Cigna Medical Coverage Policy

Effective Date ......................... 9/15/2014
Next Review Date ...................... 9/15/2015
Coverage Policy Number ............... 0305

Subject  Hammer Toe Surgery

Table of Contents
Coverage Policy ............................................. 1
General Background .................................... 2
Coding/Billing Information ......................... 4
References .................................................... 5

Hyperlink to Related Coverage Policies
Foot Care Services
Hallux Valgus Surgery (Bunionectomy)
Lower Limb Orthoses and Shoes
Metatarsophalangeal Joint Replacement

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Cigna covers hammer toe surgery as medically necessary when there is a confirmed diagnosis of hammer toe deformity and ANY of the following signs/symptoms directly attributable to the hammer toe deformity:

- difficulty walking
- significant and persistent pain
- ulceration at an area of pressure

and when EITHER of the following criteria is met:

- signs/symptoms that are unresponsive to the use of appropriate foot wear and at least six months of conservative treatment*, including at least TWO of the following:
  - padding
  - oral analgesics or anti-inflammatory medications
  - splinting
- ulceration at an area of pressure that has not responded to four weeks of local wound care

*Benefit plans may exclude coverage for the conservative treatment listed above. Please refer to the applicable plan language to determine benefit coverage.

Cigna does not cover joint replacement implants for hammer toe repair because there is insufficient evidence to demonstrate that this procedure is comparable to other treatment options and is therefore considered experimental, investigational or unproven.
Cigna does not cover hammer toe surgery for the sole purpose of improving appearance of the foot, because it is considered not medically necessary.

**General Background**

Hammer toe is the term often used to denote any toe with a dorsal contracture. While hammer toe is the most common of the lesser toe deformities (i.e., toes 2–5), it is one of several conditions that are included in this group.

A hammer toe deformity, which is a flexion contracture of the proximal interphalangeal joint, may also include an extensor contracture of the metatarsophalangeal joint. The deformity may be either fixed and rigid or flexible in which case it is passively correctable to the neutral position. This is the most common of the lesser toe deformities. Women are most commonly affected, and the incidence increases with age. Generally, this condition is present in one or two toes and not all the toes. The most commonly affected toe is the second toe. The main factors contributing to hammer toe deformity include long-term use of poorly fitting shoes. Crowding of the toes within a tight toe box may be a cause of this deformity. It may be associated with other medical conditions, such as diabetes or connective tissue disorders. A hallux valgus deformity can be a factor in development of hammer toe by placing pressure on the second toe.

A claw toe is an extension contracture of the metatarsophalangeal joint and flexion contracture of the proximal interphalangeal joint, with additional flexion contraction of the distal interphalangeal joint. This condition is frequently caused by neuromuscular diseases and is often present in all toes.

A mallet toe is a single flexion contraction at the distal interphalangeal joint, with pressure being placed on the tip of the toe. This deformity occurs less frequently than a hammer toe deformity.

A fixed hammer toe deformity of the fifth toe can include a cock-up deformity, which includes dorsiflexion of the metatarsophalangeal joint and flexion of the interphalangeal and distal interphalangeal joint.

With all of these conditions, pressure is applied on the dorsal digital surface from shoes and on distal toe surfaces directly. The chief symptom is pain. Painful digital keratoses may develop. An ulcer may also form. Contracted toes can lie over or under other toes, and painful corns can develop between the toes.

**Conservative Treatment**

In all of these conditions, initial treatment is conservative in nature. Initial treatment is often self-directed and may include: wider, lower-heeled shoes; bunion pads; ice; over-the-counter analgesics and nonsteroidal anti-inflammatory medications (NSAIDs). Shoe modifications should be attempted first, including the use of roomy footwear with an adequate toe box and low heel. This measure helps to alleviate pressure on the deformed toe, often resulting in pain relief. Conservative treatment may also include debridement, padding, anti-inflammatory injections, steroid injections, and foot orthoses. In the case of ulceration, local wound care is provided that may include cleansing, debridement, and dressings.

**Surgical Treatment**

Surgery should be considered only when all other treatment has failed. When these measures do not alleviate pain, then surgery may be considered. Cosmesis is not considered a medically necessary indication for surgery. Associated deformities (e.g., hallux valgus) must also be corrected for optimal surgical outcome and to prevent recurrence. The goal of surgery should be to relieve pain. Since lesser toe deformities include an array of deformities, the procedure will depend on the stage of deformity and the severity.

Contraindications to surgical treatment include:

- surgery when there is an active infection of the foot, unless correction of hammer toe deformity is necessary for wound management
- severe vascular insufficiency
The surgical procedure performed is determined by the stage of severity of the deformity, as follows:

- **mild deformity**: no fixed contracture at the metatarsophalangeal or proximal interphalangeal joints
- **moderate deformity**: a fixed flexion contracture at the proximal interphalangeal joint and no extension contracture at the metatarsophalangeal joint
- **severe deformity**: a fixed flexion contracture at the proximal interphalangeal joint, with a fixed extension contracture at the metatarsophalangeal joint (subluxation or dislocation of the proximal phalanx on the metatarsal head may be present in addition to the contractures)

If there is a mild deformity of the proximal interphalangeal joint, then flexor tendon transfer is performed. For a moderate deformity, resection of the head and neck of the proximal phalanx is recommended. An interphalangeal joint arthrodesis may also be performed. For a severe deformity, resection of the head and neck of the proximal phalanx, lengthening of the extensor digitorum longus, tenotomy of extensor digitorum brevis and a dorsal capsulotomy at the metatarsophalangeal joint are performed. A Kirschner wire may be used to stabilize the repair.

**Hammer Toe Surgery with Joint Replacement Implants**

The use of implants in hammer toe surgical procedures have been proposed with the objectives of the implants acting as joint spacers, improving joint stability and to improving cosmetic results (Mednick, et al., 1985). The first implants were adapted from implants used in the hand, but were hinged to allow for range of motion (ROM). Preliminary studies regarding implants took place in the 1980s using silicone implants. Two of the first implants used were the Swanson hinged great toe prosthesis that was specifically designed for lesser toes and the Sgarlato which is a double-stemmed, silastic prosthesis. These implants have also been investigated for use for the pain and deformity caused by rheumatoid or post-traumatic arthritis, degenerative joint disease, Freiberg's disease, dislocated or subluxated second metatarsophalangeal joint alone or association with hallux abducto valgus and previously resected metatarsal head(s) Fox and Pro (1987).

Examples of joint implants that are currently utilized in hammer toe surgery include but are not limited to the following:

- **Flexible Digital Implant (FDI)** (Nexa Orthopedics, Inc., San Diego, CA): this implant is composed of UltraSIL® a medical grade silicone elastomer and is available in various sizes.
- **Futura Lesser Metatarsophalageal Joint Implant** (Nexa Orthopedics, Inc., San Diego, CA): this implant is made of UltraSIL® and is a double-hinged implant available in four sizes. OsteoMed® InterPhlex Toe Implant™ (Osteomed L.P, Addison, TX): this implant is made from medical grade silicone. There are rods that have a bulb to provide stability of the joint space while the stiffness of the rod addresses the concern for toe migration.

Implants have also been proposed for use in hammertoe arthroplasty and arthrodesis procedures. They are proposed to replace the use of kirschner wires, pins or other fixation devices that are standardly used in fusion procedures. They include but are not limited to the following:

- **Weil-Carver™ Hammertoe Implant** (Biomet®, Inc.,Warsaw, Indiana): The implant is composed of amorphous non-crystalline co-polymer, LactoSorb® material. It is partially threaded, partially barbed, completely internal and available in one size.
- **Stayfuse™ Inter-Digital Fusion System** (Nexa Orthopedics, Inc., San Diego, CA): This is a titanium device that is comprised of two part threaded system. It is available in several sizes.
- **Smart Toe implant**, (Memometal Inc, Memphis, TN) was developed to be used in hammertoe arthrodesis in place of other fixation devices. It is available in the original neutral Smart Toe design and an angled version. According to the manufacturer, the Smart Toe implant uses inherent dynamic compression to secure placement and aid fusion by gently compressing the bones to be fused. It is described as a one-piece shape-memory Nitinol intramedullary implant fixation device. It is proposed to produce the desired bone fusion, without having wire exposed externally. The Smart Toe implant is intended for permanent placement in the toe.
- **TenFUSE™ PIP**: a sterile allograft that is partially demineralized to maintain inductive and conductive properties which is proposed to be used for hammer toe arthrodesis procedures. It is available in straight and angled configurations.
U.S. Food and Drug Administration (FDA): The implants used in hammer toe arthrodesis procedures have received 501(k) clearance with the K-wires as predicate devices.

Literature Review: The literature regarding the use of implants in hammertoe surgery consists mainly on case studies with most of the studies involving small number of individuals (Mednick, et al., 1985; Solitto and Werner, 1985; Fox and Pro, 1987; Sgarlato, et al., 1988). The studies include limited follow-up, varied techniques and types of implants, and lack of standardized assessment criteria. Well-designed, randomized, controlled studies comparing the use of these implants with established surgical procedures for hammer toe are lacking.

The medical literature regarding implants used in arthrodesis procedures consist of case studies or small case series (Scholl, et al., 2013; Angirasa, et al, 2012; Ellington, et al., 2010; Roukis, 2009). Well-designed, randomized, controlled studies comparing the use of these implants with established surgical procedures for hammer toe are lacking. There is insufficient evidence in the published medical literature to demonstrate the efficacy of these devices in treatment of hammer toe arthrodesis.

Professional Societies/Organizations
Academy of Ambulatory Foot and Ankle Surgery (AAFAS) published guidelines on hammertoe syndrome (2003/2009). The guidelines include the following non-surgical treatment of hammer toe:

- debridement
- padding
- shoe modifications
- oral anti-inflammatory medication (NSAIDs)
- anti-inflammatory injectables
- orthotics
- orthodigital devices

American College of Foot and Ankle Surgeons (ACFAS) published a statement on cosmetic foot surgery that includes, “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.” (2004).

Use Outside of the US
No relevant information

Summary
Evidence in the published, peer-reviewed, scientific literature, as well as textbooks and review articles indicates that initial treatment is conservative in nature, with surgical treatment medically necessary when signs/symptoms are unresponsive to conservative treatment.

There is insufficient evidence in the published medical literature to demonstrate the efficacy of joint replacement implants for hammer toe deformities. Published trials consist primarily of case series with limited follow-up, varied techniques and types of implants, and lack of standardized assessment criteria.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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)</td>
</tr>
</tbody>
</table>
Experimental/Investigational/Unproven/Not Covered:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8641</td>
<td>Metatarsal joint implant</td>
</tr>
</tbody>
</table>


References


