Hammertoe Repair

Policy

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

Aetna considers surgical repair of hammertoe deformity (also called claw toe, mallet toe) in skeletally mature individuals (i.e., after epiphyseal closure) or individuals who are 18 years of age or older medically necessary when the following criteria are met:

I. Radiographic confirmation of hammer toe deformity; and
II. Documentation of skeletal maturity; and
III. Documentation of persistent pain and difficulty walking following at least 3 months of conservative treatment under the direction of a healthcare professional which includes, but may not be limited to:

A. Corticosteroid injections
B. Debridement of associated hyperkeratotic lesions (corns, calluses)
C. Foot orthotics (shoe inserts, footgear modifications, corrective splinting) (may be contractually excluded)
D. Oral analgesics and/or nonsteroidal anti-inflammatory drugs (NSAIDs)
E. Orthotics (shoes with a wide and deep toe box) (may be contractually excluded)
F. Protective padding; and
G. Taping or adhesive devices; and

IV. Member has 1 or more of the following indications for hammertoe repair:

A. Adventitious bursitis on the dorsal surface of the hammertoe; or
B. Ankylosis of the distal interphalangeal (DIP) joint or proximal interphalangeal (PIP) joint; or
C. Inter-digital neuroma caused by the deformity; or
D. Lateral metatarsophalangeal (MTP) capsular tear caused by the deformity; or
E. Painful nail conditions secondary to persistent trauma; or
F. Presence of co-existing or causative conditions (e.g., tendon contracture) that need repair; or
G. Subluxation or dislocation of the MTP joint; or
H. Synovitis/capsulitis of the MTP joint; or
I. Ulceration of the apices.

Aetna considers repeat hammer toe surgical treatment medically necessary following failure of a previous surgical procedure.

*Radiographic confirmation must include interpretation and report of anterior/posterior and lateral views of the affected foot.

Aetna considers hammertoe repair experimental and investigational when criteria are not met.

Aetna considers fixation implants (e.g., the Acumed Hammertoe Fusion Set, the BME Hammerlock Implant, the CannuLink Intramedullary Fusion Device, the CrossTie Intramedullary Fixation System, the Futura Flexible Digital Implant, the Futura LMP Lesser Phalangeal Joint Implant, the HammerFix IP Fusion System, the Integra Hammertoe Implant, the OsteoMed Interflex IPG System, the Pro-Toe Hammertoe Implant, the Smart Toe, the StayFuse Fusion Device, the ToeGrip Device, the Two-Step Hammer Toe Implant, the Weil-Carder Hammertoe Implant, and the Wright Cann Phalinx System) experimental and investigational for hammertoe repair because of a lack of evidence of effectiveness and safety in the peer-reviewed published medical literature.
Background

Deformities of the lesser (two through five) toes are generally known as hammer toe, claw toe and mallet toe. Hammer toe refers to an abnormal flexion posture at the proximal interphalangeal (PIP) joint of one or more of the lesser four toes. The most commonly affected toe is the second, although multiple toes can be involved. If the flexion contracture is severe and of long duration, associated hyperextension of the metatarsophalangeal (MTP) joint and extension of the distal interphalangeal (DIP) joint may occur. Hammer toes are classified as either flexible (passively correctable) or rigid (not passively correctable to the neutral position). In claw toe, there is dorsiflexion of the proximal phalanx on the MTP joint and plantar flexion of the PIP and DIP joints. Mallet toes demonstrate a flexion contracture of the DIP joint only. As all of these are similar in their etiology and treatment, this policy pertains to all three deformities.

Hammer toes, claw toes and mallet toes are a very common lesser toe (toes 2 through 5) deformity that often is painful, and limits function and shoe wear selection. A hammertoe is a deformity in which the proximal inter-phalangeal joint (IPJ) is flexed. A claw toe is a deformity of the toe in which the meta-tarsophalangeal (MTP) joint is pulled up or extended. The proximal and distal joints (IPJs) are flexed, producing a toe that resembles a claw. A mallet toe is a lesser toe deformity in which the distal IPJ is flexed. Claw toes may be flexible (easily straightened) or rigid, with stiff joints or tight tendons preventing correction. A claw toe deformity can cause increased pressure or friction on the tip of the toe and over the top of the proximal and distal IP joints, due to rubbing against the shoe toe box. When the toe cocks up, the metatarsal bone is pushed downward, resulting in increased pressure under the ball of the foot (metatarsalgia). This increased pressure can result in a thick, painful callus underneath the ball (MTP joint) of that toe. In severe cases of claw toe deformity, shoe wear selection obviously can be severely limited.

Although claw toes, hammertoes, and mallet toes are technically different, they behave and look similarly, and will be discussed as one problem. They may be caused by trauma (stubbing the toe and producing a fracture or tear of the tendons
that straighten or extend the toe). More commonly, the deformity occurs slowly or chronically. Neuromuscular diseases such as cerebral palsy, polio, Charcot Marie Tooth disease, stroke, closed-head injury; or nerve injury or other rare, neuromuscular problems can cause imbalance between the extensor tendons that straighten the toe and the flexor tendons that bend the toes. This tendon imbalance can result in a progressive claw toe deformity. Inflammatory conditions such as rheumatoid arthritis, gout, systemic lupus, exanthematous disease, and Reiter's disease may cause synovitis of the joints, and result in stretching or laxity of joint ligaments which allows the deformity to develop. People with a high-arch (cavus) type foot may be prone to develop claw toes.

People with hammertoe may have corns or calluses on the top of the proximal joint of the toe or on the tip of the toe. They may also feel pain in their toes or feet and have difficulty finding comfortable shoes. Treatment is initially directed at relieving the pressure points. Unless arthritis develops, the condition is not painful. Pain occurs when pressure focuses on certain areas of the toe. Relieving the pressure will not cure the problem but will lessen the symptoms. Various pads and strappings are commercially available to reduce the deformity and relieve pressure over painful corns. If the deformity is not of long duration and an extension deformity at the MTP joint is not also present, daily manipulations and taping the toe so that the MTP is not extended occasionally can correct the flexion deformity at the proximal interphalangeal joint. A shoe with a wide, high toe box, soft upper shoe, and stiff sole to absorb dorsally directed forces against the plantar plate is appropriate. A metatarsal bar can be added to the shoe to avoid metatarsal pressure, but patients more easily accept metatarsal pads. Cushioning sleeves or stocking caps with silicon linings can relieve pressure points at the proximal IP joint and tip of the toe. A longitudinal pad beneath the toe can prevent point pressure at the tip of the toes.

Initially, hammertoes are flexible and can be corrected with simple measures but, if left untreated, they can become fixed and require surgery. The actual procedure will depend on the type and extent of the deformity. In the otherwise healthy patient with a digital deformity, selection of an appropriate procedure(s) is based upon the joint(s) involved, the associated flexibility of the contracture(s), and the related abnormalities that exist. Because the MTP joint is always dorsiflexed by definition, some correction of its position is necessary to restore a more neutral angle at the MTP joint. This consists of Z lengthening of the extensor tendon, dorsal MTP
capsulotomy, and collateral ligament release. If deviation is present in the frontal or coronal plane in addition to claw toe, the loose collateral ligament side can be imbricated instead of released.

Many different procedures have been described in the literature for the correction of hammertoe deformity. Surgical procedures utilized for the correction of hammer toe include, but may not be limited to, amputation for severe deformity, arthrodesis, arthroplasty, flexor to extensor tendon transfer, partial or total phalangectomy or tenotomy. Kirschner wires may be used as fixation devices for arthrodesis and arthroplasty. Regardless of the technique used, there are goals that need to be achieved through surgery:

- Delay rapidity of progression and severity
- Diminish discomfort
- Prevent complications such as atrophic ulcerations over osseous prominences in the individual with sensory deficit
- Provide greater stability
- Restore and/or maintain ambulatory ability.

Fixation Implants

Implants have been developed to stabilize the PIP joint, purportedly to promote fusion. Such implants are not universally accepted and are exceedingly difficult to remove should the surgery fail. Their removal could lead to substantial bone loss, making subsequent revision procedures challenging.

Pietrzak et al (2006) stated that the surgical correction of hammer toe deformity of the lesser toes is one of the most commonly performed forefoot procedures. In general, percutaneous Kirschner wires are used to provide fixation to the resected proximal inter-phalangeal joint. Although these wires are effective, issues such as pin tract infections as well as difficult post-operative management by patients make alternative fixation methods desirable. This study biomechanically compared a threaded/barbed bioabsorbable fixation implant made of a copolymer of 82 % poly-L-lactic acid and 18 % polyglycolic acid with a 1.57-mm Kirschner wire using the devices to fix 2 synthetic bone blocks together. Constructs were evaluated by applying a cantilever load, which simulated a plantar force on the middle phalanx. In all cases, the failure mode was bending of the implant, with no devices fracturing. The stiffness (approximately 6 to 9 N/mm) and peak load (approximately
8 to 9 N) of the constructs using the 2 systems were equivalent. Accelerated aging at elevated temperature (47 degrees C) in a buffer solution showed that there was no reduction in mechanical properties of the bioabsorbable system after the equivalent of nearly 6 weeks in a simulated in-vivo (37 degrees C) environment. These results suggested that the bioabsorbable implant would be a suitable fixation device for the hammer toe procedure. These findings need to be validated by additional research.

Witt and Hyer (2012) noted that hammertoes are common deformities that are often surgically treated using arthrodesis or arthroplasty of the proximal inter-phalangeal joint with percutaneous, temporary Kirschner wire fixation. However, percutaneous Kirschner wire fixation is associated with potential complications, including wire migration, breakage, and pin tract infection. Furthermore, the complications of pseudoarthrosis and nonunion are seen using this technique owing to a lack of rotational control of the Kirschner wire. Another drawback of this implant is the need for wire removal and the associated patient anxiety with this in-office procedure. In a case-series study (3 patients and a total of 7 toes), these researchers described an alternative method of hammertoe fixation using a permanently implanted, 1-piece intramedullary device used to stabilize the proximal inter-phalangeal interface. The potential advantages of this prosthesis include elimination of wire migration and breakage, enhanced control and stability of the digit, elimination of potential pin tract infection, and decreased patient anxiety since hardware removal is not required. The patients were followed-up for approximately 1 year after the surgery, and no intra-operative or post-operative complications were observed. The implant maintained proper clinical and radiographic alignment throughout the observation period, without implant failure or breakage. All patients were satisfied with the cosmetic appearance of their surgically corrected toes and were able to perform all activities of daily living without the use of assistive devices. Also, their post-operative pain and function were acceptable. The authors concluded that the implant used in the patients described in the present report appears to be a viable alternative for the treatment of hammertoe. These preliminary findings need to be validated by well-designed studies.

Scott et al (2013) noted that hammertoe digital deformity correction is a very controversial topic among foot and ankle surgeons. Current treatment options are often guided by the patient's discomfort as well as the reducibility of the affected digit. Kirschner wires (K-wires) have long been considered the gold standard for hammertoe digital repair. Although K-wires are simplistic to use as fixation, they
carry inherit risks such as pin tract infections, migration, and breakage. This has led to multiple intramedullary hammertoe devices including the PROTOE intramedullary device.

In a case-series study, Catena et al (2014) prospectively evaluated clinical and radiographic outcomes of hammertoe operative correction utilizing an internal implant (intramedullary implant) and assessed its ability to maintain post-operative alignment. A total of 29 patients (53 toes) with a painful rigid hammertoe deformity were prospectively enrolled and operatively treated with resection arthroplasty of the PIP joint and fixation with an implant. Five patients were lost to follow-up, and 24 patients (42 toes) returned at an average of 12 months for final clinical and radiographic evaluation. All patients were evaluated pre- and post-operatively by American Orthopaedic Foot and Ankle Society (AOFAS) and visual analog pain scale (VAS) scores. On physical examination, the location and magnitude of the deformity, callosities, and digit circumference were recorded. Radiological parameters evaluated were digital alignment, successful union, implant position, and bone reaction. All patients reported satisfaction at final follow-up, with an average improvement of AOFAS score from 52 (range of 24 to 87 points) to 71 (range of 42 to 95 points) points. The mean VAS pain score improved from 5 points (range of 2 to 10) pre-operatively to 1 point (range of 0 to 5) post-operatively. Of patients, 87% reported an ability to return to their pre-operative activities without limitations. Regarding digital alignment, there were no recurrent deformities or transverse plane deformities; 1 toe presented with a minor digital rotational deformity at final follow-up. Post-operative radiographs indicated 100% of proximal inter-phalangeal (PIP) joints with good alignment, and 81% demonstrated bony union. The authors concluded that this study suggested that utilization of an internal implant for hammertoe correction was safe and provided acceptable alignment, pain reduction, and improved function at final follow-up. This case-series study provided level IV evidence; its findings need to be validated by well-designed studies.

Basile et al (2015) stated that hammertoe is one of the most common foot deformities. Arthrodesis or arthroplasty of the proximal interphalangeal joint using temporary Kirschner wire fixation is the most widespread method of surgical stabilization. However, this type of fixation is associated with some potential complications that can be obviated if percutaneous fixation is avoided. These researchers prospectively collected clinical and radiographic outcomes of operative correction of hammertoe deformity using a permanently implanted 1-piece
intramedullary device. A total of 29 patients with 60 painful, rigid hammertoes were prospectively enrolled, clinically and radiographically examined, operatively treated, then followed and re-examined. The outcomes were measured in terms of the AOFAS lesser toe and VAS. After greater than or equal to 18 months of follow-up, the incidence of fusion with satisfactory radiographic alignment was 85 % (51 of 60 toes). One toe (1.67 %) developed early post-operative implant failure because of dislocation of the device, there were no cases of infection, and the mean AOFAS lesser toe score was 87.4 ± 1.3 and the mean VAS was 1.78 ± 0.94. Twenty-five patients (86.21 %) stated that they had no symptoms in the involved toes after surgery, and 4 (13.8 %) experienced occasional pain, 2 (6.9 %) of whom reported limitations of recreational activities and 2 (6.9 %) reported persistent swelling without activity limitations. The authors noted that all the patients stated that they would undergo the surgery again if they had the same pre-operative condition. Well-designed studies with larger sample size and longer follow-up are needed to validate these findings.

Obrador and associates (2018) analyzed functional outcomes in patients who had undergone PIP joint fusion using 2 types of intramedullary implant, the Smart Toe and the TenFuse, and compared them with the outcomes in patients treated with standard K-wire fixation. A retrospective review of operative hammertoe correction by a single surgeon was performed in 96 patients followed for more than 12 months. Functional outcome was assessed using the Foot Function Index (FFI), the Short Form 36 (SF-36), and the 10-point VAS validated questionnaires. Complications and fusion rates were also evaluated. Several patients in the study underwent corrections in different toes; thus, a total of 186 toes were included in the study. From these, 65 toes (34.9 %) were treated with K-wire fixation, 94 (50.5 %) with Smart Toe titanium implant, and 27 (14.5 %) with TenFuse allograft implant. No statistically significant differences in functional outcome and incidence of complications were observed among the 3 fixation groups, although the 2 intramedullary implants were associated with greater fusion rates and patient satisfaction. Breakage of the Smart Toe implant was significantly higher than that of the other fixations, with 10.6 % of implants breaking within the 1st year post-operatively; SF-36 and VAS scores decreased 12 months after surgery for the 3 types of fixation, with no statistically significant differences observed. The authors concluded that the use of Smart Toe and TenFuse implants provided operative outcomes comparable to those obtained using a K-wire fixation and slightly better patient satisfaction. They stated that these findings suggested that utilization of these implants for hammertoe correction was a reasonable choice that provided
good alignment, pain reduction, and improved function at final follow-up. However, they are more expensive than K-wires. These investigators stated that for this reason, in-depth cost-benefit studies are needed to justify their use as a standard treatment.

Albright and colleagues (2018) stated that hammertoe deformities are one of the most common foot deformities, affecting up to 1/3 of the general population. Fusion of the joint can be achieved with various devices, with the current focus on percutaneous K-wire fixation or commercial intramedullary implant devices. These investigators examined if surgical intervention with percutaneous K-wire fixation versus commercial intramedullary implant is more cost effective for PIP joint arthrodesis in hammertoe surgery. A formal cost-effectiveness analysis using a decision analytic tree model was conducted to investigate the healthcare costs and outcomes associated with either K-wire or commercial intramedullary implant fixation. The outcomes assessed included long-term costs, quality-adjusted life-years (QALYs), and incremental cost per QALY gained. Costs were evaluated from the healthcare system perspective and were expressed in U.S. dollars at a 2017 price base. These researchers found that commercial implants were minimally more effective than K-wires but carried significantly higher costs. The total cost for treatment with percutaneous K-wire fixation was $5,041 with an effectiveness of 0.82 QALY compared with a commercial implant cost of $6,059 with an effectiveness of 0.83 QALY. The incremental cost-effectiveness ratio of commercial implants was $146,667. With an incremental cost-effectiveness ratio of greater than $50,000, commercial implants failed to justify their proposed benefits to out-weigh their cost compared to percutaneous K-wire fixation. The authors concluded that percutaneous K-wire fixation would be preferred for arthrodesis of the PIP joint for hammertoes from a healthcare system perspective.

**CannuLink Intramedullary Fusion Device**

In a retrospective, comparative study, Richman and colleagues (2017) compared the outcomes of hammertoe correction performed with K-wire fixation versus a novel intramedullary fusion device (CannuLink). A retrospective review of hammertoe correction by a single surgeon was performed from June 2011 to December 2013. A total of 60 patients (95 toes) underwent K-wire fixation and 39 patients (54 toes) underwent fusion with the CannuLink implant. Average age was 61.7 years and 61.4 years, respectively. Average length of follow-up was 12.9 and 12.3 months, respectively. Patients were evaluated for medical co-morbidities,
smoking status, inflammatory arthritis, peripheral vascular disease, peripheral neuropathy, pre- and post-operative VAS, bony union percentage, revision rate, complications (hardware and surgery-related), and persistent symptoms at last follow-up. There was no significant difference in demographics or co-morbidities between the 2 groups (p > 0.05). In the K-wire group, 16 patients (18 toes) remained symptomatic at last follow-up (27 %); 9 toes (9.5 %) had recurrent deformity, 3 toes (3 %) developed a late infection because of the recurrent deformity, and 1 toe (1 %) developed partial numbness; 1 patient suffered a calf deep vein thrombosis (DVT) and peroneal nerve neuritis, 1 patient developed foot-drop, and 3 patients continued to complain of pain; 5 toes required revision surgery (5.3 %). In the intramedullary group, 3 (7.7 %) patients remained symptomatic and all were associated with a complication; 1 patient developed chronic regional pain syndrome (CRPS) in the foot, a calf DVT, and a nonfatal pulmonary embolus. A 2nd patient developed a painless recurrent deformity. A 3rd patient had wound dehiscence. Nobody had hardware failure or required a 2nd operation. The authors concluded that the CannuLink intramedullary device for hammertoe correction resulted in fewer complications, only 1 recurrent deformity, and no re-operations compared with K-wire fixation. Level of Evidence = III. This was relatively small study (n = 39 for the CannuLink group) and the follow-up was short-term (12.3 months).

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 "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>28285</td>
<td>Correction, hammertoe (e.g., interphalangeal fusion, partial or total phalangectomy)</td>
</tr>
<tr>
<td>28286</td>
<td>Correction, cock-up fifth toe, with plastic skin closure (e.g., Ruiz- Mora type procedure)</td>
</tr>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
<td></td>
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<tr>
<td>CrossTie Intraosseous Fixation System - no specific code:</td>
<td></td>
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<tr>
<td>Other CPT codes related to the CPB:</td>
<td></td>
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<tr>
<td>11044 - 11047</td>
<td>Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed)</td>
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<tr>
<td>Code</td>
<td>Code Description</td>
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<td>-------------------------------------------------------</td>
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<tr>
<td>73620 - 73630</td>
<td>Radiologic examination, foot</td>
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**HCPCS codes not covered for indications listed in the CPB:**

CannuLink intramedullary fusion device - no specific code:

L8641 Metatarsal joint implant

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J0702</td>
<td>Injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg</td>
</tr>
<tr>
<td>J0833</td>
<td>Injection, cosyntropin, not otherwise specified, 0.25 mg</td>
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<tr>
<td>J0834</td>
<td>Injection, cosyntropin (Cortrosyn), 0.25 mg</td>
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<td>J1020</td>
<td>Injection, methylprednisolone acetate, 20 mg</td>
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<td>J1030</td>
<td>Injection, methylprednisolone acetate, 40 mg</td>
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<tr>
<td>J1040</td>
<td>Injection, methylprednisolone acetate, 80 mg</td>
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<td>J1094</td>
<td>Injection, dexamethasone acetate, 1 mg</td>
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<td>J1100</td>
<td>Injection, dexamethasone sodium phosphate, 1 mg</td>
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<tr>
<td>J1700</td>
<td>Injection, hydrocortisone acetate, up to 25 mg</td>
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<td>J1710</td>
<td>Injection, hydrocortisone sodium phosphate, up to 50 mg</td>
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<td>J1720</td>
<td>Injection, hydrocortisone sodium succinate, up to 100 mg</td>
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<tr>
<td>J2650</td>
<td>Injection, prednisolone acetate, up to 1 ml</td>
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<tr>
<td>J2920</td>
<td>Injection, methylprednisolone sodium succinate, up to 40 mg</td>
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<td>Injection, methylprednisolone sodium succinate, up to 125 mg</td>
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<td>J3300</td>
<td>Injection, triamcinolone acetonide, preservative free, 1 mg</td>
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<td>J3301</td>
<td>Injection, triamcinolone acetonide, not otherwise specified, 10 mg</td>
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<td>J3302</td>
<td>Injection, triamcinolone diacetate, per 5 mg</td>
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<td>J3303</td>
<td>Injection, triamcinolone hexacetonide, per 5 mg</td>
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<td>L3000 - L3030</td>
<td>Foot, insert/plate, removable</td>
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**ICD-10 codes covered if selection criteria are met:**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>E64.3</td>
<td>Sequelae of rickets [hammertoe, claw toe, mallet toe]</td>
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<tr>
<td>G57.60 - G57.63</td>
<td>Lesion of plantar nerve [interdigital neuroma]</td>
</tr>
<tr>
<td>L97.501 - L97.529</td>
<td>Non-pressure chronic ulcer of other part of foot [of apices]</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0636 Hammertoe Repair

There are no amendments for Medicaid.