CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 12/15/2008
Next Review Date……..3/15/2010
Coverage Policy Number 0305

Subject Hammer Toe Surgery

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Hyperlink to Related Coverage Policies

Foot Care Services
Hallux Valgus Surgery
Lower Limb Orthoses
Metatarsophalangeal Joint Replacement of the Hallux

INSTRUCTIONS FOR USE

*Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2008 CIGNA*

Coverage Policy

CIGNA covers hammer toe surgery as medically necessary when BOTH of the following criteria are met:

- confirmed diagnosis of hammer toe deformity with ANY of the following signs/symptoms attributable to the hammer toe deformity:
  - difficulty walking
  - significant and persistent pain
  - ulceration at an area of pressure

- signs/symptoms that are unresponsive to at least six months of conservative treatment*, including ALL of the following:
  - padding
  - oral analgesics or anti-inflammatory medications
  - appropriate footwear
  - splinting

  *CIGNA HealthCare 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.

Lesser Toe Deformities
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.

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 cased 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 Implants that are currently utilized in hammer toe surgery 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 compromised of two part threaded system. It is available in several sizes.
- 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.
- Future Lesser Metatasophalageal Joint Implant (Nexa Orthopedics, Inc., San Diego, CA): this is implant is made of UltraSIL® and is a double-hinged implant available in four sizes.

Literature Review: Sollitto and Werner (1985) reported on a retrospective study of 22 patients (47 toes) that used the silastic hammertoe implant. Follow-up ranged from seven months to three years, with average 15 months. Dislocations were noted in three cases, bony regrowth occurred in five cases and prolonged edema was noted in four patients. Poor purchase power of operative digit was noted in one case. In addition, the authors observed that there was not an appreciable increase in transverse plane stability or active flexion and no increase in flexor purchase power at the involved phalangeal joint.

Mednick et al. (1985) reported on findings of a study of the effectiveness of digital implants in lesser toes. The study included 34 patients with an average age of 49. The study utilized 40 silastic finger joint implant (Swanson design) and 22 silastic hammertoe implants, with choice left to discretion of the surgeon. The average length of follow-up was one year eight months for the finger implant patients and eight months for the hammer toe patients. Radiographs of the implants indicated that there were 30 implants with good seating where the joint space was adequate and symmetrical on both sides of the hinge. Two hinged implants had fair seating with joint

space that was asymmetrical with limited joint ROM. Of the 16 non-hinged evaluated, 14 had good implant seating, one implant with fair seating and limited joint ROM and one had poor seating with large asymmetrical joint spacing and no ROM. Regarding toe position it was noted that 31 digits with hinged implants had normal toe position; two digits were deviated laterally and one contracted at the involved joint that had poor cosmetic results but adequate stability. Of the nonhinged implants it was noted that three of the 21 were laterally deviated and remaining had normal toe position. ROM was subjectively determined to be normal in 22 of 40 hinged implants, limited in 17 and absent in one. In the nonhinged implants, ROM was noted to be normal in 7 of 21 implants evaluated, limited in 13 and absent in one. Prolonged edema was noted to be the major complication. Limited joint motion was associated all 19 of the implants with prolonged edema. Other complications included: three digits has postoperative scar contracture; two implants were removed.

Fox and Pro (1987) reported on 23 procedures where the Sgarlato lesser metatarsophalangeal joint where used. The authors noted that 23 joints were considered successful and seven were considered failures. Complications included removal of toe implant, superficial dehiscence, postoperative swelling and postoperative stress fracture.

Sgarlato et al. (1988) analyzed the results of 920 lesser toe hammer toe correction that were performed with the use of the Sutter Lesser Toe Implant. The implant was used to replace the proximal phalangeal head, which is resected during the arthroplasty procedure. It is noted that contraindications of the implant are: compromised vascular status to the toes, open wound or ulcer, proximal phalangeal shaft that is too small; or when the primary deformity is at the metatarsophalangeal joint. The lesser toe implant has a hinged body and small stems which are rectangular to prevent rotation and is made of medical –grade silicone elastomer with an internal Dacron mesh. The procedures were performed on: 293 implants in fifth toe; 171 implants in fourth toe; 153 implants in third toe; 303 implants in second toe. Seven implants were removed due to infection or irritation. Edema of the toe was reported, with the second toe more likely to become edematous. From this review it appeared that the toe implant acts as a spacer, stabilizing the distal toe to align with the proximal phalanx.

Summary
A hammer toe deformity is a flexion contracture of the proximal interphalangeal joint and may also include an extensor contracture of the metatarsophalangeal joint. The primary symptom is pain. Review of the literature, including textbooks and review articles indicates that initial treatment should be conservative treatment, 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: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
28285	Correction, hammertoe (e.g., Interphalangeal fusion, partial or total phalangectomy)
28286	Correction, cock-up fifth toe, with plastic skin closure (e.g., Ruiz-Mora type procedure)

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis	Description

Codes	
707.15	Ulcer of other part of foot
719.7	Difficulty in walking
729.5	Pain in soft tissues of limb
735.3	Hallux malleus
735.4	Other hammer toe (acquired)
735.5	Claw toe (acquired)
735.8	Other acquired deformity of toe
735.9	Unspecified acquired deformity of toe

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
L8641	Metatarsal joint implant

References

1. Academy of Ambulatory Foot and Ankle Surgery. Hammertoe syndrome. National Guideline Clearinghouse. 2003. Accessed January 23, 2008. Available at URL address: http://www.guideline.gov/summary/summary.aspx?doc_id=4242&nbr=3242&string=hammer+AND+toe

2. American Orthopaedic Foot & Ankle Society (AOFAS). AOFAS position statement on cosmetic foot surgery. Accessed January 23, 2008. Available at URL address: http://www.aofas.org/i4a/pages/index.cfm?pageid=3672

3. Behrman RE, Kleigman RM, Jenson HB, editors. Nelson textbook of pediatrics. 17th ed. Philadelphia, PA: Saunders; 2004. p. 2258-61.

4. Burns S. Common foot problems. Prim Care. 1996 Jun;23(2):281-97.

5. Canale T, editor: Campbell's operative orthopaedics. 10th ed. St. Louis, MO: Mosby, Inc.; 2003. p. 4052-60.

6. Chambers HG. Ankle and foot disorders in skeletally immature athletes. Orthop Clin North Am. 2003 Jul;34(3):445-59.

7. Coughlin MJ. Common causes of pain in the forefoot in adults. J Bone Joint Surg Br. 2000 Aug;82(6):781-90.

8. Coughlin MJ. Lesser-toe abnormalities. J Bone Joint Surg Am. 2002 Aug;84-A(8):1446-69.

9. DeLee JC, Drez D, Miller MD, editors. DeLee and Drez's orthopaedic sports medicine. 2nd ed. Philadelphia, PA: W.B. Saunders; 2003. p. 2552-66.

10. Fox IM, Pro AL .Lesser metatarsophalangeal joint implants. J Foot Surg. 1987 Mar-Apr;26(2):159-63.

11. Freeman DB. Corns and calluses resulting from mechanical hyperkeratosis. Am Fam Physician. 2002 Jun 1;65(11):2277-80.

12. Frontera W, Silver J, editors. Essentials of physical medicine and rehabilitation. 1st ed. Philadelphia, PA: Hanley and Belfus, Inc.; 2002. p. 426-430.

13. Konkel KF, Menger AG, Retzlaff SA. Hammer toe correction using an absorbable intramedullary pin. Foot Ankle Int. 2007 Aug;28(8):916-20.

14. Mednick DL, Nordgaard J, Hallwhich D, Holewski J, Burns AE, Gerbert J. Comparison of total hinged and total nonhinged implants for the lesser digits. J Foot Surg. 1985 May-Jun;24(3):215-8.

15. Noble J, Levinson W. Textbook of primary care medicine. 3rd ed. St. Louis, MO: Mosby, Inc.; 2001. p. 1212-21.

16. Norn SE, Coughlin RR. How to examine a foot and what to do with a bunion. Prim Care. 1996 Jun;23(2):281-97.

17. Pietrzak WS, Lessek TP, Perns SV. A bioabsorbable fixation implant for use in proximal interphalangeal joint (hammer toe) arthrodesis: Biomechanical testing in a synthetic bone substrate. J Foot Ankle Surg. 2006 Sep-Oct;45(5):288-94.

18. Singh D, Angel J, Bentley G, Trevino S. Fortnightly review: Callosities, corns, and calluses. BMJ. 1996;312:1403-6.

19. Sgarlato TE, Carine TA, Andrews MC. Sutter lesser toe implant. J Am Podiatr Med Assoc. 1988 Jul;78(7):335-8.

20. Sollitto RJ, Werner MS. A preliminary report on the status of implants for the lesser toes. J Foot Surg. 1985 Nov-Dec;24(6):453-5.

21. U.S. Food and Drug Administration (FDA). Sgarlato lesser toe implant. 510(k) Premarket Notification. Accessed January 29, 2008. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=PMN&ID=K884739

22. U.S. Food and Drug Administration (FDA). Lesser metatarsal phalangeal joint implant. Nexa Orthopedics, Inc. 510(k) Premarket Notification. Accessed January 29, 2008. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=PMN&ID=K023531

23. Wheeless CR, author; Lightdale N, Field J, Danney C, resident editors. Wheeless' textbook of orthopaedics. 1996. Last updated December 17, 2007. Duke Orthopaedics. Accessed February 6, 2008. Available at URL address: http://www.wheelessonline.com/ortho/hammer_toes

24. Yu GV, Vincent A, Khoury W. Feature: Exploring New Advances In Digital Arthrodesis. Podiatry Today. 2003 Sept; (16) Issue 9, 40-54. Accessed February 6, 2008. Available at URL address: http://www.podiatrytoday.com/article/1902#

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0305	Hammer Toe Surgery