Clinical Policy Title: Bunionectomy (hallux valgus surgery)

Clinical Policy Number: 14.03.10

Effective Date: July 1, 2017
Initial Review Date: May 19, 2017
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Related policies:
None.

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of bunionectomy to be clinically proven, and therefore, medically necessary, if all of the following conditions are met:

- Pain and other symptoms that interfere with normal daily activities.
- Symptoms have persisted for at least six months.
- Conservative (medical and non-medical) attempts to correct symptoms have been unsuccessful.
- X-rays confirm the hallux valgus angle exceeds 15°, the intermetatarsal angle exceeds 9°, and the proximal phalangeal articular angle exceeds 6° (Pique-Vidal, 2009; Thomas, 2009).

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

Any procedure for bunions that are done for cosmetic purposes in which there are no symptoms interfering with normal function of the foot is not considered medically necessary.

**Alternative covered services:**

- Debridement of associated hyperkeratotic lesions.
- Corticosteroid injections into the affected area.

**Background**

A bunion is a bony protrusion at the base of the big toe (hallux) that leans against the first metatarsal bone. It can damage skin, and cause discomfort and pain during normal walking, because the body’s weight pushes against the area of convergence between the toe and metatarsal (NICE, 2010). Bunions can be caused by a variety of factors, including family history, poor foot structure, arthritis, and use of tight shoes. They often commence in early adulthood, and are more common in women.

Bunions are recognizable not just by the presence of the growth, but also if this growth is swollen, red, shiny, warm, and tender. A bursa at the top of the metatarsal bone can be especially painful. A number of cases can be resolved through footwear-related changes, including wearing larger shoes or avoiding uncomfortable shoes such as high heels. Other basic treatments include orthotic padding, rest, and ice. Ongoing and worsening discomfort suggests that medical assistance is needed (Thomas, 2009).

The diagnosis of bunions, along with the presence of symptoms, is made through X-rays. One criterion is the hallux valgus angle between the longitudinal axes of the proximal phalanx and first metatarsal bone of the big toe. A normal hallux valgus angle is below 15°, while mild is 15 to 18°, moderate is 21 to 39°, and severe is over 40°. Another criterion is the intermetatarsal angle, formed between the longitudinal axes of the first and second metatarsal bones. A normal intermetatarsal angle is below 9°, while mild is 9 to 11°, moderate is 12 to 17°, and severe is over 18°. A third criterion is the proximal phalangeal articular angle, formed by a line drawn perpendicular to the phalangeal articular surface and the longitudinal axis of the proximal phalanx. A normal proximal phalangeal articular angle is below 6°, while mild is 6 to 10°, moderate is 11 to 20°, and severe is over 21° (Pique-Vidal, 2009).

Non-surgical treatments include debridement of associated hyperkeratotic lesions, which usually is effective in helping to reduce symptoms. In cases where bursitis or inflammation exists, a corticosteroid injection into the affected area may be helpful. Taping to reduce and splint flexible deformities may be performed, especially in the setting of an early crossover second toe deformity (Thomas, 2009).
Surgery can include a variety of osseous and soft tissue procedures that are often selected by the degree and flexibility of the deformity. Tenotomy, or lengthening of the tendon, may be appropriate, sometimes accompanied by capsular/ligamentous release or by phalangeal head resection/ flexor tendon transfer. Phalangeal head resection and arthrodesis of the joint are relatively common osseous procedures. Other cases require osseous procedures including metatarsal osteotomy, partial metatarsal head resection, and phalangeal base resection (Thomas, 2009).

Soft tissue procedures are often used to complement osseous procedures. They include all of the above-listed procedures for flexible deformities. Partial amputation of the big toe, or total amputation of the adjoining toe, may be considered in some cases, especially if the second toe is affected. Surgical repairs of associated tears of the plantar plate may also be indicated (Thomas, 2009).

Surgical technique involves making small incisions close to the hallux metatarsophalangeal joint, removing the bunion, and dividing the metatarsal. Bone fragments are stabilized using plates, screws, or wires, and the foot can be supported using dressing or plaster in the corrected position (NICE, 2010).

The decision to have surgery, and what intervention to use, for patients with bunions can be a challenging one, as recurrence of hallux valgus is a common complication (Raikin, 2014). Optimizing outcomes in bunion surgery is a function of restoring anatomic alignment, imparting first ray stability, excellence in surgical technique, and accounting for other causes that may contribute to first ray instability (Haas, 2009).

Searches

Prestige Health Choice 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 April 11, 2018. Search terms were: “bunion” and “bunionectomy.”

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

The National Institute of Clinical Excellence (NICE, 2010) and American College of Foot and Ankle Surgeons (Thomas, 2009) have produced guidelines for diagnosing and treating bunions.

Minimally invasive surgery to treat bunions have been developed to reduce rehabilitation time, reduce costs, and increase patient satisfaction. Perhaps the first systematic review of the literature for bunionectomy was published in 2009, a review of the efficacy of the increasingly more common minimally invasive bunion procedures, as opposed to traditional open procedure. However, three studies (n = 184) failed to produce strong evidence for or against minimally invasive bunionectomy, due to methodological limits (Roukis, 2009).

A review of 26 studies with 2197 procedures (1830 of which were minimally invasive) showed clinical outcome scores jumped significantly after hallux valgus procedures. Some studies followed patients for several years after surgery. Complication rates for minimally invasive procedures tended to be higher, but appeared to be related to improper use of the technique. Authors stopped short of recommending systematic use of minimally invasive surgery to correct hallux valgus, until large randomized trials are conducted (Maffulli, 2011). A study of 81 feet compared minimally invasive distal chevron osteotomy with a counterpart for open procedures for mild to moderate hallux valgus; both techniques showed substantial improvement in postoperative clinical scores, with no difference between the two (Brogan, 2016).

Percutaneous hallux valgus surgery, purported to be a major advancement in bunion treatment, was the subject of an analysis of 18 studies (n=1534). Although some investigators revealed no major complications, others described deformity recurrence in 7.8 percent of cases, stiffness of the first metatarsophalangeal joint in 9.8 percent, malunion in 4 - 8.7 percent, and infection rates from 1.9 - 14.3 percent. Complications were elevated even in informed surgeons (Bia, 2018).

A systematic review of four studies (n = 2843 feet) found the average reductions in hallux valgus angle and intermetatarsal angle of 20.1° and 8.1°, respectively (Schuh, 2013). Another review of 29 studies (n=1470 feet) followed patients for an average of 28.5 months. Average reduction in intermetatarsal angle varied by type of arthrodesis procedure for hallux valgus deformity, namely 9.12° for screw fixation, 9.75° for staple fixation, 12.41° for combined locking plate with screw fixation, 14.36° for screw with K-wire fixation, 8.50° for pin fixation, and 8.60° for external fixation (Willegger, 2015).

A systematic review of 15 studies (n=701) of hallux valgus surgery compared reduction of the first intermetatarsal angle after arthrodesis. Subjects with intermetatarsal angle over and under 15° experienced an average reduction of 5.42° and 3.70°, respectively. Thus, the procedure is more efficacious for more severe cases (Dayton, 2014).
Complications were reported for 18.7 percent of feet after hallux valgus surgery, with 12.8, 3.2, and 2.7 percent classified as major, minor, and other. Reductions and complications varied with the type of procedure (Schuh, 2013). Minimally invasive surgery is more likely to yield better outcomes in non-severe (Type I) cases (Waizy, 2012). A review of 21 papers of minimally invasive hallux valgus surgery (n=2195 procedures) warned that many reports presented at meetings are never published in peer-reviewed journals, and many journal articles are not high quality, i.e., Level 4, case series without control groups (Trnka, 2013).

Long-term recurrence of post-operative hallux valgus was addressed in a 2014 study of 100 consecutive patients followed for an average of 7.9 years (range 5.8 to 9.4) following distal chevron osteotomy for hallux valgus. The recurrence rate of hallux valgus deformity at final follow-up was 73 percent; however all recurrences were painless and no additional surgery was required. Authors concluded that preoperative congruence, distal metatarsal articular angle, sesamoid position, hallux valgus angle, and I/II intermetatarsal angle affected recurrence (Pentikainen, 2014).

Concerns over high recurrence rates after surgery in adolescents treated for hallux valgus – any surgery should be postponed until skeletal maturity (Chell, 2014) - prompted a 2015 systematic review. Nine studies (n=201 procedures, median age 14) followed adolescents – 91 percent of whom were female – for a median of 41.6 months. Average American Orthopedic Foot and Ankle Society score, a measure of outcomes, was 85.8; scores from 80 to 100 are considered good to excellent, and 86 percent of patients expressed satisfaction. Statistically significant improvements were reported for the inter-metatarsal angle, hallux valgus angle, and distal metatarsal articular angle (Harb, 2015).

A Cochrane review of 21 systematic reviews, randomized controlled trials, or observational studies concluded that there was not enough evidence to judge the effectiveness and safety of non-surgical methods of treating hallux valgus, night splints, orthoses, and slipper casts (Ferrari, 2009). Another Cochrane review of 11 trials found that custom foot orthoses are effective at relieving foot pain for hallux valgus (n=209), with even greater effectiveness than for other conditions (Hawke, 2008).

The long-term efficacy of hallux valgus surgical procedures remains a concern. A review of 162 feet in 118 patients with an average of 5.2 years post-surgery (4.7 to 6.0) found one-third of the feet were asymptomatic, and 25.9 percent of patients were dissatisfied with the procedure (Chong, 2015).

A meta-analysis of 24 studies showed no significant difference between types of bunion surgeries in levels of post-operative pain (Klugarova, 2017). A meta-analysis of 28 studies reviewed success rates for 5th metatarsal osteotomies for bunionettes (all ages). The overall success rate was 93 percent, and all forms of osteotomy were rates highly successful (Martin, 2018).

Policy updates:

A total of four peer-reviewed references were added to, and one peer-reviewed reference removed from, this policy in April 2018.
Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chong (2015)</strong></td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Results of hallux valgus surgery after 5 years | - Review of 118 patients (162 feet) who underwent surgery for hallux valgus.  
- Patients followed for mean of 5.2 years (4.7 to 6.0).  
- 73.9% of procedures were reported as satisfactory.  
- Only 32.7% of patients were considered completely asymptomatic.  
- 25.9% of patients were dissatisfied with surgery. |
| **Harb (2015)** | **Key points:**                   |
| Review of adolescent hallux valgus after surgery | - Systematic review of 9 studies (n=140, 201 osteotomies), 91% female, mean age 14.5.  
- Patients followed for average 41.6 months.  
- Mean post-operative American Orthopedic Foot and Ankle Society score was 85.8 (80 to 100 = good to excellent).  
- Statistically significant improvement in inter-metatarsal angle, hallux valgus angle, and distal metatarsal articular angle.  
- 86% were satisfied or very satisfied with outcomes. |
| **Willegger (2015)** | **Key points:**                   |
| Complications of first tarsometatarsal joint arthrodesis for hallux valgus deformity | - Systematic review of 29 studies (n=1268, 1470 feet) of patients with hallux valgus who underwent joint arthrodesis.  
- Mean follow up after surgery was 28.5 months.  
- Average correction of the intermetatarsal angle (degrees) was 9.12 for screw fixation, 9.75 for staple fixation, 12.41 for combined locking plate with screw fixation, 14.36 for screw with K-wire fixation, 8.50 for pin fixation, and 8.60 for external fixation.  
- Overall complication rate was 16.05%. |
| **Maffulli (2011)** | **Key points:**                   |
| Safety and efficacy of minimally invasive surgery for hallux valgus correction | - Systematic review of literature.  
- Minimally invasive procedures may provide better outcome for patients who would not recover well from traditional open approaches, due to decreased recovery and rehabilitation times.  
- While preliminary results are encouraging, it is not possible to recommend systematic use of minimally invasive surgery for hallux valgus correction. |

References

Professional society guidelines/other:


Peer-reviewed references:


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

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

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.

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<th>Description</th>
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<td>28292</td>
<td>Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method</td>
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