

**Subject: Total Ankle
Arthroplasty/Replacement**
Number: 0285

Effective Date: 2/15/2006
Revision Date: 2/15/2007

INSTRUCTIONS FOR USE

This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2007 Intracorp/CareAllies

Total ankle arthroplasty/replacement is considered experimental, investigational or unproven and thus not medically necessary for any indication.

General Background

Total ankle arthroplasty (TAA) is the process of replacing a diseased ankle with a prosthetic ankle. The procedure is employed as an alternative to ankle arthrodesis for conditions such as severe osteoarthritis, post-traumatic arthritis and rheumatoid arthritis of the ankle. 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. 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 did seem 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. Despite this, there has been a renewed interest in ankle arthroplasty. More recently, authors have proposed 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 (Canale, 2003). These designs differ not only in the bearing surface, but also in 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). Authors agree, however, that further improvement in design of the ankle replacement device is required to improve patient outcomes (Gill, 2004; Rippstein, 2002; Saltzman, 2000).

U.S. Food and Drug Administration (FDA)

Ankle prostheses used for ankle replacement are regulated by the FDA as Class II devices. According to the FDA, at least 10 of these devices have been approved under the FDA 510(k) process since 1977. Some of the devices for ankle replacement frequently reported in the published literature include, but are not limited to:

- Agility™ Total Ankle System (DePuy, Inc., Warsaw, IN), a two-component design
- Scandinavian Total Ankle Replacement (STAR) (Waldemar Link GmbH & Co., Hamburg, Germany), a three-component design
- Buechel-Pappas (BP) Ultra Total Ankle Replacement (Endotec, South Orange, New Jersey), a three-component design
- TNK Ankle (Kyocera Corporation, Kyoto, Japan), a two-component design

The Scandinavian, Buechel-Pappas, and TNK devices are not FDA-approved devices. The Agility Total Ankle System has been approved by the FDA for use in the U.S. In May 2002, the FDA granted 510(k) approval for the Agility Total Ankle System because it was considered substantially equivalent to another device already on the market. 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 510(k) summary stated that the Agility Total Ankle System is substantially equivalent to the Agility Ankle, formerly called the Alvine Ankle. The Agility Total Ankle System is intended for cemented use only and is indicated for patients with a failed previous ankle surgery (FDA, K020541).

Literature Review

A search of the peer-reviewed, published scientific literature reveals insufficient data to allow consistent conclusions in terms of safety and efficacy of total ankle replacements. Most of the published clinical trials are case series and are not well-designed clinical studies. Furthermore, 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. Pain relief, improved functional mobility and long-term durability of the prosthetic device are clinical outcomes useful in comparing safety and efficacy of TAA to ankle arthrodesis.

From 1974 to 1988, 204 primary Mayo (i.e., constrained design) TAA procedures (179 patients) were performed at the Mayo clinic. In an early published study by Kitaoka and Patzer (1996), 143 patients were evaluated (160 arthroplasties) for an average of nine years (range 2–17 years). 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. 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 no longer recommended TAA with the constrained MAYO implant, due to the high rates of complications and reoperations.

Pyeovich 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). 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 concluded 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.

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 authors used the Ankle Osteoarthritis Scale 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 believe talar component subsidence will increase failure over time; however, in conclusion, the results were encouraging and patient satisfaction remained high.

Spirit and associates (2004) reported on 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. 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 $54\% \pm 11.5\%$. 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' final conclusion was 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. All told, the functional outcome of this procedure remains to be seen.

Valderrabano et al. (2004) conducted a prospective study to determine midterm 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. Follow-up evaluation was conducted after an average of 3.7 years and consisted of interview, clinical examination, dynamic pedobarography and radiographic assessments. The average age of the population was 56.1 years. 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 American Orthopedic Foot and Ankle Society hindfoot score from 24.7 points preoperatively to 84.3 points at follow-up. 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 concluded that the results were encouraging; however, their complications and potential problems were higher than previously reported. Further follow-up evaluation is required to determine long-term outcomes.

Sooahoo and Kominski (2005) conducted a cost-effective analysis to evaluate whether currently available literature justifies the emerging use of total ankle arthroplasty and concluded that, "The currently available literature has not yet shown that total ankle arthroplasty predictably results in levels of durability and function that make it cost-effective at this time. However, the reference case of this analysis does demonstrate that total ankle arthroplasty has the potential to be a cost effective alternative to ankle fusion." The reference case assumes that the theoretical functional advantages over ankle fusion will be borne out in future clinical trials.

Stengel et al. (2005) conducted a systematic meta-analysis review of studies exploring the efficacy of three-component total ankle prostheses. 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 endpoint (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 concluded 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. In addition, the performance of ankle arthroplasty compared to ankle fusion, the current reference standard, remains to be defined in a well-designed randomized trial.

In 2006, Kopp et al. retrospectively reviewed the results of total ankle arthroplasty using the Agility 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 nonweightbearing activity in a short-leg cast followed by a removable boot, followed by an additional six weeks of protected nonweightbearing 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 2mm or less in width) or lysis (radiolucency of greater than 2mm) 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. The authors concluded that further long-term studies are needed; however, the intermediate results are promising.

Some authors have reported on the results of non-FDA approved ankle replacement devices such as the Beuchel-Pappas (mobile-bearing design) ankle replacement system and have shown inconsistent results (San Giovanni, et al, 2006; Doets, et al., 2006). These two groups of authors reported the results of their case series of 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 concluded that further clinical trials are 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 a learning curve associated with the surgery. Nonetheless, Doets and colleagues concluded that good results can be achieved with total ankle prosthesis for the treatment of inflammatory joint disease when proper indications are 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 postsurgery. Failure can be related to prosthetic design, position of the prosthesis, and biologic factors. In summary, the authors concluded that early migration patterns may have been related to surgical and tibial fixation techniques.

In a Technology Brief conducted by Hayes (2006), authors evaluated published, peer-reviewed literature evaluating the Agility ankle prosthesis that involved at least one-year follow-up. Hayes concluded the current evidence regarding safety and efficacy is promising but insufficient to support adoption or use at this time.

Professional Societies /Organizations

A position statement of 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. As with all total joint replacements, you should consult an orthopedic surgeon."

Summary

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 and stability of the device and rate of complications, have not been as successful. The available evidence suggests that the lifespan of the device is short-term and therefore not practical for use in younger patients. Many authors 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 are currently no ankle replacements that have shown improved long-term results, and none are currently approved by the U.S. Food and Drug Administration (FDA) for uncemented use. While TAA is supported as a treatment option by the American Orthopedic Foot and Ankle Society (AOFAS), the long-term results of most new designs remain unknown. As a result, further scientific research involving well-designed randomized controlled clinical trials with long-term patient outcome data is needed before the role of TAA can be established.

Coding/Billing Information

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

Experimental/Investigational/Unproven/Not medically necessary:

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

***Note: Experimental, investigational or unproven and not medically necessary when used to report total ankle replacement**

HCPSC Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description
	All codes

***Current Procedural Terminology (CPT®) ©2006 American Medical Association: Chicago, IL.**

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