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Clinical Appropriateness Guidelines

Musculoskeletal

Appropriate Use Criteria: Small Joint Surgery

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA-approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for ongoing services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Small Joint Surgery of the Foot and Ankle

General Requirements and Documentation

The following general requirements apply to all indications except where they differ from the specific requirements. The specific requirements take precedence over any stated general requirement.

These guidelines address foot and ankle procedures when performed on an **elective, non-emergent** basis and not as part of the care of an acute fracture.

The terms in the section provide operational definitions when they are referenced as requirements in the guideline.

Documentation supporting medical necessity and a clearly stated plan of care should be submitted at the time of the request and must include the following components:

Clinical notes describing symptom duration and severity, specific functional limitations related to symptoms, and type and duration of all therapeutic measures provided. If conservative management is not appropriate, the reason must be clearly documented.

Conservative management offered by the provider or other health professionals for this condition(s) should include footwear modification and/or padding/accommodative devices (e.g., foot orthosis) **AND** at least one of the following complementary strategies to reduce inflammation, alleviate pain, and improve function:

- Activity modification
- Anti-inflammatory medications and analgesics
- Corticosteroid injection(s)
- Debridement of associated hyperkeratotic lesions, such as corns or calluses

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

If conservative management is not appropriate, the medical record must clearly document why such an approach is not reasonable.

Reporting symptom severity – Severity of pain and its impact on function are key factors in determining the need for intervention. For this guideline's purposes, significant pain and functional impairment refer to pain rated ≥ 3 on the VAS scale and associated with difficulty performing daily activities, such as walking and wearing reasonable shoes.

Imaging report – The provider shall submit a detailed imaging report for studies obtained within the past 12 months. In the absence of a detailed report, the provider may submit a report from an independent radiologist. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure. Where applicable, radiographic imaging must include weight-bearing anterior-posterior and lateral views of the affected foot.

Imaging reports should describe the presence or absence of subchondral cysts, subchondral sclerosis, periarticular osteophytes, joint subluxation, or avascular necrosis. The degree of joint space narrowing should also be noted. Where applicable, the requesting provider should measure and record the key angular deformity indices in the medical record.

General Recommendations

Tobacco cessation – Adherence to a tobacco cessation program resulting in abstinence from tobacco and nicotine products for at least 6 weeks prior to surgery is strongly recommended.

Diabetes – It is strongly recommended that a patient with a history of diabetes maintain a hemoglobin A1C of 8% or less prior to any joint replacement surgery.

Body Mass Index (BMI) – It is strongly recommended that any patient with a BMI equal to or greater than 40 attempt weight reduction prior to surgery.

Where there are patient-specific modifiable comorbidities that may adversely impact patient reported outcomes or the health status of the patient, a shared decision-making process to discuss these modifiable comorbidities with the patient is strongly recommended and should be documented.

Hallux Rigidus Surgery

Description and Scope

This guideline addresses surgery for hallux rigidus when performed as an **elective, non-emergent** procedure.

Hallux rigidus is a painful arthritis of the first metatarsophalangeal (MTP) joint, which can cause stiffness and progressive loss of motion. It is the most common arthritic condition of the foot. The first MTP joint develops progressive degenerative changes resulting in pain, inflammation, and limited motion. The condition is more prevalent in females than males and has an average age of onset of about 50 years. Over 95% of patients have it bilaterally and two thirds have a positive family history.

A variety of scales have been used to grade the severity of hallux rigidus, although the scales proposed by Hattrup and Johnson and Coughlin and Shurnas are most common. For the purposes of interpretation of this guideline, either scale can be used (see [Table 1](#)) to determine whether hallux rigidus is mild, moderate or severe. Radiographic confirmation of hallux rigidus must include weight-bearing anterior-posterior (ap) and lateral view of the affected foot.

Table 1. Grading Scales for Hallux Rigidus

Radiographic	Clinical	Qualitative	Hattrup and Johnson ¹	Coughlin and Shurnas ²
No radiographic evidence for osteoarthritis	No pain +/- mild stiffness		-	0
Mild-to-moderate osteophyte formation with no joint space involvement	Mild pain maximal with flexion, mild stiffness	Mild	I	1
Moderate osteophyte formation and joint space narrowing; subchondral sclerosis	Moderate-to-severe pain constant at the extremes of motion, moderate-to-severe stiffness	Moderate	II	2
Marked osteophyte formation and loss of the joint space, cystic changes with or without subchondral sclerosis	Nearly constant pain (3), pain throughout the range of motion (including midrange) (4)	Severe	III	3 or 4

1. Hattrup SJ, Johnson KA. Subjective results of hallux rigidus following treatment with cheilectomy. *Clin Orthop Relat Res.* 1988(226):182-91.

2. Coughlin MJ, Shurnas PS. Hallux rigidus. Grading and long-term results of operative treatment. *J Bone Joint Surg Am.* 2003;85(11):2072-88.

After non-surgical intervention, a variety of surgical interventions are available to treat hallux rigidus. Cheilectomy involves removal of excess osteophytes and is done to alleviate osseous impaction of the proximal phalanx and metatarsal head through debridement of the articulating joints. Arthrodesis is the most common treatment for patients with advanced hallux rigidus but carries additional risks including the potential for loss of foot function and joint motion, diminished gait efficiency, failure of fixation, nonunion, and transfer metatarsalgia. Alternatives include resection arthroplasty. More recently, implant arthroplasty of the first MTP joint has been proposed as an alternative to arthrodesis for more advanced hallux rigidus as a way of restoring joint motion.

Clinical Indications

Hallux Rigidus Surgery

Surgery for hallux rigidus (including cheilectomy or osteotomy) is considered medically necessary in skeletally mature patients when **ALL** the following requirements are met:

- Mild/moderate hallux rigidus confirmed by radiography with **EITHER** of the following:
 - Limited and/or painful range of motion of the first MTP joint
 - Activity limiting pain referable to the first MTP joint
- Significant pain and functional impairment of the first MTP joint persist after at least 12 weeks of supervised conservative management or nonhealing ulcer on the dorsum of the great toe
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

First Metatarsophalangeal Joint Arthrodesis

First MTP joint arthrodesis is considered medically necessary in skeletally mature patients when **ALL** the following requirements are met:

- Limited and/or painful range of motion first MTP joint
- Significant pain and functional impairment of the first MTP joint
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Presence of **ONE** of the following:
 - Severe hallux rigidus confirmed by radiography
 - Failed prior hallux valgus/rigidus surgery

First Metatarsophalangeal Joint Arthroplasty

First metatarsophalangeal joint arthroplasty is considered medically necessary in skeletally mature patients when **ALL** the following requirements are met:

- **ONE** of the following implant types* will be used:
 - Total prosthetic replacement arthroplasty with double stemmed silastic implants only
 - Metallic hemiarthroplasty (metatarsal or phalangeal based)
- Limited and/or painful range of motion of the first MTP joint
- Significant pain and functional impairment of the first MTP joint
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Presence of **ONE** of the following:
 - Severe hallux rigidus** confirmed by radiography
 - Failed prior hallux rigidus surgery

*See [Exclusions](#) for a list of excluded implants.

**Resection arthroplasty is an alternative to arthrodesis.

Contraindications

All Hallux Rigidus Procedures

- Active infection of the joint
- Active systemic bacteremia
- Active skin infection
- Inadequate bone stock for osteotomy or arthrodesis
- Inadequate vascular perfusion to the foot

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to, the following:

- Asymptomatic hallux rigidus
- Surgical intervention solely for the purposes of improved cosmesis
- Implant arthroplasty with **ANY** of the following:
 - Ceramic prosthesis including, but not limited to, Moje implant
 - Modular implants including, but not limited to:
 - Metis® prosthesis
 - OsteoMed ReFlexion 1st MTP Implant System
 - ToeMotion with/without HemiCAP® Implant
 - Toefit-Plus™ prosthesis
 - Molded cylindrical implants including, but not limited to, Cartiva® Implant
 - Bioabsorbable implants including, but not limited to, bioabsorbable poly-L-D-lactic acid RegJoint® inter-positional implant
- Metatarsophalangeal joint arthroplasty for any other indications not included here
- Charcot neuroarthropathy

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Hallux Valgus and Bunionette Surgery

Description and Scope

This guideline addresses surgery for hallux valgus when performed as an **elective, non-emergent** procedure.

Hallux valgus is a common deformity of the first ray (great toe) characterized by a lateral deviation of the proximal phalanx at the level of the metatarsal joint. It is frequently associated with a concomitant medial (varus) deviation of the first metatarsal. The result is a bony prominence or “bump” on the medial side of the first metatarsophalangeal joint. This is often referred to as a “bunion” and may be associated with soft tissue swelling and pain. In addition, the articular surface of the first metatarsal may have a valgus (lateral) inclination also contributing to the deformity. As the deformity progresses the sesamoid complex will shift laterally aided by the deforming force of the adductor tendon and the lateral capsule tightens while the medial side attenuates. When conservative management fails, the surgical correction of bony and/or soft tissue hallux valgus is often performed, and over 100 different surgical techniques have been described in the literature. Surgical procedures for hallux valgus include simple bunionectomy, various soft tissue procedures, metatarsal and phalangeal osteotomies, resection arthroplasty, and metatarsophalangeal arthrodesis.

Bunionette deformity, also known as Taylor's bunion, involves the fifth metatarsal head with a painful lateral bony prominence. It is often associated with constrictive footwear causing pain, inflammation, keratosis, and ulceration. When conservative management fails, surgical methods include condylar excision, proximal or distal osteotomies.

For arthrodesis indications, please see the criteria for [hallux rigidus](#).

Clinical Indications

Hallux Valgus Surgery

Hallux valgus surgery is considered medically necessary when **ALL** the following requirements are met:

- Skeletally mature patient
- Significant pain and functional limitation of the first metatarsophalangeal joint and/or presence of a pre-ulcer (e.g., [Wagner](#) grade 0-1) that persists after at least 12 weeks of supervised conservative management **OR** nonhealing ulcer at the site of the bunion or the second toe
- Radiographic confirmation of an elevated hallux valgus angle (HVA) (metatarsophalangeal angle greater than 15 degrees or intermetatarsal angle greater than 9 degrees)
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

First Metatarsophalangeal Joint Arthrodesis for Hallux Valgus

First metatarsophalangeal joint arthrodesis is considered medically necessary for treatment of hallux valgus when **ALL** the following requirements are met:

- Skeletally mature patient
- Significant pain and functional limitation of the first MTP joint and/or presence of a pre-ulcer (e.g., [Wagner](#) grade 0-1) that persists after at least 12 weeks of supervised conservative management **OR** nonhealing ulcer at the site of the bunion or the second toe
- Radiographic confirmation of an elevated hallux valgus angle (HVA), (metatarsophalangeal angle greater than 15 degrees), or intermetatarsal angle (greater than 9 degrees)
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- History of prior hallux valgus correction with recurrence of moderate to severe deformity

- Grade I arthritic change of the first MTP joint (see [Table 1](#) for hallux rigidus grading scales)

Bunionette Surgery

Bunionette surgery is considered medically necessary when **ALL** the following requirements are met:

- Skeletally mature patient
- Significant pain and functional limitation of the fifth MTP joint and/or presence of a pre-ulcer (e.g., [Wagner](#) grade 0-1) that persists after at least 12 weeks of supervised conservative management **OR** nonhealing ulcer at the site of the bunionette or the fourth toe
- Radiographic confirmation of an elevated intermetatarsal angle (greater than 9 degrees) or presence of lateral bony prominence when only simple exostectomy/resection lateral eminence is planned
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

Contraindications

All Hallux Valgus/Bunionette Procedures

- Active infection of the joint
- Active systemic bacteremia
- Active skin infection
- Inadequate bone stock for osteotomy or arthrodesis
- Inadequate vascular perfusion to the foot

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to the following:

- Asymptomatic hallux valgus or bunionette deformity
- Surgical intervention solely for the purposes of improved cosmesis

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Metatarsal Osteotomy

Clinical Indications

Metatarsal osteotomy is considered medically necessary in skeletally mature patients when **ALL** the following criteria are met:

- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Significant pain and functional impairment caused by the metatarsal deformity and/or presence of a pre-ulcer (e.g., [Wagner](#) grade 0-1) that persist after at least 12 weeks of supervised conservative management **OR** non-healing ulcer attributed to the metatarsal deformity
- Physical examination or imaging confirmation of an anatomical difference requiring osteotomy

Contraindications

All Osteotomy Procedures

- Active infection of the joint
- Active systemic bacteremia
- Active skin infection
- Inadequate bone stock for osteotomy or arthrodesis
- Inadequate vascular supply to the foot

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to the following:

- Asymptomatic lesser toe or metatarsal deformities
- Surgical intervention solely for the purpose of improved cosmesis

Lesser Toe Deformities

Description and Scope

This guideline addresses surgery for lesser toe deformities when performed as an **elective, non-emergent** procedure and not as part of the care of an acute fracture.

Deformities of the lesser (two through five) toes are generally known as hammer toe, claw toe, and mallet toe. A related deformity of the great toe is known as a hallux malleus.

Hammer toe is characterized by flexion deformity of the proximal interphalangeal joint of one or more of the lesser four toes. In severe or chronic conditions, it may be associated with either flexion or extension of the distal interphalangeal or hyperextension of the metatarsophalangeal joint. The most commonly affected toe is the second, although multiple toes can be involved. Hammer toes are considered flexible if passively correctable or rigid if not correctable to the neutral position.

Mallet toe is characterized by flexion deformity at the distal interphalangeal joint only.

Claw toe deformity is characterized by flexion deformities of the proximal interphalangeal and distal interphalangeal joints as well as hyperextension at the metatarsophalangeal joint.

The main bony procedures used in the treatment of second hammertoe are excisional arthroplasty and arthrodesis of the proximal interphalangeal joint. Arthrodesis of the proximal interphalangeal joint represents the standard treatment for rigid and structured deformities not suited for manual correction. This procedure is performed by removing the articular surfaces of the proximal and intermediate phalanges. Although many systems such as cannulated screws or absorbable pins have been designed for the fixation of arthrodesis, the K-wire is the most utilized traditional method. Surgical management of lesser toe deformity may also include soft-tissue release, tendon transfer, joint resection, joint fusion, metatarsal shortening, or a combination of procedures.

Clinical Indications

Lesser Toe Deformity Surgery

Lesser toe deformity surgery is considered medically necessary in skeletally mature patients when **ALL** the following criteria are met:

- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Significant pain and functional impairment caused by the lesser toe deformity and/or presence of a pre-ulcer (e.g., [Wagner](#) grade 0-1) that persist after at least 12 weeks of supervised conservative management **OR** non-healing ulcer attributed to the lesser toe deformity
- Physical examination or imaging confirmation of a lesser toe deformity

Contraindications

All Lesser Toe Deformity Procedures

- Active infection of the joint
- Active systemic bacteremia
- Active skin infection
- Inadequate bone stock for osteotomy or arthrodesis

- Inadequate vascular supply to the foot

Exclusions

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to the following:

- Asymptomatic lesser toe deformities
- Surgical intervention solely for the purposes of improved cosmesis

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Ankle Arthritis

Description and Scope

This guideline addresses surgery for ankle osteoarthritis when performed as an **elective, non-emergent** procedure and not as part of the care of an acute fracture.

Ankle osteoarthritis presents in approximately 1% of the world's adult population. The primary cause of ankle osteoarthritis is trauma associated with pain, dysfunction, and impaired mobility. Other causes include rheumatic diseases, gout, hemochromatosis, avascular necrosis, hemophilia, and postinfectious conditions. In the early stages, conservative management may decrease pain and preserve function. Ankle arthrodesis or total ankle arthroplasty may be indicated for advanced cases. Ankle arthrodesis was considered the gold standard treatment in patients with end-stage ankle osteoarthritis until the 1970s, when the first total ankle arthroplasty procedures were described. Although gait efficiency is decreased with ankle arthrodesis, most surgeons still consider it as the procedure of choice to alleviate pain in patients with end-stage ankle osteoarthritis.

Ankle arthrodesis is regarded as a reliable treatment for end-stage ankle arthritis because it yields good results with a low complication rate. A commonly reported risk of ankle arthrodesis is adjacent joint degeneration that occurs more frequently in those with arthritis of the ipsilateral hindfoot and midfoot.

Total ankle arthroplasty was first performed in 1970 as an alternative treatment option to ankle arthrodesis—the gold standard at the time for end-stage ankle degenerative joint disease. Initially, total ankle arthroplasty had high rates of subsidence, loosening, and revision. However, with the advances in implant design such as uncemented implants as well as fixed and mobile-bearing surfaces, total ankle arthroplasty has resulted in improved outcomes.

Clinical Indications

Ankle Arthrodesis

Ankle arthrodesis is considered medically necessary in skeletally mature patients when **ALL** the following criteria are met:

- Radiographic confirmation of Kellgren-Lawrence grade 3 or 4 arthritis of the tibiotalar joint **OR** avascular necrosis of the talus
- Significant pain and functional impairment due to arthritis of the ankle that persist after at least 12 weeks of supervised conservative management (unless radiographs show Kellgren-Lawrence grade 4)
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)

Ankle arthrodesis may also be indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

Total Ankle Arthroplasty

Total ankle arthroplasty is considered medically necessary in skeletally mature patients when **ALL** the following criteria are met:

- Radiographic confirmation of Kellgren-Lawrence grade 3 or 4 arthritis of the tibiotalar joint **OR** avascular necrosis of the talus without collapse
- Significant pain and functional impairment due to arthritis of the ankle that persist after at least 12 weeks of supervised conservative management (unless radiographs show Kellgren-Lawrence grade 4)
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Device is FDA approved

Total ankle arthroplasty may also be indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

Revision Total Ankle Arthroplasty

Revision total ankle arthroplasty is considered medically necessary in skeletally mature patients when **ALL** the following criteria are met:

- Aseptic loosening
- Radiographic confirmation of implant problem and significant pain and functional impairment due to the identified implant problem
- Documentation of adequate lower extremity vascular perfusion (e.g., strong, palpable pedal pulses)
- Device is FDA approved
- Reconstruction after periprosthetic infection with lab and clinical confirmation of infection resolution
- **Ongoing disabling pain or implant loosening** with recent evaluation for prosthetic joint infection, including:
 - Preoperative investigation using serologic testing and
 - **IF** there are abnormal laboratory findings, at least **ONE** of the following:
 - Synovial fluid testing, such as leukocyte count and neutrophil percentage, aerobic and anaerobic bacterial cultures, leukocyte esterase, alpha defensin testing (Synovasure®), synovial fluid CRP, synovial fluid PCR for bacteria
 - Intraoperative plan for histopathology and/or aerobic and anaerobic tissue cultures using implant sonication for cultures or PCR

Contraindications

Ankle Arthrodesis

- Active infection of the joint
- Active systemic bacteremia
- Active skin infection

Ankle Arthroplasty Procedures

- Intra-articular corticosteroid injection within the past 6 weeks in the joint being replaced
- Active infection of the joint
- Active systemic bacteremia
- Charcot neuroarthropathy
- Active skin infection
- Inadequate bone stock
- Severe anatomic deformity in adjacent ankle structures, including hindfoot, forefoot and knee joint
- Prior surgery or injury that has adversely affected ankle bone quality
- Extensive avascular necrosis of the talar dome
- Malalignment (e.g., varus or valgus deformity greater than 15 degrees) not correctable by surgery

- Inadequate vascular supply to the foot/ankle
- Absence of the medial or lateral malleolus or both
- Severe osteoporosis, osteopenia, or other conditions resulting in poor bone quality, as this may result in inadequate bony fixation
- High demand sports activities (e.g., contact sports, jumping)
- Immunosuppressive therapy
- Insufficient ligament support that cannot be repaired with soft tissue stabilization
- Insufficient musculature such that proper component positioning or alignment is not possible
- Neurologic impairment with dynamic muscular imbalance across the ankle joint
- Prior fusion of the ankle
- Psychiatric problems that hinder adequate cooperation during perioperative period

Exclusions for all ankle procedures

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to the following:

- Asymptomatic ankle osteoarthritis
- Surgical intervention solely for the purposes of improved cosmesis
- Non-FDA approved total ankle replacement devices

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Medical necessity reviews are initiated by submitting the correct AMA CPT codes. Specific CPT codes for services should be used when available. The submitted codes must accurately identify the service or procedure to be performed. If no such code exists, contact the health plan directly and report the service or procedure using the appropriate unlisted procedure or Not Otherwise Classified (NOC) code (which often ends in 99). Do not submit a code that is "close to" the procedure performed in lieu of an unlisted code. Correct coding demands that the code reported is appropriate for the service provided (i.e., a code that most accurately represents the service provided), and not a code that is similar but represents another service. (*CPT® Assistant*, December 2010) Nonspecific or NOC codes may be subject to additional documentation requirements and review.

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27702	Arthroplasty, ankle; with implant (total ankle)
27703	Arthroplasty, ankle; revision, total ankle
27704	Removal of ankle implant
27870	Arthrodesis, ankle, open
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)
28285	Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)

28286	Correction, cock-up fifth toe, with plastic skin closure (eg, Ruiz-Mora type procedure)
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28292	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with resection of proximal phalanx base, when performed, any method
28295	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with proximal metatarsal osteotomy, any method
28296	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with distal metatarsal osteotomy, any method
28297	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with proximal phalanx osteotomy, any method
28299	Correction, hallux valgus with bunionectomy, with sesamoidectomy when performed; with double osteotomy, any method
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal
28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each
28310	Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe
28315	Sesamoidectomy, first toe (separate procedure)
28750	Arthrodesis, great toe; metatarsophalangeal joint

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

Appendix

Wagner classification of diabetic foot ulcers

Grade	Description
0	Skin intact but bony deformities lead to "foot at risk"
1	Superficial ulcer
2	Deeper, full thickness extension
3	Deep abscess formation or osteomyelitis
4	Partial gangrene of forefoot
5	Extensive gangrene

History

Status	Review Date	Effective Date	Action
Revised	04/21/2025	11/15/2025	Independent Multispecialty Physician Panel (IMPP) review. Revised Clinical Appropriateness Framework to address unlisted procedures and post-service authorization. General criteria – lowered VAS pain rating threshold from 4 to 3. Hallux Rigidus Surgery – added criterion for nonhealing ulcer on dorsum of great toe. Revision Total Ankle Arthroplasty – added criteria related to periprosthetic joint infection. Total Ankle Arthroplasty – added contraindication for “intra-articular corticosteroid injection within the past 6 weeks in the joint being replaced.” Minor clarifications in multiple sections.
Revised	04/15/2024	11/17/2024	IMPP review. First MTP joint arthrodesis and first MTP joint arthroplasty: removed 3-month requirement for conservative management. For first MTP joint arthroplasty, added allowance for failed prior hallux rigidus surgery. Ankle arthrodesis and total ankle arthroplasty – removed requirement for conservative management when there is severe osteoarthritis. Revision total ankle arthroplasty – added requirement for reconstruction after the management of periprosthetic infection. Added required language to General Clinical Guideline per new Medicare regulations. Updated references.
Updated	n/a	01/01/2024	Annual CPT code update. Description changes for 28292, 28295, 28296, 28297, 28298, 28299.
Revised	04/12/2023	11/05/2023	IMPP review. Procedures for hallux rigidus, hallux valgus, bunionette and lesser toe deformities – removed poor wound healing as a contraindication. Hallux valgus surgery – added allowance for pre-ulcer and criterion for simple exostectomy/resection medial eminence. Separated bunionette surgery indications from hallux valgus surgery; added indication for first MTP joint arthrodesis. Separated metatarsal osteotomy criteria into a standalone indication; added exclusion for improved cosmesis. Ankle arthritis – new indication for revision total ankle arthroplasty. Ankle arthroplasty – removed severe ankle deformity and peripheral neuropathy as contraindications. Added references. Added guidance for correct coding to code section.
Revised	05/09/2022, 11/11/2021	09/11/2022	IMPP review. Removed requirement for 6 months of symptoms from all indications. For Ankle Arthritis indications, reduced conservative management requirement to 3 months. Added peripheral neuropathy/Charcot joint exclusion for hallux rigidus surgery. In contraindications (all procedures), removed “with non-healing ulcerative wounds” for peripheral vascular disease.
Revised	11/11/2021	06/12/2022	IMPP review. New indication for first metatarsophalangeal joint arthroplasty with criteria for select implants. Hallux rigidus surgery exclusions: clarified specific types of excluded implants; excluded metatarsophalangeal joint arthroplasties for any other indications; removed exclusion for percutaneous osteotomy. Hallux valgus/bunionette: removed exclusion for implant arthroplasties. Lesser toe deformities: removed exclusions for implant arthroplasties and intramedullary fixation devices.
Revised	12/03/2020	03/14/2021	IMPP review. Clarified requirements for imaging reports. Removed radiographic requirement for confirmation of lesser toe deformities. Ankle arthrodesis and total ankle arthroplasty added as new indications for revision of failed previous reconstructions. Removed total ankle arthroplasty requirements for adjacent joint or inflammatory arthritis. Clarified contraindications only apply to total ankle arthroplasty.
Created	05/11/2020	11/01/2020	Original effective date. IMPP review.