

Podiatry

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Bunionectomy (MCG ORG: S-260 ISC, 30th Edition)
- Foot: Transmetatarsal Amputation (MCG ORG: S-500 ISC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
28292	Correction, hallux valgus (bunionectomy) with sesamoidectomy, when performed; with resection of proximal phalanx base
28295-28299	Correction, hallux valgus (bunionectomy) with various osteotomy and resection techniques, including proximal metatarsal and double osteotomy
0Q8N0ZZ, 0Q8P0ZZ, 0QQN0ZZ (and related)	Division and repair of metatarsal/tarsal structures for hallux valgus correction (ICD-10-PCS procedure)
28800	Amputation, foot; transmetatarsal
28805	Amputation, foot; transmetatarsal at metatarsophalangeal joint, with related soft tissue management
0Y6M0Z4, 0Y6N0Z4 (and related)	Detachment at foot, transmetatarsal level (ICD-10-PCS procedure)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding podiatry and foot surgery services, including bunionectomy for symptomatic hallux valgus and transmetatarsal amputation for limb-threatening foot pathology, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of foot surgery services and to determine when such services are medically necessary.

Foot disease in the Medicare Advantage population spans elective correction of painful deformity through limb salvage for diabetic foot infection, peripheral arterial disease, and gangrene, the latter carrying high amputation and mortality risk. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary limb-preserving surgery and inappropriate approval of elective procedures performed without adequate trial of conservative management.

Potential Clinical Harms:

Bunionectomy: Inappropriate denial of bunionectomy for a symptomatic bunion that causes severe pain, ulceration at the metatarsophalangeal joint, gait abnormality, or inability to wear fitted shoes, after failure of nonoperative therapy, could prolong disabling pain, progressive deformity,

and skin breakdown. In an elderly population, untreated painful deformity contributes to reduced mobility, deconditioning, and falls risk.

Transmetatarsal amputation: Inappropriate denial of transmetatarsal amputation for a foot ulcer with severe infection, gangrene, osteomyelitis, ischemic necrosis, severe trauma, malignancy, severe burn, or frostbite could allow ascending infection, sepsis, and the need for a higher and more disabling amputation. Delay of indicated foot-level amputation in diabetic and vascular patients is associated with progression to below-knee or above-knee amputation and increased mortality.

Clinical Benefits:

Bunionectomy: MCG criteria provide validated indications drawn from an orthopedic surgery textbook and a narrative review, reserving bunionectomy for a symptomatic bunion causing severe symptoms that have not responded to nonoperative therapy such as shoe modification, bunion shield, and splinting. By requiring documented failure of conservative measures, the criteria directly counter the harm of prolonged disabling deformity while avoiding nonindicated elective surgery, and support appropriate ambulatory-level care.

Transmetatarsal amputation: MCG criteria specify the limb-threatening indications for transmetatarsal amputation, including foot ulcer with severe infection, gangrene, osteomyelitis, ischemic necrosis, trauma, malignancy, burn, and frostbite, citing surgical evidence and specialty society guidance. This directly addresses the harm of ascending infection, sepsis, and progression to higher amputation identified above, while the guideline supports appropriate inpatient-level care with a goal length of stay of 3 days postoperative; analysis of national hospital discharge data shows 31% of patients undergoing transmetatarsal amputation were discharged in 3 days or less.

Reduction of unwarranted variation and overutilization: MCG criteria also identify circumstances where a less invasive alternative is appropriate (e.g., continued nonoperative management for a bunion that has not been adequately trialed, wound care and revascularization where limb salvage without amputation remains feasible), reducing unnecessary surgical exposure in this population. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current surgical specialty society guidelines and high-quality evidence. Use of these criteria ensures patients receive the most clinically appropriate level of care, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for specific podiatry and foot surgery services, including bunionectomy and transmetatarsal amputation. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., severity of symptomatic deformity and required trial of conservative management for bunionectomy, or the infectious, ischemic, and traumatic indications for foot-level amputation) required to distinguish indicated from nonindicated procedures and inpatient-appropriate from ambulatory-appropriate care.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard

- Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For bunionectomy and transmetatarsal amputation, no specific NCD or LCD fully establishes clinical procedural thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation. Where applicable LCDs address foot surgery, MCG criteria are used to supplement and do not replace them.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for these specific foot surgery services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of bunionectomy for symptomatic hallux valgus after failure of nonoperative therapy;
- Medical necessity and appropriateness of transmetatarsal amputation for limb-threatening foot infection, ischemia, trauma, malignancy, and related conditions;
- Appropriate level of care (ambulatory versus inpatient), expected clinical course, and identification of complications that warrant inpatient admission or stay extension following foot surgery.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of foot surgery services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure surgical services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Bunionectomy (MCG ORG: S-260 ISC)

Bunionectomy is the surgical correction of a symptomatic bunion (hallux valgus) and is indicated when the deformity causes severe symptoms such as pain, ulceration at the metatarsophalangeal joint, gait abnormalities, or difficulty wearing fitted shoes, and when nonoperative therapy has been tried and failed. The procedure is treated as ambulatory, recognizing that an ambulatory procedure may include one postoperative overnight stay depending on payer and regulatory definitions, including the CMS Two-Midnight Rule.

Foot: Transmetatarsal Amputation (MCG ORG: S-500 ISC)

Transmetatarsal amputation is a foot-level amputation indicated for treatment of foot ulcer with severe infection, gangrene, or osteomyelitis, as well as severe trauma, malignancy, severe burn, severe frostbite, and ischemic necrosis. It is performed to control infection and salvage maximal functional limb length. The guideline carries a goal length of stay of 3 days postoperative, reflecting inpatient-level perioperative care.

Evidence Summary

Bunionectomy (MCG ORG: S-260 ISC)

The evidence for the clinical indications in this guideline includes 10 published peer-reviewed articles, 1 Cochrane systematic review, and 2 book sections. Key evidence includes:

- An orthopedic surgery textbook and a narrative review support bunionectomy for patients with a bunion that causes severe symptoms (e.g., pain or ulceration at the metatarsophalangeal joint, gait abnormalities, or difficulty wearing fitted shoes) that have not responded to nonoperative management.
- The criteria require that nonoperative therapy, such as shoe modification, bunion shield, and splinting, has been tried and failed before bunionectomy is considered appropriate.

Foot: Transmetatarsal Amputation (MCG ORG: S-500 ISC)

The evidence for the clinical indications in this guideline includes 14 published peer-reviewed articles, 1 specialty society or other evidence-based guideline, and 3 book sections. Key evidence includes:

- Surgical evidence and specialty society guidance support transmetatarsal amputation for foot ulcer with severe infection, gangrene, or osteomyelitis, where foot-level amputation is required to control infection and preserve functional limb length.
- Additional supported indications include severe trauma, malignancy, severe burn, severe frostbite, and ischemic necrosis (e.g., secondary to vasoconstrictor therapy, warfarin therapy, or arterial line complications).
- Analysis of national hospital discharge data shows 31% of hospitalized patients with a principal procedure of transmetatarsal amputation were discharged in 3 days or less, supporting the MCG goal length of stay of 3 days postoperative.

Rationale (from MCG)

Use of these MCG care guidelines helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate setting for foot surgery. The evidence-based clinical criteria assist the clinician in the decision to appropriately perform a procedure and to determine the appropriate level of care, including, for transmetatarsal amputation, identification of complex factors that make it reasonable to expect a necessity for hospital care across 2 or more midnights and CMS Two-Midnight Rule exceptions for Medicare enrollees. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 15 (Covered Medical and Other Health Services)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5

- Medicare Coverage Determinations: Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

References with Citation Summary -- Bunionectomy (MCG ORG: S-260 ISC, 30th Edition)

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References with Citation Summary -- Foot: Transmetatarsal Amputation (MCG ORG: S-500 ISC, 30th Edition)

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