Orthopedics

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Knee Arthroplasty, Total (MCG ORG: S-700 ISC, 30th Edition)
- Facet Joint Injection (MCG ORG: A-0695 AC, 30th Edition)
- Epidural Corticosteroid Injection (MCG ORG: A-0225 AC, 30th Edition)
- Knee MRI (MCG ORG: A-0052 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486, 27487	Revision of total knee arthroplasty, one or both components
0SRC0J9, 0SRD0J9 (and related)	Replacement of knee joint with synthetic substitute (ICD-10-PCS procedure)
64490-64495	Paravertebral facet joint or facet joint nerve injection, cervical/thoracic and lumbar/sacral, with image guidance
0213T-0218T	Paravertebral facet joint injection with ultrasound guidance (emerging technology codes)
62320-62323	Injection of diagnostic or therapeutic substance into the epidural space, cervical/thoracic and lumbar/sacral, with or without imaging guidance
64479-64484	Transforaminal epidural injection of anesthetic and/or steroid, cervical/thoracic and lumbar/sacral, including each additional level
73721-73723	Magnetic resonance imaging, any joint of lower extremity (knee), without contrast, with contrast, or without followed by with contrast
77021	Magnetic resonance guidance for needle placement (e.g., for biopsy, aspiration, injection)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding orthopedic services, including total knee arthroplasty for advanced knee disease, facet joint injection and epidural corticosteroid injection for spinal pain, and knee magnetic resonance imaging for evaluation of internal derangement and other knee 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 orthopedic services and to determine when such services are medically necessary.

Musculoskeletal disease and spinal pain are leading sources of disability, procedural utilization, and variation in the Medicare Advantage population. These services range from definitive joint replacement to diagnostic and therapeutic spinal injections and advanced imaging, each with distinct indications and alternatives. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary services and inappropriate approval of procedures performed without adequate indication or trial of conservative management.

Potential Clinical Harms:

Total knee arthroplasty: Inappropriate denial of total knee arthroplasty for symptomatic degenerative joint disease with disabling pain, functional disability, and significant radiographic arthritis, after failure of nonoperative management, could prolong immobility, deconditioning, falls risk, and loss of independence in an elderly population. Denial of arthroplasty for posttraumatic joint destruction, osteonecrosis unamenable to joint-preserving surgery, or limb salvage for malignancy could allow progressive joint destruction and permanent disability.

Facet joint injection: Inappropriate denial of diagnostic facet joint or medial branch block in a patient with chronic spinal pain who is a candidate for facet neurotomy could prevent confirmation of the pain generator, leading to either an unguided therapeutic neurotomy or continued unmanaged chronic pain and its associated functional and psychological harms.

Epidural corticosteroid injection: Inappropriate denial of epidural corticosteroid injection for cervical or lumbar radicular pain that has failed noninvasive treatment could prolong radicular pain and neurologic symptoms, and may push patients toward earlier surgery or escalating opioid use when a less invasive intervention was appropriate.

Knee MRI: Inappropriate denial of knee MRI for suspected ligament, meniscal, or tendon injury, suspected infection, neoplasm evaluation, or unexplained localized knee pain could delay diagnosis of a surgically correctable or oncologic condition, allowing progression and a worse functional or survival outcome.

Clinical Benefits:

Total knee arthroplasty: MCG criteria provide validated indications drawn from an orthopedic surgery textbook, a specialty society guideline, and narrative reviews, supporting total knee arthroplasty for symptomatic degenerative joint disease with disabling pain and functional disability supported by significant radiographic findings, as well as posttraumatic destruction, osteonecrosis, and limb salvage. By tying the procedure to these specific indications and to documented failure of nonoperative management, the criteria directly counter the harms of prolonged disability and progressive joint destruction identified above, while supporting appropriate ambulatory-level care: analysis of Medicare procedure data shows 87% of patients undergoing total knee arthroplasty were discharged the day of or the day after surgery.

Facet joint injection: MCG criteria require diagnostic block to confirm the facet joint as the source of spinal pain in patients who are candidates for facet neurotomy, with chronic spinal pain of at least 3 months' duration and failure of nonoperative management. Evidence demonstrates at least moderate certainty of at least moderate net benefit for this diagnostic use, directly countering the harm of unguided neurotomy by ensuring the pain generator is confirmed before a therapeutic procedure is performed.

Epidural corticosteroid injection: MCG criteria reserve epidural corticosteroid injection for cervical or lumbar radicular pain after failure of noninvasive treatment, in the absence of coagulopathy, local malignancy, or infection. The supporting evidence, including a systematic review and meta-analysis of randomized trials, establishes a net benefit for radicular pain, directly addressing the harm of prolonged radicular symptoms and premature escalation to surgery or opioids identified above.

Knee MRI: MCG criteria apply diagnostic accuracy evidence demonstrating at least moderate certainty of at least moderate net benefit, recognizing MRI as a superior imaging modality for the knee due to excellent spatial resolution and tissue contrast across bone, joint, ligament, tendon,

infection, and neoplasm indications. Appropriate use of these criteria directly mitigates the harm of delayed diagnosis of surgically correctable or oncologic knee conditions identified above.

Reduction of unwarranted variation and overutilization: MCG criteria also identify circumstances where a less invasive or conservative alternative is appropriate (e.g., continued nonoperative management before arthroplasty, physical therapy and pharmacotherapy before spinal injection, and reservation of advanced imaging for indicated presentations), reducing unnecessary procedural and imaging 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 and thresholds drawn directly from current orthopedic and pain medicine 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 orthopedic services, including total knee arthroplasty, facet joint injection, epidural corticosteroid injection, and knee MRI. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., radiographic severity and failed conservative management for arthroplasty, dual diagnostic block requirements for facet injection, radicular pain and treatment-failure criteria for epidural injection, and the specific clinical presentations warranting knee MRI) required to distinguish indicated from nonindicated services 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 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (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 total knee arthroplasty, facet joint injection, epidural corticosteroid injection, and knee MRI, 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 spinal injections or advanced imaging, 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 orthopedic 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 total knee arthroplasty for degenerative, posttraumatic, and other qualifying knee conditions after failure of nonoperative management;
- Medical necessity and appropriateness of diagnostic facet joint injection in candidates for facet neurotomy, and of epidural corticosteroid injection for radicular pain after failed noninvasive treatment;
- Medical necessity and appropriateness of knee MRI for the specific bone, joint, soft-tissue, infectious, and neoplastic indications described;
- Appropriate level of care (ambulatory versus inpatient), expected clinical course, and identification of complications that warrant inpatient admission or stay extension following arthroplasty.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of orthopedic services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure surgical, procedural, and imaging 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

Knee Arthroplasty, Total (MCG ORG: S-700 ISC)

Total knee arthroplasty is the surgical replacement of the knee joint with a prosthesis and is indicated for symptomatic degenerative joint disease, failure of previous osteotomy, posttraumatic joint destruction, distal femur or tibial plateau fracture in osteoporotic patients, limb salvage for malignancy, congenital deformity, hemophilic arthropathy, tenosynovial giant cell tumor with joint destruction, osteonecrosis unamenable to joint-preserving surgery, and revision of previous arthroplasty. 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.

Facet Joint Injection (MCG ORG: A-0695 AC)

Facet joint injection, including medial branch nerve block and intra-articular injection, is an ambulatory procedure used primarily as a diagnostic block to confirm the facet joint as the source of spinal pain in patients who are candidates for facet neurotomy. Dual diagnostic blocks are necessary to diagnose facet pain. Indications require chronic spinal pain of at least 3 months' duration and failure of nonoperative management.

Epidural Corticosteroid Injection (MCG ORG: A-0225 AC)

Epidural corticosteroid injection is an ambulatory procedure indicated for cervical or lumbar radicular pain after failure of noninvasive treatment, in the absence of coagulopathy or high

bleeding risk, local malignancy, or local or systemic infection. It is used to reduce radicular pain and may defer or avoid the need for surgical intervention.

Knee MRI (MCG ORG: A-0052 AC)

Knee magnetic resonance imaging is an ambulatory diagnostic study indicated for evaluation of bone anatomy or structural defects, cancer or neoplasm, known or suspected infection, joint anatomy or structural defects, ligament/muscle/tendon injury, localized knee pain, patellar instability, peripheral neuropathy, and postoperative assessment. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Knee Arthroplasty, Total (MCG ORG: S-700 ISC)

The evidence for the clinical indications in this guideline includes 20 published peer-reviewed articles, 1 specialty society or other evidence-based guideline, and 1 book section. Key evidence includes:

- For symptomatic degenerative joint disease (e.g., disabling pain, functional disability) supported by significant radiographic findings of arthritis, an orthopedic surgery textbook, a specialty society guideline, and narrative reviews support total knee arthroplasty when patients have failed appropriate nonoperative management.
- Additional supported indications include failure of previous proximal tibial or distal femoral osteotomy, posttraumatic joint destruction, fracture in osteoporotic patients, limb salvage for malignancy, hemophilic arthropathy, tenosynovial giant cell tumor with joint destruction, and osteonecrosis unamenable to joint-preserving surgery.
- Analysis of procedure data for a Medicare-insured population shows 87% of patients undergoing total knee arthroplasty were discharged the day of or the day after surgery, supporting ambulatory-level care.

Facet Joint Injection (MCG ORG: A-0695 AC)

The evidence for the clinical indications in this guideline includes 27 published peer-reviewed articles, 1 specialty society or other evidence-based guideline, and 1 Cochrane systematic review. Key evidence includes:

- For diagnostic block, evidence demonstrates at least moderate certainty of at least moderate net benefit. The goal of facet joint injection is to diagnose facet joint pain and determine whether a patient is a candidate for facet neurotomy.
- Controlled diagnostic block evidence supports the requirement for dual diagnostic blocks to diagnose facet pain, with the confirmatory block warranted when the first block produced 80% or greater relief of primary pain for a duration consistent with the anesthetic agent used.

Epidural Corticosteroid Injection (MCG ORG: A-0225 AC)

The evidence for the clinical indications in this guideline includes 39 published peer-reviewed articles, 3 specialty society or other evidence-based guidelines, and 1 Cochrane systematic review. Key evidence includes:

- For cervical radicular pain, evidence demonstrates a net benefit, supported in part by a systematic review and meta-analysis of randomized trials, justifying epidural corticosteroid injection after failure of noninvasive treatment.
- For lumbar radicular pain, the criteria require failure of noninvasive treatment (e.g., NSAIDs, exercise, physical therapy, spinal manipulation) and absence of coagulopathy, local malignancy, and infection before injection is appropriate.

Knee MRI (MCG ORG: A-0052 AC)

The evidence for the clinical indications in this guideline includes 134 published peer-reviewed articles, 13 specialty society or other evidence-based guidelines, and 5 book sections. Key evidence includes:

- For bone anatomy and structural defect evaluation, evidence demonstrates at least moderate certainty of at least moderate net benefit. MRI is a superior imaging modality for the knee due to its excellent spatial resolution and tissue contrast.
- Specialty society guidance supports knee MRI across the range of listed indications, including ligament, meniscal, and tendon injury, suspected infection, neoplasm evaluation and staging, and postoperative assessment of cartilage and ligament repair.

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 orthopedic surgical, procedural, and imaging services. For the arthroplasty guideline, the evidence-based clinical criteria assist the clinician in the decision to appropriately perform the procedure and to determine the appropriate level of care, including 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. For the injection and imaging guidelines, the criteria help the clinician decide when a diagnostic or therapeutic procedure or advanced imaging study is appropriate, including the requirement for failed conservative management where applicable. 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 (total knee arthroplasty); 42 CFR 419.22; 42 CFR 422.101 (facet joint injection, epidural corticosteroid injection, and knee MRI)
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- 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

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