



# CIGNA MEDICAL COVERAGE POLICY

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## Subject Total Ankle Arthroplasty

### Table of Contents

Coverage Policy .....	1
General Background .....	1
Coding/Billing Information .....	8
References .....	8
Policy History.....	12

### Hyperlink to Related Coverage Policies

- Inpatient Acute Rehabilitation
- Occupational Therapy
- Outpatient Acute Rehabilitation
- Physical Therapy
- Speech/Language Therapy

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## Coverage Policy

**CIGNA does not cover total ankle arthroplasty/replacement for any indication because it is considered experimental, investigational or unproven.**

## General Background

Total ankle arthroplasty (TAA) is the process of replacing a diseased ankle with a prosthetic ankle. The procedure has been proposed as an alternative to ankle arthrodesis for conditions such as severe osteoarthritis (OA), post-traumatic arthritis and rheumatoid arthritis of the ankle. Arthritic ankle joints frequently result in decreased range of motion, swelling, joint stiffness, pain with weight-bearing activity, instability secondary to pain, and, in some cases, visible joint deformity. Conservative management typically consists of medications for pain control, limiting activity, the use of ankle braces to stabilize the joint, shoe modifications, heat, and physical therapy to control the pain associated with ankle arthrosis. When conservative management fails, ankle arthrodesis (i.e., ankle fusion) has been the standard surgical treatment of choice to control the pain of severe ankle arthritis. During an ankle arthrodesis, the joint is fused together, limiting up-and-down movement. While pain may be relieved with ankle arthrodesis, the development of progressive degenerative arthritis in adjacent joints is common. Current techniques for ankle arthrodesis achieve fusion in 80% to 90% of patients (Pickering RM, 2003). Complications such as nonunion have been reported and may lead to a second surgery. Ankle arthroplasty, an alternative to arthrodesis, is intended to improve mobility and function of the joint and is thought to reduce progression of arthritis in adjacent joints.

The ankle joint is a small joint relative to the weight bearing and stress it must withstand. As a result, designing joint replacements for the ankle has been challenging. Originally encouraged by the success of hip and knee arthroplasty, several ankle implants for ankle arthroplasty have been designed, dating as far back as the 1970s. Use of early ankle prosthetic devices for joint replacement seemed promising, with improved short-term outcomes, but did not result in improved long-term outcomes; many failed due to loosening of the joint and high complication rates. Nevertheless, there has been ongoing interest in ankle arthroplasty and proponents suggest that new designs for the prosthetic devices have led to improved performance. With newer joint replacements, designs can now be divided into two groups: two-component, fixed-bearing designs and three-component, mobile-bearing designs (Crockerall, Guton, 2003). These designs differ in both the bearing surface and the portion of the ankle joint that they replace. Two-component systems can be further categorized as constrained, semiconstrained and unconstrained. Constraint of the implant is defined as the ability to limit rotational, anterior-posterior and medial-lateral displacements to within normal ranges. Constrained designs offer the advantage of greater stability but compromise mobility. Unconstrained systems and multiaxial systems with free-gliding core both show lower loosening rates than constrained designs, but because of an unphysiologically large range of motion, they are associated with stability problems (Bauer, et al., 1996).

Despite newer designs, ankle arthroplasty is still considered to be in "evolution" and salvage after failure can be challenging (Sledge, 2005). Although originally encouraged by the successful outcomes of hip and knee arthroplasty, the intermediate and long-term clinical outcomes of total ankle arthroplasty (TAA) such as durability, stability of the device, and rate of complications, have not been as successful. Crockerall and Guton, (2003) stated that intermediate and long-term results have not equaled those of total hip and knee arthroplasty and does not support widespread application outside of investigational centers. The available evidence in the medical literature suggests the lifespan of the device is short-term and therefore not practical for use in younger patients, although there is no consensus regarding patient selection criteria. Authors generally agree that further development in prosthetic design is required (Gill, 2004; Rippstein, 2002; Saltzman, 2000). Complications such as wound infection, delayed healing and poor implant survival have been associated with TAA. While uncemented and unconstrained second-generation replacements have shown better short-term results, there is insufficient data to show improved long-term results with the use of similar, more recent designs. Furthermore, Cracchiolo and DeOrio (2008) noted although interest in total ankle replacements is increasing, midterm clinical results are few and in many cases have not been validated by independent practitioners. Additionally, the authors noted no level I or II studies have been published and that design rationale for the implants and instruments should be carefully evaluated.

### **U.S. Food and Drug Administration (FDA)**

Most ankle prostheses are regulated by the FDA as Class II devices. Class II devices are those for which general controls alone are insufficient to ensure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance. According to the FDA, at least 10 ankle devices have been approved under the FDA 510(k) process since 1977. Under the 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the device prior to marketing. Mobile bearing total ankle replacement systems are classified as Class III devices. Class III devices require more stringent regulatory review and approval (e.g., premarket approval).

Some of the more recent devices for ankle replacement evaluated in the published literature have been granted 510(k) approval based on various predicate devices. The FDA approved devices include the following: Agility™ Total Ankle System (DePuy, Inc., Warsaw, IN); Eclipse Total Ankle Implant (Kinetikos Medical, Inc. Carlsbad, CA); Salto Tolaris Total Ankle Prosthesis (Tornier, St. Ismier, France); and the INBONE Total Ankle System, formerly know as the Topez Ankle System (INBONE Technologies, Boulder, CO).

Other non-FDA-approved devices evaluated in the literature include, but are not limited to, the following: Buechel-Pappas (BP) Ultra Total Ankle Replacement (Endotec, South Orange, NJ); TNK Ankle (Kyocera Corporation, Kyoto, Japan), and Scandinavian Total Ankle Replacement (STAR) (Waldemar Link GmbH & Co., Hamburg, Germany) (see note below).

In April 2007, the FDA Orthopaedic and Rehabilitation Devices Panel recommended approval of the PMA application for the Scandinavian Total Ankle Replacement (STAR) System. The FDA will consider the

recommendation before making a final decision for approval. The STAR ankle system is a three- component, nonconstrained mobile-bearing implant, intended for non-cemented use as a method of replacing a painful arthritic and/or severely deformed ankle due to rheumatoid arthritis, primary arthrosis, or posttraumatic arthrosis.

### **Literature Review**

In an early study published by Kitaoka and Patzer (1996), high complication rates and reoperations were of some concern to the authors. The authors reported on 160 TAAs using a primary MAYO ankle device (i.e., constrained design) at the Mayo clinic for an average of nine years (range 2–17 years). The overall results were rated as good, fair, poor or as a failure based on presence of pain, walking distance, the need for a walking aid, radiographic evidence of loosening and the patient's perception of improvement. Thirty-one ankles had good results; 35 had fair results, and seventeen had poor results. Failure, defined as removal of the implants, occurred in 57 arthroplasties (36%). Adequate preoperative and follow-up radiographs were available for 101 ankles (89 patients). There was evidence of loosening in eight (8%) tibial components and 58 (57%) talar components. Complications occurred after 19 of the 160 total arthroplasties, and 94 additional reoperations were performed on 66 of the 160 ankles. Based on those findings, the authors ceased to recommend TAA with the constrained MAYO implant for rheumatoid arthritis or osteoarthritis of the ankle, due to the high rates of complications and reoperations.

### **Literature Review—FDA Approved Devices**

Clinical trials evaluating FDA approved devices are limited in quantity and quality; however most of the studies evaluate the Agility Ankle prosthesis measuring clinical outcomes such as improvement in pain and function, complication rates, failure rate and rate of revision. Studies comparing ankle arthroplasty to ankle arthrodesis are few.

**Agility Total Ankle System:** More recent studies, with newer devices, have been more encouraging. In a prospective case series, Pyevich et al. (1998) reported on the intermediate-term results of uncemented ankle components performed with arthrodesis of the tibiofibular syndesmosis. Between 1984 and 1993, 95 patients (100 ankles) underwent total ankle arthroplasty with insertion of the Agility Ankle prosthesis. At the average time of follow-up (4.8 years), 83 patients (86 arthroplasties) were alive, and 12 patients (14 arthroplasties) had died. One patient had a resection of the implant. The remaining 82 patients (85 arthroplasties) were the basis for the clinical evaluation. Follow-up consisted of interview, clinical exam, radiographic assessment (n=54), and written and telephone questionnaires (n=28). Outcome measures included pain, function and alignment based on American Orthopedic Foot and Ankle Society (AOFAS) scores, range of motion based on radiographic evaluation, healing and patient satisfaction. Of the 85 arthroplasties performed, 83 (98%) were considered to have provided pain relief. Sixty (73%) of the 82 patients reported an increase in functional level as a result of ankle replacement. Radiographic follow-up was conducted preoperatively, early postoperatively, at six months, at two years and at the time of the most recent follow-up (4.8 years). At two years post-procedure, 98 ankles were available for radiographic evaluation. Sixty-one ankles demonstrated successful fusion of the syndesmosis; 37 did not. Of the patients available for follow-up at 4.8 years, successful fusion was demonstrated in 54 ankles. Reported lack of fusion of the syndesmosis was associated with lysis around the tibial component and migration of the tibial component. The authors reported that early clinical results were encouraging; however, the radiographic findings were cause for concern, and further follow-up was needed to determine long-term efficacy. The authors did not find that radiographic findings were related to the clinical findings (i.e., functional level, pain relief) at the time of follow-up. Limitations of the study include lack of a control or comparison group.

Knecht et al. (2004) continued the study by Pyevich et al. (1998) with five years of further follow-up and the addition of 32 total ankle arthroplasties. The study was a retrospective case series in design and evaluated the Agility Total Ankle prosthesis for the treatment of ankle arthritis. The authors used the Ankle Osteoarthritis Scale (AOS) to assess clinical outcomes and radiographs of all patients who had adequate studies available for an average duration of nine-year follow-up. The rate of major revision (i.e., requiring removal or replacement of one or both of the metal components) was 11% (n=14); seven patients had a new TAA, and seven had an ankle arthrodesis. Implant failure consisted of impaction/settling, lessening and migration, tibial component fracture, malalignment, and deep infection. Secondary procedures (i.e., any procedure to the foot or ankle related to the ankle replacement) were performed in eight ankles; six had an arthrodesis, and two had a revision. As with the previous study, patient satisfaction with the procedure remained high. Questions were raised in the previous study regarding the clinical relevance of radiographic signs of lysis and migration in patients who seemed to be doing well. The ankles that had suggestive signs of component instability or loosening seemed to have less

favorable clinical outcome and more often needed revision or arthrodesis. Higher pain and disability scores were also associated with progressive lysis, circumferential lucency and anterior-posterior zone-3 lucency. Talar component subsidence was more common and more likely to be progressive than was tibial component subsidence. The authors hypothesized talar component subsidence would increase failure over time; however, the results were encouraging and patient satisfaction remained high. The study was limited by the retrospective design and lack of preoperative comparisons, such as pain and range of motion.

Spirit and associates (2004) reported the results of a retrospective case series evaluating reoperation and failure after total ankle arthroplasty with second-generation devices. Reoperation and failure were defined as removal or replacement of components, ankle arthrodesis, or below-the-knee amputation after TAA with a second-generation implant. The authors also sought to determine demographic and clinical predictors of reoperation and failure. They reviewed 306 primary total ankle arthroplasties (303 patients) with the Agility Total Ankle System between 1995 and 2001. A total of 58% of the patients had adjuvant surgical procedures at the time of the TAA. Average patient age was  $53.5 \pm 14.2$  years. At a mean of 33 months postoperatively, they retrospectively reviewed records with regard to patient age, patient gender, indications for index procedure, adjuvant procedures, timing and frequency of reoperation, and the indications for and type of reoperations performed. Eighty-five patients (28%) underwent 127 reoperations involving 168 surgical procedures. The most common procedures were joint debridement, correction of axial malalignment, and component replacement. Eight patients underwent below-the-knee amputation. Kaplan-Meier analysis revealed that the cumulative five-year survival rate with reoperation as the end point was  $54\% \pm 11.5\%$ . Thirty-three ankles (10.8%) were considered to have a failed TAA. Kaplan-Meier analysis revealed that with failure as the end point, five-year survival rate was  $80\% \pm 8.7\%$ . Age was found to be the only significant predictor of reoperation and failure post-ankle arthroplasty based on Cox regression analysis. The authors found that there was a relatively high rate of reoperation due to complications. Age was the only patient-related factor found to have an adverse effect on both reoperation and failure rate. The prosthesis was salvageable in most patients with complications; however, the functional outcome of the salvageable prosthesis was yet to be determined. Limitations of this study include retrospective design and the performance of adjunct procedures, making the ability to generalize results difficult.

In 2006, Kopp et al. retrospectively reviewed the results of total ankle arthroplasty using the Agility Total Ankle prosthesis in 41 consecutive patients (43 ankles) between 1998 and 2002. The evaluation included preoperative and postoperative questionnaires, physical examination, and radiographs. Thirty-eight patients (40 ankles) were available for review at the time of follow-up. One patient died, one patient moved out of the area and was lost to follow-up, and one patient underwent a revision because of aseptic loosening. The diagnoses that were most common among the group of patients were post-traumatic arthritis and rheumatoid arthritis. The average follow-up was 44.5 months, and the average age of the population at time of surgery was 63. Postoperative protocol included six weeks of nonweight-bearing activity in a short-leg cast followed by a removable boot, followed by an additional six weeks of protected nonweight-bearing in a removable walking boot. Range of motion was initiated once the incision had successfully healed. All 40 ankles had improvement of pain postoperatively. Eighty-five percent of the ankles had improved sagittal range of motion. Additionally, there was reported improvement in activity limitation and walking improvement. Thirty-four of 40 ankles demonstrated lucency (i.e., a radiolucency line of 2 mm or less in width) or lysis (radiolucency of greater than 2 mm) on radiographs, although the degree of involvement varied. Twelve perioperative complications occurred, including nonunion of syndesmosis, intraoperative malleolar fracture, wound complications, and vascular complications. Postoperative complications included malalignment of the ankle caused by component positioning or ligamentous instability (seven patients), and subsequent procedures were required for scar debridement or localized osteotomy to improve range of motion or to relieve local impingement symptoms (five patients). The authors reported migration or subsidence was common and involved 18 ankles. While further long-term studies are needed to support improved clinical outcomes, the intermediate results of this study seem promising.

#### **Literature Review—Non-FDA Approved Devices**

**The Scandinavian Total Ankle Replacement (STAR) Prosthesis:** Valderrabano et al. (2004) conducted a prospective study to determine mid-term results of total ankle replacement using the Scandinavian Total Ankle Replacement (STAR) prosthesis. The study group consisted of 68 total ankle replacements, performed in 65 patients with follow-up evaluation conducted after an average of 3.7 years. Evaluation consisted of interview, clinical examination, dynamic pedobarography and radiographic assessments. The average age of the population was 56.1 years and the indication for all patients was severe pain refractory to nonoperative treatments. At follow-up, the authors reported that 35 patients were totally pain-free. The overall clinical score

was graded as excellent or good in 67 ankles. There was an increase in the AOFAS hind foot score from 24.7 points preoperatively to 84.3 points at follow-up ( $p < 0.05$ ). Three patients had a ballooning bone lysis on the tibial side; 43 ankles had periarticular hypertrophic bone formation; nine ankles required revision surgery; and 14 ankles required secondary or additional operations. No ankle had to be converted to arthrodesis. Most of the patients were satisfied with the outcome of the operation and functioning of the implant. The authors reported that the complications and potential problems found in their study were higher than previously reported studies. This study is limited by small population and lack of controls or comparison group and further follow-up evaluation would be helpful to determine long-term outcomes.

Stengel et al. (2005) conducted a systematic meta-analysis of studies exploring the efficacy of three-component total ankle prostheses, some of which included the STAR prosthesis, New Jersey Low Contact Stress, the Ramses, the ESKA and the Beuchel-Pappas. Of 1830 citations identified, 18 met the author's inclusion criteria, which consisted of a minimum sample size of 20 patients, at least one year follow-up, and a clinically relevant end point (e.g., results of ankle scoring, range of motion, complications, and survival rates). The investigation showed some evidence of efficacy for total ankle arthroplasty on patient-centered outcomes and that arthroplasty may slightly improve the total range of motion. The authors noted that the available literature suggests ankle arthroplasty with meniscal-bearing implants provides an acceptable benefit-risk ratio. Ankle arthroplasty does improve pain relief and joint mobility in end-stage arthritis. The overall methodological quality, sample sizes and short-term follow-up restrict any further inferences, however. In addition, the authors noted the performance of ankle arthroplasty compared to ankle fusion, the current reference standard, remains to be defined in a well-designed randomized trial.

Wood and colleagues reported the five-year results of a prospective case series of 200 total ankle replacements using the STAR mobile bearing ankle replacement prosthesis (Wood, et al., 2008). Evaluation consisted of AOFAS Scores and radiological reviews. The authors reported that 67.5% of the patients had good relief from pain without complications and satisfactory radiographs. A total of 25 ankles had aseptic loosening: ten had minimal symptoms that did not progress and did not require further surgery, one required a bone graft, four were revised and ten were fused. A life-table analysis showed survival at five years as 93.3% and survival at ten years as 80.3%. The study results did not support that total ankle replacement prevents progression of arthritis however the authors noted most of the patients in the study had pre-operative arthritic changes.

**Hintegra Ankle:** Lee et al. (2008) reported the results of a comparative trial evaluating the perioperative complications of the Hintegra ankle device in two groups of patients: Group A (initial 25 cases) and Group B (subsequent 25 cases). The results demonstrated there were no major wound complications requiring soft-tissue coverage in either group (although in Group A there a deep wound infection). Minor complications in Group A compared to Group B consisted of fracture ( $n=4$ ,  $n=1$ , respectively), minor wound problems ( $n=3$  both groups), nerve injury ( $n=3$ ,  $n=0$ , respectively), tendon injury ( $n=1$  both groups) and heterotopic ossification ( $n=3$ ,  $n=0$ , respectively). Regarding tibial and talar component malposition, the authors noted a decrease in Group B compared to Group A ( $n=9$ ,  $n=7$ , respectively). The results confirmed that surgeon experience influenced complication rate and that there is a steep learning curve associated with the procedure.

**Beuchel-Pappas Ankle Replacement System:** Authors have reported results in the medical literature for the Beuchel-Pappas ankle replacement system (San Giovanni, et al, 2006; Doets, et al., 2006), another non-FDA approved device. These two groups of authors reported the results of their case series for total ankle replacement, consisting of patients with mainly rheumatoid arthritis, (31 and 93 ankles, respectively). The average follow-up was approximately eight years. Both of these studies demonstrated high failure rates and lacked comparison groups, although the authors reported that most patients were satisfied with the result of their ankle replacement. Intraoperative malleolar fractures were commonly reported by both authors. San Giovanni and colleagues reported complications, which included wound dehiscence, stress fractures, and malleolar nonunion. Additionally, five implants in this study group were interpreted as being at risk for failure due to marked tibial or talar component subsidence. This group of authors agreed that further clinical trials were warranted to determine long-term efficacy. Doets and colleagues reported that in their study group, 17 patients died (unrelated to the total ankle replacement), and 15 patients required revision surgery with either ankle arthrodesis or an implant exchange due to aseptic loosening, primary or secondary axial deformity with edge-loading, deep infection, and a severe wound healing problem. The authors reported a mean eight-year overall survival rate of 84% in patients with inflammatory joint disease. In addition, they reported that a learning curve is associated with the surgery. Nonetheless, Doets and colleagues acknowledged that good results could be

achieved with total ankle prosthesis for the treatment of inflammatory joint disease when proper indications were applied.

Nelissen et al. (2006) reported on the results of patients who received the Beuchel-Pappas ankle replacement system for treatment of rheumatoid arthritis (n=15). This group of authors evaluated early migration patterns believed to explain variations of failure. Nelissen and colleagues reported initial progressive migration of the mobile-bearing prosthesis into upward anterior and valgus tilting that decreased at three months, and that the migration stabilized by six months post-surgery. Failure can be related to prosthetic design, position of the prosthesis, and biologic factors. Early migration patterns may have been related to surgical and tibial fixation techniques.

Ali et al. (2007) reported the results of a case series of 35 patients who received the Beuchel Pappas uncemented ankle prosthesis for total ankle replacement (mobile-bearing). The average follow-up period was five years; all procedures were performed for OA in nondiabetic patients. The authors reported both functional and radiological results. AOFAS scores were 34.6 preoperatively, and 76 at follow-up, a significant improvement ( $p<0.001$ ). The average scores for pain, function and alignment were 30, 40, and 9, respectively. The authors reported 66% of patients were completely pain-free or had occasional discomfort. Radiographs showed no evidence of gross subsidence or lucency. Although the patient was asymptomatic, one implant was poorly positioned. There was evidence of avascular necrosis in the talus of one patient; the patient remained asymptomatic at three years. There were two intraoperative medial malleolar fractures, two superficial wound infections and no deep infections or nerve injuries. One tibial component required revision. Limitations of the study included short-term follow-up, small sample size and lack of a comparison group.

#### **Literature Review—National Joint Registry Reports**

More recently, authors have begun to report on data from national joint registries and, in particular, on replacement survival rates. Hosman et al. (2007) reported a national joint registry review of TAAs. The information reported by this group of authors is based on the New Zealand National Joint Registry. The authors reviewed data for 202 TAAs performed between 2000 and 2005, with follow-up at six years. The four prostheses recorded were the Agility Total Ankle System, the STAR, the Mobility, and the Ramses Total Ankle. Review of the data took place at approximately 28 months post-procedure. Fourteen revisions were recorded (7% failure rate), with loosening of components identified as the main reason for failure. A six-month post-procedure questionnaire evaluating pain, activity and function was returned by 74% of the patients and suggested that unfavorable patient scores at six months indicated an increased likelihood of subsequent failure.

Fevang et al. (2007) reported on TAA data obtained from the Norwegian Arthroplasty Register between 1994 and 2005. The mean follow-up time for all patients was four years. There were 257 TAAs performed; 32 were cemented and 212 were noncemented. Four types of prostheses were used: the Norwegian Thompson Parkridge Richards (TPR), STAR, Ankle Evolution System (AES), and HIntegra. Revision were performed in 27 cases. The authors reported an overall five- and ten-year survival rate of 89% and 76%, respectively. Prosthesis survival was the same for cemented (Norwegian TPR prosthesis) versus uncemented (STAR prosthesis). The authors acknowledged that the survival rate after TAA remains much lower than knee (94–96%) and hip (98%) replacements.

Henricson et al. (2007) reported on data from a national ankle replacement registry in Sweden between 1993 and 2005 using third-generation devices, including the STAR prosthesis, Beuchel-Pappas, AES, HIntegra, and Mobility prosthesis. A total of 531 replacements were reported to the register; 101 ankles were revised (19%). The estimated overall five- and ten-year survival rate was 78% and 62%, respectively.

**Literature Review— Other:** SooHoo and colleagues (2007) conducted an observational study comparing reoperation rates following ankle arthrodesis and TAA. The authors used population-based data from all inpatient admissions in California over a ten-year period of time (1995–2004). A discharge database was used to identify the patients; however, the authors did not note the type of prosthetic ankle device implanted. Both short-term (90 days post-primary surgery) and long-term outcomes (one and five years post-primary procedure) were assessed, including rates of major revision surgery, pulmonary embolism, amputation, infection and subtalar joint fusion. A total of 4705 ankle fusions and 480 TAAs were performed during the study period. The mean age of the patients were 55 years and 59 years, respectively; a significant difference ( $p<0.001$ ). Ankle fusion patients had a significantly higher rate of complicated diabetes ( $p<0.001$ ) compared to TAA patients. At 90 days postoperatively, the TAA patients had a higher rate of major revision surgery and had an increased rate

of device-related infection compared to the ankle arthrodesis patients. The rates for major revision surgery at one and five years for TAA were 9% and 23%, respectively; for ankle arthrodesis, the rates of major revision surgery were 5% and 11%, respectively. The patients treated with ankle arthrodesis had a higher rate of subtalar fusion at five years (2.8%) compared to TAA (0.7%). The authors confirmed that patients who undergo TAA are more likely to require revision surgery compared to patients who undergo ankle arthrodesis and have a higher risk of device-related infection. Limitations of the study include patient populations that were not comparable to each other; the presence of subtalar arthritis, which is a potential complication to arthrodesis; and the limited data available from the administrative databases. There was no data regarding functional outcomes or for procedures performed on an outpatient basis (surgery or readmissions).

Haddad et al. (2007) conducted a systematic review of the literature addressing the intermediate and long-term outcomes of TAA and ankle arthrodesis in terms of ankle function, pain, revision, conversion to arthrodesis, implant survival and quality of life. The publications included in their review were published between 1990 and 2005 and included 49 primary studies (56 treatment arms, 2114 patients). Ten studies focused on TAA (n=852), and 39 studies focused on ankle arthrodesis (n=1262). No studies directly compared TAA and ankle arthrodesis. Follow-up time ranged from two to nine years in the TAA group of studies and two to 23 years in the arthrodesis group of studies, with an average of five years across both groups. The efficacy results associated with second-generation implants, including the Agility ankle, New Jersey Low Contact Stress Ankle, Beuchel-Pappas, TNK, STAR, and Salto prosthesis were reported. Patients treated with TAA were older than those undergoing ankle arthrodesis and were mainly female. The authors' analysis was limited because efficacy outcomes were variable across the studies. The five- and ten-year implant survival rates following TAA were 78% and 77%, respectively. A revision was required in 7% of patients who underwent TAA, most commonly for loosening and/or subsidence. Five percent of the TAA patients were converted to arthrodesis. Below-the-knee amputation was performed in 1% of the patients treated with TAA. The ankle arthrodesis group had a 10% nonunion rate. Nine percent underwent revision because of nonunion, and 5% of the patients underwent below-the-knee amputation. The authors noted significant heterogeneity in almost all studies; therefore, results should be interpreted with caution. The review was limited by the variability of reported outcomes and the tools to assess outcomes, differences in patient populations, differences in study follow-up times, and lack of direct comparison between TAA and ankle arthrodesis. However, the authors acknowledged that although the evidence was limited, the intermediate results suggest the two procedures are comparable.

Some authors have evaluated mechanical properties, such as gait analysis, associated with total ankle replacement. In 2007 Valderrabano and colleagues reported the results of a prospective study evaluating gait characteristics of patients who underwent total ankle replacement. The authors compared 15 patients with OA of the ankle with 15 age and gender-matched control subjects using clinical and three-dimensional hindfoot gait analysis. The subjects received the Hintegra Ankle system. The authors confirmed that ankle OA caused significant reduction of the AOFAS scores and SF-36 scores compared to healthy controls and significant change in the recorded gait characteristics. At three months post surgery, most results of the patients with OA showed a trend away from the results of normal subjects (i.e., function was below preoperative baseline) and at 12 months patients who underwent total ankle replacement changed gait characteristics towards results of the normal subjects (i.e., function was above preoperative baseline). Houdijk et al (2008) compared mechanical load and stiffness of the ankle joint following replacement with the Beuchel-Pappas ankle (n=10) with healthy control subjects (n=10). The authors noted there were no significant differences in mechanical load of the ankle joint, peak joint moments or stiffness compared to controls although there was a difference for internal work at the step which may have been related to varying walking speeds. In the author's opinion, function of the ankle joint did not appear to be influenced by total ankle replacement. Using gait analysis, Piroiu et al. (2008) evaluated patients who underwent total ankle arthroplasty (n=12), patients who underwent ankle arthrodesis (n=12) compared to a healthy control group (n=12). The authors reported that neither treatment with ankle arthrodesis or total ankle replacement fully restored normal movement or walking speed. Ankle arthrodesis resulted in more rapid gait with longer step length compared to the replacement group and the timing of gait demonstrated greater asymmetry. The ankle replacement group had greater movement at the ankle, a symmetrical timing of gait and restored ground reaction force pattern. Improved timing of gait would support a reduction in limp with ankle replacement although the gait is significantly slower.

In 2005 ECRI published an emerging technology evidence report evaluating total ankle replacement as a treatment for degenerative ankle disease and concluded that total ankle replacement should only be performed at orthopedic specialty centers that perform a high volume of ankle procedures. ECRI noted that there is a substantial learning curve associated with total ankle replacement and there is insufficient evidence available to

determine safety and efficacy due to incomplete and vague reporting of outcomes and lack of generalization to a broader population. A total of twelve uncontrolled case series using three different ankle systems involving 1,003 patients were evaluated as part of the initial review. In the 2008 update six comparison studies, 13 case series, two systematic reviews, and 15 narratives indicated that failure rates remained high compared to hip and knee replacement. ECRI noted that despite new evidence total ankle replacement seemed to remain in the developmental phase and further clinical studies should continue to monitor the technology.

### Professional Societies /Organizations

A position statement by the American Orthopaedic Foot and Ankle Society (AOFAS), released June 6, 2003, indicates the following: "Ankle arthritis has many treatment options, both operative and non-operative. Operative treatment is available for patients with persistent symptoms. Surgical options include joint debridement, distraction arthroplasty, osteotomy, ankle arthrodesis, and total ankle arthroplasty. Total ankle arthroplasty is a viable option for the treatment of ankle arthritis." According to the AOFAS there has been no recent update to this position.

### Summary

Evidence in the peer-reviewed, published scientific literature is insufficient to allow strong conclusions in terms of safety and efficacy of total ankle arthroplasty (TAA). Published evidence evaluating total ankle replacement is primarily in the form of retrospective, case series and lacks controlled trials. Generally, the outcomes of the studies demonstrate improvement in pain scores following TAA. However, comparison between clinical studies regarding TAA is difficult and limited by heterogeneous study populations, differences in type of prosthetic designs and lack of standardized outcome measures. Follow-up time varies across studies as well as scoring systems used to assess clinical outcomes. Clinical outcomes such as pain relief, improved functional mobility and long-term durability of the prosthetic device would be helpful in comparing the safety and efficacy of TAA to ankle arthrodesis. Furthermore, there is no clear consensus among authors regarding patient selection criteria. Although TAA is supported as a treatment option by the American Orthopedic Foot and Ankle Society (AOFAS), this recommendation is not supported by the weight of currently available medical evidence as the long-term results and comparative effectiveness of total ankle replacement remain unknown. As a result, further scientific research, involving well-designed randomized controlled clinical trials with long-term net health outcome data, are still required to clearly define and establish a role for TAA.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

### Experimental/Investigational/Unproven/Not Covered:

CPT <sup>®*</sup> Codes	Description
27700 <sup>†</sup>	Arthroplasty, ankle
27702 <sup>†</sup>	Arthroplasty, ankle; with implant (total ankle)
27703 <sup>†</sup>	Arthroplasty, ankle; revision, total ankle

**Note:** Experimental, investigational or unproven and not covered when used to report total ankle arthroplasty/replacement.

ICD-9-CM Diagnosis Codes	Description
	All codes

\*Current Procedural Terminology (CPT<sup>®</sup>) © 2008 American Medical Association: Chicago, IL.

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	2/15/2008	0285	Total Ankle Arthroplasty/Replacement

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.