonunion achieved in the remainder.

Complications consisted of secondary contracture of the distal interphalangeal (IP) joint (23 percent), displaced fixation (13 percent) and malunion (7 percent). No patient developed ulceration, and no additional surgery was performed. Based on this small cohort, the authors declared the use of this
implant for arthrodesis of the PIP joint in neuropathic patients with diabetes appears to be safe and reliable.

Coughlin (2000) notes that the K-wire technique has traditionally been the most utilized method for performing PIP fusion as it is fast, cheap, and simple to implant. On the other hand, the K-wire fixation method predisposes patients to infections, a lack of compression and rotational control and, finally, discomfort at removal. The intramedullary devices aim to solve the weak points of the K-wire technique and seem to achieve slightly better outcomes than those of K-wire, especially regarding patient satisfaction and malalignment of the arthrodesis.

The new intramedullary devices seem to provide good clinical results; however, the cost of manufacture and their advanced materials of construction have a higher price compared to the K-wire. Currently, a paucity of medical evidence exists in the literature to justify the use of almost all of these new devices. Coillard (2014) reported a 20 times higher price of these devices compared to the use of K-wire for PIP fixation. More cost-benefit studies are necessary to understand whether the benefits of hammertoe implants can justify the use of these devices as the standard treatment of the future.

The American College of Foot and Ankle Surgeons (ACFAS 2004) has published the following statement on cosmetic foot surgery:

“Surgery performed solely for the purpose of improving the appearance or size of the foot or ankle carries risks without medical benefit, and therefore should not be undertaken.”

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Guelfi (2015)</td>
<td><strong>Key points:</strong></td>
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</tbody>
</table>
| Arthrodesis of proximal inter-phalangeal joint for hammertoe: intramedullary device options | - PIP joint arthrodesis represents the standard treatment for hammertoe.  
  - 93% – 100% of patients report good or excellent satisfaction.  
  - Radiological arthrodesis is achieved in 60.5% – 100% of cases.  
  - Major complications requiring surgical revision number between 0% and 8.6%.  
  - The use of newer devices provides good results; however, their high price is a drawback.  
  - Cost-benefit studies are necessary to justify routine use of intramedullary devices as standard treatment. |
<p>| Coillard (2014) | <strong>Key points:</strong>                   |
| Stabilization of proximal | - PIP joint implantation was carried out in 117 patients and 156 toes in a prospective |</p>
<table>
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| interphalangeal joint in lesser toe deformities with an angulated intramedullary implant | study.  
- The proportion of joints fused on postprocedure X-rays was 83.8% (95% CI: 77.8, 89.7) after one year.  
- Postoperatively, 98% of patients reported “satisfaction” with the operative outcome.  
- Complication rates reported for new devices and K-wire are similar.  
- With regard to reoperation, no differences were found between newer devices and K-wire (i.e., revision was required in one case). |
| Bussewitz (2014) | Key points:  
- K-wires are not inferior to digital implants.  
- High cost of digital implants can only be justified by the demonstration of significantly superior outcome.  
- K-wire associated complications can be addressed simply by removal of the wire.  
- Removal of failed digital implant arthrodesis is complex, causes bone destruction, and results in permanent swelling and local symptoms. |
| Fazal (2013) | StayFuse for proximal interphalangeal joint fusion  
Key points:  
- PIP joint fusions of the lesser toes with a StayFuse implant were conducted in 150 toes in 140 consecutive patients.  
- The mean age of patients was 69.5 years, and the mean follow-up was 18 months.  
- Of the PIP joints, postoperative radiologic fusion was 73%.  
- The mean preoperative AOFAS score improved from 22.9 to 81.6 at follow-up.  
- There were implant-related complications in eight toes.  
- Ninety-five percent of the patients were satisfied with the procedure and 3.3% of the patients needed revision surgery. |
Key points:  
- Compared SmartToe implant to K-wire. In a retrospective analysis of 28 patients.  
- Authors evaluated postoperative days seven, 14, 21, 28, and 56, and six months for pain, complications, arthrodesis achieved and return-to-work status.  
- There was no evidence of significant complications.  
- This study was funded with a research grant by MMI-USA (Stryker Foot and Ankle). |
Key points:  
- Retrospective study (n= 86) reported no significant difference in number of revisions utilizing K-wire with the buried technique (8.6% against 10.7% P = 0.754) versus a SmartToe implant.  
- There were 58 SmartToe implants and 28 buried K- wires in the series.  
- No statistically significant difference was found between the rate of malunion, nonunion, fracture of internal fixation, and the need for revision surgery.  
- Authors concluded that SmartToe and buried K-wire are both viable choices for hammertoe. |
| Zelen (2013) | Digital arthrodesis  
Key points:  
- Study found PIP joint fusion offers good long-term correction and predictability for correction of hammertoe. |
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<td>Roukis (2009)</td>
<td>Key points:</td>
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<td>A one-piece shape-metal Nitinol intramedullary internal fixation device for arthrodesis of the proximal interphalangeal joint in neuropathic patients with diabetes</td>
<td>• Retrospective study of 10 patients (30 toes) with diabetes, dense peripheral neuropathy, and rigid structural toe contracture. • All were treated with a Nitinol implant of the PIP joint. • Fusion was achieved in 28 of 30 toes (93%). • Complications included contracture of the distal interphalangeal joint (23%), displaced fixation (13%), and malunion (7%). • No patient developed ulceration and no additional surgery was performed. • Authors declared Nitinol implant in neuropathic patients with diabetes to be safe and reliable.</td>
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<td>Key points:</td>
<td>• K-wire technique has traditionally been the preferred method of PIP fusion. • It is fast, cheap, and simple to implant. • K-wire fixation method predisposes to infection, is less stable structurally, and causes discomfort at removal. • Intramedullary devices seem to achieve slightly better outcomes than those of K-wire (i.e., patient satisfaction and malalignment).</td>
</tr>
<tr>
<td>Coughlin (2000)</td>
<td>Key points:</td>
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<tr>
<td>Operative repair of the fixed hammertoe deformity</td>
<td>• Types of complications reported for the intramedullary devices and K-wire are similar and save superficial infections. • Taking into consideration the major complications (i.e., reoperation) of the new devices compared to K-wire, no differences were found.</td>
</tr>
<tr>
<td>Ellington (2010)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Radiographic analysis of proximal interphalangeal joint arthrodesis with an intramedullary fusion device for lesser toe deformities</td>
<td>• ACFAS statement on cosmetic foot surgery: o “Surgery performed solely for the purpose of improving the appearance or size of the foot or ankle carries risks without medical benefit, and therefore should not be undertaken.”</td>
</tr>
<tr>
<td>American College of Foot and Ankle Surgeons. (ACFAS, 2004)</td>
<td>Key points:</td>
</tr>
<tr>
<td>ACFAS Position Statement — Cosmetic Surgery</td>
<td></td>
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</tbody>
</table>
Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCD):**
No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>28285</td>
<td>Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy)</td>
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<tr>
<td>26860</td>
<td>Arthrodesis, interphalangeal joint, with or without internal fixation</td>
<td></td>
</tr>
<tr>
<td>26861</td>
<td>Each additional interphalangeal joint (list separately in addition to 26860)</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>M20.30</td>
<td>Hallux varus (acquired), unspecified foot</td>
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<tr>
<td>M20.31</td>
<td>Hallux varus (acquired), right foot</td>
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<tr>
<td>M20.32</td>
<td>Hallux varus (acquired), left foot</td>
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<tr>
<td>M20.40</td>
<td>Other hammer toe(s), (acquired) unspecified foot</td>
<td></td>
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<tr>
<td>M20.41</td>
<td>Other hammer toe(s), (acquired) right foot</td>
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<tr>
<td>M20.42</td>
<td>Other hammer toe(s), (acquired) left foot</td>
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<tr>
<th>HCPCS Level II Code</th>
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<tr>
<td>L8658</td>
<td>Hallux implant</td>
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