CIGNA MEDICAL COVERAGE POLICY

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

Subject **Total Ankle Arthroplasty/Replacement**

Effective Date 2/15/2011
Next Review Date 2/15/2012
Coverage Policy Number 0285

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Coverage Policy

CIGNA covers total ankle arthroplasty/replacement for a skeletally mature individual as medically necessary for the treatment of severe inflammatory arthritis (e.g. rheumatoid arthritis), severe osteoarthritis, or post-traumatic arthritis of the ankle, as an alternative to ankle arthrodesis, when ALL of the following criteria have been met:

- moderate to severe ankle pain that limits activities of daily living
- failure of at least six months of conservative therapy (i.e., anti-inflammatory medications, orthotic devices, activity modification, physical therapy)
- any **ONE** of the following:
  - ➢ arthritis in adjacent joints of the involved extremity (i.e., subtalar, midfoot)
  - ➢ severe arthritis of the contralateral ankle
  - ➢ previous arthrodesis of the contralateral ankle
- absence of **ALL** the following:
  - ➢ active infection
  - ➢ insufficient bone/osteonecrosis
  - ➢ loss of musculature in the affected limb/insufficient ligament support
  - ➢ vascular insufficiency in the affected limb
  - ➢ Charcot's or other peripheral neuropathy
  - ➢ neurological impairment
  - ➢ severe ankle deformity precluding proper alignment

> ➢ malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
> ➢ absence of medial or lateral malleolus, or both
> ➢ poor skin conditions secondary to surgical scars or trauma

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.

Several ankle implants for ankle arthroplasty have been designed and implanted, dating as far back as the 1970s. Initial reported clinical outcomes were poor and since that time, technology and instrumentation has continued to evolve in hopes of improving patient outcomes. Some of the devices currently available and reported on in the published literature are second or third generation devices.

Currently there are two groups of joint replacement designs: 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 have been associated with stability problems.

When compared to hip and knee replacement procedures, in general, the reported outcomes from TAA such as device durability and stability, and complication and failure rate have not been as favorable. Complications such as wound infection, delayed healing and poor implant survival are associated with TAA. In addition, patient selection criteria have not been clearly defined and there is some debate regarding the optimal candidate. Evidence in the medical literature suggests the lifespan of the device is short-term and therefore not practical for use in younger patients or those who are very active. According to textbook sources it has been suggested that optimal candidates are those greater than age 50, however the age of patients involved in the clinical trials vary. Other criteria include those who are not obese (e.g., have an adequate bone size to body weight ratio), who have minimal deformity, good range of motion of the ankle, and a good soft-tissue envelope. With the development of improved designs and instrumentation, authors have reported improvement of implant survivorship. While uncemented and unconstrained second-generation replacements have shown better short-to intermediate-term results, data supporting improved long-term results with the use of similar, more recent designs, is limited. In many cases, clinical results have not been validated by independent practitioners.

Despite lack of consensus on patient selection criteria, authors agree careful patient selection is essential to successful outcomes. Inclusion criteria within published clinical trials vary as well as the device selected, however TAA is intended as an alternative to ankle fusion in patients with debilitating end-stage arthritis, loss of ankle function, and pain that is refractory to conservative treatment for at least six months. FDA approved indications vary depending on device type: fixed-bearing or mobile-bearing. In general these devices are intended for adult patients with reduced activity levels, who have severe rheumatoid arthritis, post-traumatic

arthritis or osteoarthritis of the ankle. Contraindications also vary depending on device type, but include the following:

- active infection
- insufficient bone/osteonecrosis
- loss of musculature in the affected limb/insufficient ligament support
- vascular insufficiency in the affected limb
- Charcot's or other peripheral neuropathy
- neurological impairment
- severe ankle deformity precluding proper alignment
- malalignment or severe deformity of involved or adjacent anatomic structures (e.g. hindfoot, forefoot, knee)
- absence of medial or lateral malleolus, or both
- poor skin conditions secondary to surgical scars or trauma
- patient age, weight or activity levels that introduces unnecessary risk of failure
- skeletal immaturity

U.S. Food and Drug Administration (FDA)
Most ankle prostheses are regulated by the FDA as Class II devices and 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. The FDA classifies mobile bearing total ankle replacement systems as Class III devices. Class III devices require more stringent regulatory review and approval (e.g., premarket approval).

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) and the Scandinavian Total Ankle Replacement (S.T.A.R.® Ankle) (Small Bone Innovations, Morrisville, PA). In August of 2010 the FDA granted 510(k) approval for the INBONE™ II Total Ankle System (Wright Medical Technology, Arlington, TN). According to the FDA this device differs from the predicate device, INBONE Total Ankle, in articulating surface geometry and added stability in the talar dome (FDA, K100886).

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).

Literature Review—FDA Approved Devices
Original constrained designs from the 1970's were abandoned primarily due to unacceptable high complication and reoperation rates (Kitaoka, Patzer, 1996). With refinement of devices and improved instrumentation, the clinical outcomes of TAA procedures using more recent designs have improved. However, clinical trials specifically evaluating FDA approved devices are limited in quantity and quality. Much of the literature prior to FDA approval was in the form of retrospective and prospective case series without controls or comparison groups. The clinical outcomes were mixed; some studies demonstrated high failure and complication rates, which seemed to improve with surgeon experience. Surgeon experience is a contributing factor to overall success. In addition, several of the studies were conducted by surgeons who designed the device and/or were funded by the manufacturer which could induce bias. Of the more recent FDA approved devices, most studies evaluate the Agility Ankle or the STAR prosthesis, measuring clinical outcomes such as improvement in pain and function, complication rates, failure rate and rate of revision. Follow-up evaluations are on average two to five years with some studies reporting results beyond that. Studies comparing ankle arthroplasty to ankle arthrodesis are few and data comparing mobile bearing designs to fixed-bearing designs is lacking.

Agility™ Total Ankle System: The Agility prosthesis is a two-component semi-constrained device intended for cemented use only. According to the FDA the initial 510(k) approval was granted in 1992, since that time the device has been revised with subsequent approval through the (510k) process. The most recent approved device is the Agility Lp Total Ankle prosthesis (510[k] K053569).

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 is limited by the retrospective design and lack of preoperative comparisons, such as pain and range of motion.

Spirt 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 ± 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% ± 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% ± 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.

In 2009 Claridge et al. reported the results of a retrospective case series involving 28 total ankle arthroplasties performed over a period of five years using the Agility™ Total Ankle prosthesis (a second generation device). The average follow-up period was 59.8 months (range of 21 to 104). Follow-up evaluation consisted of AOFAS questionnaires which demonstrated significant improvement in hindfoot scores, with pain relief as the main factor for improving the score, followed by improved function. Ninety-two percent of patients reported improvement in their pain level and 81% reported an increase in their activity level; 83% had had increased walking distance post surgery. Radiograph evaluation was also performed which included anteroposterior, lateral and mortise views. Improvement in ankle range of motion was reported for 71% of patients and 81% had subjective improvement in their gait. The authors noted a high complication rate which included wound healing (n=5), intraoperative fracture (n=2), nonunion syndesmosis (n=1), subsidence (n=2), postoperative fracture (n=3), deep infection (n=4), aseptic loosening (n=2) and technical error (n=2). The authors did note however that the complications were evenly distributed; there were not more complications in the cases performed earlier in the study compared to those later. One patient underwent arthrodesis at seven months and a second patient was considering arthrodesis at 104 months; both had titling of the tilting of the tibial component. This group of authors acknowledged that due to the high complication rate, they abandoned TAA and shifted to ankle arthrodesis which as a more predicatable outcome and lower rate of complications.

The Scandinavian Total Ankle Replacement (S.T.A.R. ® Ankle): The STAR ankle system is a three-component, nonconstrained mobile-bearing implant, intended for non-cemented use and allows four axes of rotation. This device recently received FDA approval through the PMA process (FDA, P050050). As part of the approval process the manufacturer is required to conduct two post-approval studies: the first is a prospective multicenter single arm designed trial, involving a continued access cohort, to determine the eight year survivorship and effectiveness of the STAR device in comparison to arthrodesis from historical controls. A second study (prospective, multicenter single arm design) involving additional subjects, is required to examine the performance of the device under actual conditions of use, and compared to the continued access cohort. The recently approved STAR device is also in its third generation. Several authors have evaluated and reported on the STAR device since the initial phases of development making comparisons across studies difficult. The reported clinical outcomes from these earlier studies in the peer-reviewed published scientific literature were mixed, some were less successful than more recent designs, sample populations were small, few authors compared outcomes to arthrodesis and long-term improvement in health outcomes was not firmly established.

Kofoed et al. (2004) evaluated 58 individuals in a patient-controlled prospective study, who underwent TAA with a meniscal bearing ankle prostheses. The authors compared fixation with cement (n=33) to fixation without cement (n=25). The mean follow-up was 9.4 years; failure was defined as prosthesis revision or change to

arthrodesis for any reason. A total of nine patients had revision in the cemented group and one had revision in the uncemented group. Survivorship analysis for 12 years based on life-tables showed a 70% rate for cemented and 95.4% for uncemented. Clinical scores for the uncemented group were higher compared to the cemented group, 91.9± 7.4 and 74.2± 19.3, respectively.

In 2004 Valderrabano et al. 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. Complications and potential problems found in this study were higher than previously reported studies. Limitations of the study include small population and lack of controls or comparison group; further follow-up evaluation would be helpful to determine long-term outcomes (Valderrabano, et al., 2004).

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 Buechel-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 results of a prospective case series of 200 total ankle replacements using the STAR mobile bearing ankle replacement prosthesis, at a minimum of five years after operation (Wood, et al., 2008). Evaluation consisted of AOFAS Scores and radiological reviews. The authors reported that at an average of 88 months follow-up (range 60-156 months), 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.

Shutte et al (2008) reported the short-term results of a prospective case series involving 47 subjects who underwent TAA with the STAR prosthesis. The average follow-up was 28 months, with 45 prostheses surviving and four known failures. Significant improvement in pain and task difficulties was reported using the Foot Function Index, a self-assessment tool for measuring pain and disability. Major or minor complications occurred in 16 patients during surgery. There were no significant differences found in the occurrence of complications with regard to the indication for surgery, nor in the timing of the surgery (early or late in the study). The mean postoperative Kofoed score (clinical score for ankle function) was 68; in 21 patients the result was considered poor, 5 moderate, 10 good and 8 excellent. Radiographs demonstrated radiolucent lines, osteolysis and malposition in 31 cases at follow-up. The authors noted that TAA is technically challenging, often involve complex deformities, and should only be performed by experienced orthopedic foot and ankle surgeons.

Wood et al. 2009 reported the results of a randomized prospective trial comparing the Beuchal-Pappas device (n=100) to the STAR implant (n=100). Both devices are mobile-bearing devices. Minimum follow-up was 36 months with an average follow-up of 54 months. The authors noted that the Beuchal-Pappas device changed during the trials from nitrided titanium to cobalt chrome, although there was no related effect on clinical

outcomes. AOFAS scores were used to assess pain and function postoperatively; range of motion was also assessed using goniometer and radiographs were measured pre and postoperatively. The primary outcome was failure of the replacement by either fusion or revision. In all, 16 (8%) TAAs failed, 14 underwent fusion and two had revision. A total of four other patients required secondary surgery other than fusion or revision. There were 163 surviving patients at the time of the review and mean AOFAS scores for pain and function improved similarly in both groups. The ROM did not worsen following surgery however few gained any marked increase. Survivorship was similar for both Beuchal-Pappas devices; although there was a trend toward higher failure rate for the Beuchal-Pappas group compared to the STAR group although it was not statistically significant. Ankles that had a preoperative varus or valgus deformity did show a greater incidence of failure, particularly when the deformity was more than 15°. Based on the degree of deformity, the authors noted a predicted failure rate at six years which exceeded 25% for the Beuchal-Pappas and 10% for the STAR. Overall, the six year survivorship for the whole study group was 86.5% (95.0% STAR and 79% for the Beuchal-Pappas).

Karantana and associates (2009) retrospectively reviewed 45 patients (52 ankles) who had primary TAA using the STAR device to assess survivorship. The authors reported their results regarding survivorship, reason for revision, functional AOFAS scores, radiograph appearance, complication rate rates and described additional surgery performed without component revision. Seven of the subjects had bilateral arthroplasties. Prosthesis survival at 5 years was 90% and 84% at 8 years. Overall revision rate was 17%. Subsequent surgery, excluding component revision, was performed in nine of 52 ankles (17%). Eight subjects required revision surgery; six required component revision and two required fusion. The complication rate was low (21%) and included wound infections and fractures (both intraoperative and postoperative). The incidence of component migration and loosening was low. The mean post-operative AOFAS score was 78 although all patients did not have preoperative comparison to determine a clinical gain.

Hobson et al (2009) reported the results of a comparative trial involving 111 subjects who underwent TAA using the STAR device. The authors compared patients with a hindfoot deformity up to 10° (Group A) with those who had deformity of 11° to 30° (Group B). The average time of follow-up was four years. The authors reported 18 failures (14.6%) overall, with no significant difference in survival between groups A and B. The patients were assessed using AOFAS Scores which demonstrated a significant difference between Group A (77) and B (86), difference of nine. There was no difference between groups in postoperative ROM and complications. In group B correction of hindfoot deformity was achieved to within 5° of neutral in 27 ankles, however gross instability was the most common mode of failure in this group. The results support that TAA can safely be performed in patients with hindfoot deformity of up to 30°, however the authors stressed the need to achieve adequate correction of alignment and instability.

In 2009 Saltzman et al. published the results of a prospective, controlled multicenter investigational device exempt (IDE) trial evaluating the STAR ankle device. The study was a noninferiority designed trial involving 15 different sites in the U.S. and compared safety and efficacy of the STAR device with arthrodesis. The study population was selected by a 2:1 method, and consisted of 158 ankles for the STAR group and 66 for the arthrodesis group (Pivotal study groups). A second group of patients (n=448 ankles) whose surgery was performed after completion of enrollment were also reported on (Continued Access group). The authors noted the implant was not modified between the two series and that the foot and ankle surgeons were experienced with ankle fusion although they had very limited experience with either the anterior approach to or implantation of total ankle components. Follow-up was conducted at 24 months using standard scoring systems which included Visual Analog Scale (VAS), Short Form-36, and the Buechel-Pappas (BP) scale. Success was defined as 40+ point improvement in total BP score, no device failure, revision or removal, radiograph success, and no major complications. The long-term advantages including functional benefits, revision and reduction of hindfoot arthritis were not evaluated in this study. The results of the study demonstrated intraoperative fracture occurred in 9.5% of the Pivotal group, (mainly of the malleoli); the Continued Access group had a lower rate of 4.8%. Adverse events were more common in the arthroplasty group compared to the fusion group; the Continued Access group had significantly less complications compared to the Pivotal arthroplasty group. No significant differences were seen between the Pivotal and Continued Access groups in major complications. The Pivotal STAR group demonstrated better function and equivalent pain relief compared to the arthrodesis group. The Pivotal arthroplasty group had a mean improvement of 40 points and the fusion group had a mean 26 point improvement in the BP score at 24 months follow-up. The Continued Access group also had significant improvement compared to the Pivotal STAR group. Mean improvement in VAS was similar in the Pivotal STAR and fusion groups; however in the Continued Access group the mean pain reduction was significantly improved compared to the fusion group. At 24 month follow-up, 16.5% of the Pivotal STAR group required a secondary

surgical intervention, of which 7.6% required revision or removal, compared to 10.6% of the fusion group who required secondary surgery, of which 10.6% required revision or removal. The Continued Access group required even less secondary surgical procedures (8.5%) compared to the Pivotal group. Patient satisfaction was similar in the Pivotal STAR and fusion groups and was reported as good to excellent. At 24 month follow-up the Pivotal arthroplasty group demonstrated significantly greater efficacy and overall success compared to the fusion group.

Saltzman et al. (2010) reported the results of a retrospective study, and compared clinical and radiograph outcomes between ankle replacement and ankle arthrodesis subjects. The authors matched a group of subjects who received the STAR device (n=42) and compared them to a group of arthrodesis subjects (n=29) from the same period. Only 88% of the ankle replacement and 79% of the ankle arthrodesis group were able to complete follow-up (average of 4 years). The ankle replacement group had better mean AOS pain and disability scores compared to the arthrodesis group. Significant differences were noted only in the SF-36 mental component score and AOS pain scale. There were no significant differences in the preoperative and postoperative osteoarthritis between the ankle replacement and arthrodesis group. The arthroplasty group had more pain relief and more postoperative complications that required surgery.

Salto Total Ankle: Bonnin et al. (2011) analyzed longer-term survivorship and causes of failure of the Salto prosthesis in a cohort of previously studied subjects. The authors retrospectively reviewed 96 prospectively followed subjects with 98 prostheses implanted between 1997 and 2000 (prior to FDA approval in the U.S.). A total of 85 subjects had a minimum follow-up of 6.8 years, mean follow-up was 8.9 years. The reported survival rate was 65% with any reoperations of the ankle as the endpoint and 85% with revision of a component as the end point. Six prostheses were removed for arthrodesis and 18 ankles underwent reoperation without arthrodesis. Three main causes of reoperations were bone cysts, fracture of polyethylene, and unexplained pain. The authors noted few patients developed loosening and/or subsidence.

Literature Review—Non-FDA Approved Devices
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.

Buechel-Pappas Ankle Replacement System: Authors have reported results in the medical literature for the Buechel-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 Buechel-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 Buechel 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.

Ankle Evolutive System (AES)
Authors have also published outcome data for the Ankle Evolutive System, a mobile bearing ankle system similar to the Buechel Pappas model (Henricson, et al., 2010; Rodriguez, et al., 2010; Morgan, et al., 2010; Koivu, et al., 2009; Besse, et sl., 2009). Most of the studies are retrospective or prospective case series involving small patient populations. Average follow-up within these studies ranged from two years to 4.5 years. Functional outcome and patient satisfaction were comparable to other similar devices however some authors acknowledged concern for osteolysis. Theoretically, osteolysis may occur as a result of foreign body reaction caused by the wear of particles, such as polyethylene, cement or metal. Koivu et al., (2009) reported the risk for osteolysis was found to be 3.1 times higher with implants with titanium hydroxyapatite porous coating. As a result of tibia implant interface cysts in 62% of their cases and talar implant interface cysts in 43% of cases, Besse et al. (2009) stopped implantation of the AES prosthesis and recommended preventive grafting for severe lysis. Data supporting safety and efficacy of this ankle system is lacking and the clinical benefits of the Ankle Evolution System are yet to be determined. Rodriguez et al. (2010) reported the results of a retrospective case series (n=21) assessing medium term follow-up of the AES device. A total of 14 patients (77%) developed osteolysis of .5 to 1 cm or greater on conventional radiograph at an average follow up of 39.4 months. Henricson et al. (2010) reported only three cases of osteolysis around components out of a total of 93 subjects.

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. Revisions 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, Buechel-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.

Skytta et al. (2010) evaluated the survival of two ankle designs and factors that were associated with survival using data from the nationwide arthroplasty registry in Finland. The data was obtained between 1982 and 2006 and consisted of 645 operations; 573 were primary and 72 were revisions. The authors evaluated only ankle designs that were used in more than 40 surgeries and only implants with a mean follow-up of at least two years and more than 20 subjects at risk at three years. Two devices met criteria, which included the STAR and the AES ankles. Indications for surgery included rheumatoid arthritis (49%), posttraumatic arthritis (22%), primary osteoarthritis (19%) and other arthritis and diseases (10%). The authors noted no differences in survival rates between the two designs. The five-year survivorship for the whole cohort was 83% using revision for any reason as endpoint and 95% using revision for aseptic loosening as endpoint. Age and sex did not have any significant effect on survival. A total of 59 revisions were reported during 1997-2006, the seven year survivorship for the whole group was 78%. The most common reasons for revision were aseptic loosening (30%), instability (39%), primary malalignment (8%), infection (7%), fracture of the meniscal implant (5%), and periprosthetic fracture (2%). The authors concluded a high number of complications were associated with balance and instability and required a detailed understanding of not only the ankle joint but hindfoot as well.

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, Buechel-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). Houdijik et al (2008) compared mechanical load and stiffness of the ankle joint following replacement with the Buechel-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.

Gougoulais et al (2010) published the results of systematic review of the literature evaluating the outcomes of TAA. The authors identified 13 studies published between 2003 and 2008 reporting on 1105 TAAs using various ankle prostheses. There were no randomized trials available for review; all studies reviewed were level IV evidence. With revision, arthrodesis or amputation as the end point, the authors identified 108 failures (9.8%). The weighted follow-up for all prostheses was 5.2 years. Eight studies provided Kaplan-Meier survivorship analysis ranging from 67% at 6 years to 95.4% as 12 years. Failures were salvaged with revision TAAs in 62% and amputations were rare (1%). Ankle scores improved after TAA in all studies although improvement in ankle ROM was relatively small. The overall failure rate was approximately 10% at 5 years (range of 0% to 32%) with variation between different centers. Superiority of one type of design over another was not supported by the available data. Several limitations were noted regarding the literature reviewed and included surgeon experience, heterogeneity in study design, variable follow-up periods, variable assessment scales, clinical outcomes that were often not validated, methods to assess patient satisfaction were not rigorous, and measures regarding radiograph assessment varied and were often not standardized.

Technology Assessment
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, 2005). Since that time, ECRI updated the complete report in 2007 and more recently in November 2009. ECRI continues to acknowledge that there is a substantial learning curve associated with total ankle replacement. Furthermore, TAA is complex surgery with a potential for high complication rates, surgeons considering performing TAA must have an excellent understanding of anatomy and lower-extremity biomechanics and adequate training in the particular TAA system they intend to use. Furthermore, appropriate patient selection, preoperative planning to ensure correct component size and positioning, and corrections of existing ankle deformities are critical to optimizing the outcomes of TAA.

Professional Societies /Organizations
A position statement by the American Orthopaedic Foot and Ankle Society (AOFAS) was updated in 2009. The AOFAS considers TAA an acceptable and viable alternative to ankle arthrodesis in select patients with ankle arthritis. According to the AOFAS, patients who may benefit from this procedure include adult patients with primary, post-traumatic and rheumatoid arthritis who have moderate or severe pain, loss of mobility, and loss of function of the involved ankle. Additionally, the individual should have completed several months of conservative treatment, should have satisfactory vascular perfusion in the involved extremity, and must have adequate soft-tissue coverage about the ankle that affords a safe surgical approach. In such patients, high-level evidence indicates that TAA safely relieves pain and may provide superior functional results when compared to ankle

fusion. The AOFAS position further indicates that TAA should be performed by board-certified or board eligible allopathic or osteopathic orthopedic surgeons with appropriate training and education (AOFAS, 2009).

In March 2010 the American College of Foot and Ankle Surgeons (ACFAS) published a position statement on total ankle replacement surgery. The position of the ACFA S states, " Total ankle replacement surgery is currently a safe and effective treatment option for select patients with end stage ankle arthritis; studies have shown total ankle replacement surgery improves function, reduces pain, and promotes improved quality of life."

Summary

Evidence in the peer-reviewed, published scientific literature evaluating total ankle arthroplasty (TAA) is primarily in the form of retrospective or prospective case series and joint registry data, with few controlled clinical trials. Generally, the outcomes of these studies demonstrate improvement in pain and function scores following TAA, results that are comparable to ankle arthrodesis in some studies and better in other studies. Data supporting one type of device versus others are lacking. The overall failure rate is approximately 10% at five years; implant survival ranges from 85-90% on average at five years, with survival rates of approximately 75-80% at 8 to 10 years. Nevertheless, 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. Additional long-term clinical studies supporting improved outcomes such as pain relief, functional mobility and durability of the prosthetic device would be helpful in comparing the safety and efficacy of TAA to ankle arthrodesis. However, there is sufficient data in the peer-reviewed published scientific literature, including support from professional societies that for a carefully selected subset of individuals, TAA may be considered a safe and effective alternative to ankle arthrodesis.

Coding/Billing Information

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

Covered when medically necessary when used to report total ankle arthroplasty/replacement:

CPT®* Codes	Description
27700	Arthroplasty, ankle
27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle

HCPCS Codes	Description
C1776	Joint device, implantable
L8699	Prosthetic implant, not otherwise specified

ICD-9-CM Diagnosis Codes	Description
714.0-714.4	Rheumatoid arthritis
715.17	Primary localized osteoarthrosis, ankle and foot
715.27	Secondary localized osteoarthrosis, ankle and foot
715.37	Localized osteoarthrosis not specified whether primary or secondary, ankle and foot
715.97	Osteoarthrosis, unspecified whether generalized or localized, ankle and foot
716.17	Traumatic arthropathy, ankle and foot
716.57	Unspecified polyarthropathy or polyarthritis, ankle and foot
716.67	Unspecified monoarthrtitis, ankle and foot
716.87	Other specified arthropathy, ankle and foot
V43.66	Organ or tissue replaced by other means, joint, ankle

	All codes

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

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