Hyaluronic Acid, Intra-Articular Injection

ACG: A-0306 (AC)
Link to Codes

MCG Health
Ambulatory Care
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Clinical Indications

- Current Role Remains Uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See the Inconclusive or Non-Supportive Evidence section for more detailed analysis of the evidence base.(1)(2)(3)(4)(5)(6)(7)(8)(9)(10)(11)

Alternatives

- Alternatives include(9)(23)(29):
  - Cognitive behavioral therapy
  - For osteoarthritis:
    - Brace. See Knee Braces AC for further information.
    - Osteoarthritis rehabilitation. See Osteoarthritis Rehabilitation AC for further information.
    - Pharmacotherapy (eg, acetaminophen, anti-inflammatory medications)
  - Patient education in self-management and exercise
  - Physical therapy

Evidence Summary

Background

Hyaluronic acid is a viscous solution hypothesized to restore rheologic properties of the synovial fluid of an osteoarthritic joint, with the goal of improving the ability of the joint to absorb shock, dissipate energy, and move more freely.(12)(13)(14)(15)(16) **(EG 2)**

Inconclusive or Non-Supportive Evidence

The evidence for the recommendations found in this guideline includes 30 published peer reviewed articles, 6 specialty society or other evidence-based guidelines, and 1 Cochrane systematic review.

For acute sprain of the ankle, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A study randomized 158 competitive athletes to receive either intra-articular hyaluronic acid or placebo, as well as standard care consisting of rest, ice, compression, and elevation. As compared with placebo,

active injection resulted in significantly shorter time to pain-free and disability-free return to sport (11 days vs 17 days), as well as reduced pain, improved satisfaction, and fewer recurrent ankle sprains. Further studies are needed to confirm these results.(17) **(EG 1)**

For adhesive capsulitis of the shoulder, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A randomized study assigned 68 patients with adhesive capsulitis of the shoulder to either intra-articular hyaluronic acid or corticosteroids; after 12 weeks, improvements in pain and range of motion were comparable in each group, and longer-term follow-up was not performed; confirmatory data from larger studies are required.(18) **(EG 1)**

For osteoarthritis of the ankle, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review including 7 randomized controlled trials of intra-articular hyaluronic acid for ankle osteoarthritis found no evidence to support the use of hyaluronic acid as a treatment. The authors recommend against its use in practice until future high-quality studies find evidence of efficacy.(6) **(EG 1)**

For osteoarthritis of the first metatarsophalangeal joint, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A randomized placebo-controlled trial of 151 patients reported that hyaluronic acid injection was no more effective in reducing symptoms than a placebo.(19) **(EG 1)**

For osteoarthritis of the hip, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 8 randomized controlled trials (807 patients) evaluating the efficacy of hyaluronic acid for hip osteoarthritis found no difference in pain scores among patients treated with intra-articular hyaluronic acid, corticosteroid, platelet-rich plasma, or saline placebo. The authors concluded that hyaluronic acid could not be recommended for hip osteoarthritis.(7) **(EG 1)** A review article and a systematic review and meta-analysis found that either there was no significant difference in effectiveness between hyaluronic acid and placebo in patients with hip osteoarthritis or, if there was a statistically significant improvement, its clinical significance was likely to be small; neither article could recommend the routine use of this intervention until larger randomized studies confirm its effectiveness.(20)(21) **(EG 1)** An evidence-based subspecialty clinical practice guideline states that strong evidence does not support the use of intra-articular hyaluronic acid because it does not perform better than placebo for pain, stiffness, or function in patients with symptomatic osteoarthritis of the hip.(22) **(EG 2)** A specialty society guideline makes a strong recommendation against intra-articular hyaluronic acid for hip osteoarthritis based on the absence of benefit demonstrated in clinical trials.(9) **(EG 2)** Another specialty society guideline recommends education, exercise programs, and nonselective NSAIDs for the nonsurgical management of hip osteoarthritis.(23) **(EG 2)**

For osteoarthritis of the knee, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Systematic reviews and meta-analyses have concluded that evidence does not support the use of intra-articular hyaluronic acid for osteoarthritis of the knee because patient benefit was not clinically meaningful as assessed by outcomes involving pain relief or functional improvement.(5)(8)(24)(25)(26) **(EG 1)** A meta-analysis of 12 randomized controlled trials (1794 patients) comparing intra-articular hyaluronic acid and intra-articular corticosteroids for knee osteoarthritis found, at 1 month post procedure, that intra-articular corticosteroids were associated with improved visual analog scale scores for pain. At 3 months post procedure, there was no difference between the groups in visual analog scale scores or Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores; at 6 months post procedure, intra-articular hyaluronic acid was associated with improved visual analog scale and WOMAC scores compared with intra-articular corticosteroids. However, intra-articular hyaluronic acid was associated with more treatment-related adverse events compared with intra-articular corticosteroids.(27) **(EG 1)** A systematic review of 18 randomized trials evaluating intra-articular hyaluronic acid, particularly in elderly patients, was unable to draw definitive conclusions as to whether improvements in function were clinically relevant or impacted the need for total knee replacement; however, few serious adverse events were noted.(4) **(EG 1)** A double-blind randomized controlled study of 196 patients with mild to moderate knee arthritis found, at 6-month follow-up, that 3 intra-articular injections of hyaluronic acid (at weekly intervals) resulted in similar improvement in pain and functional scores compared with placebo.(28) **(EG 1)** A specialty society clinical practice guideline used stringent selection criteria to identify 17 high-strength and 11 moderate-strength studies that assessed the impact of hyaluronic acid injection for treatment of symptomatic osteoarthritis of the knee. Meta-analysis showed that, although there were statistically significant treatment effects for WOMAC pain, function, and stiffness subscale scores, none of the improvements were thought to be clinically important benefits; a moderate recommendation against the use of hyaluronic acid for this indication was issued.(29) **(EG 2)** Another specialty society guideline makes a conditional recommendation for intra-articular hyaluronic acid for knee osteoarthritis based on expert experience in the absence of direct supportive evidence from randomized controlled trials.(23) **(EG 2)** A specialty society guideline, based on a review of randomized controlled trials and systematic reviews, conditionally recommends against intra-articular hyaluronic acid for knee osteoarthritis, noting that the best available evidence failed to demonstrate a benefit.(9) **(EG 2)** Other specialty society practice guidelines have endorsed the use of intra-articular hyaluronic acid for knee osteoarthritis, while acknowledging that evidence for this indication remains inconsistent and controversial, suggesting that more individualized data should be accumulated to help predict which patients may benefit most from such therapy.(10)(11) **(EG 2)**

For osteoarthritis of the shoulder, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A meta-analysis of 2120 patients from 19 randomized controlled trials reported significant improvement in pain and functional scores, but not shoulder range of motion, after intra-articular hyaluronic acid injection; in comparison with steroid injection, improvement was modestly better with hyaluronic acid injection. However, the authors were concerned with significant heterogeneity and other quality issues across all studies, and they recommended that additional studies be performed.(30) **(EG 1)** A subsequent double-blind randomized placebo-controlled study including 300 patients with glenohumeral osteoarthritis found no clinically significant advantage from hyaluronic acid derivatives.(31) **(EG 1)** For shoulder impingement,

randomized controlled trials have not demonstrated clinical benefit as compared with corticosteroid injections or placebo.(32)(33) **(EG 1)** A specialty society clinical practice guideline strongly recommends against the use of hyaluronic acid in the treatment of glenohumeral joint osteoarthritis based on strong evidence from high-quality studies demonstrating no benefit from this treatment.(34) **(EG 2)**

For osteoarthritis of the trapeziometacarpal joint, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 10 randomized trials including 673 patients with trapeziometacarpal osteoarthritis compared intra-articular injection with either corticosteroid or another agent (hyaluronic acid, platelet-rich plasma, bupivacaine, hypertonic dextrose, or normal saline) and found, in 7 studies including hyaluronic acid, no difference in pain or functional outcomes (grip and tip pinch strength) between corticosteroids and hyaluronic acid. However, the authors noted that small sample sizes, high risk of bias, and significant heterogeneity among included studies limited the results.(35) **(EG 1)**

For rheumatoid arthritis of the knee, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A meta-analysis found 5 randomized controlled trials with 720 patients that, when pooled, resulted in significant effect sizes in favor of hyaluronic acid in terms of improvement of pain and inflammation, as well as overall treatment effectiveness. However, the authors cautioned that the number and sizes of studies were small and that several sources of bias were present, such as with regard to language, type of preparation used, and conflicting results from larger vs smaller studies. The authors recommended that additional large randomized controlled trials be undertaken.(36) **(EG 1)**

For rotator cuff tendinopathy, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis of 23 studies evaluating the effectiveness of injection therapies to treat rotator cuff pathologies (including 4 studies comparing hyaluronic acid intra-articular injection with corticosteroid or placebo intra-articular injections) found, at short-term (3 to 6 weeks) and long-term (24 or more weeks) follow-up, no difference in pain reduction or functional improvement between groups. The authors noted that heterogeneity between studies and publication bias for short-term effects limited the results; further well-designed studies were recommended.(37) **(EG 1)** A specialty society clinical practice guideline reported that, for patients with rotator cuff injuries, hyaluronic acid intra-articular injection provided little benefit compared with corticosteroid or placebo intra-articular injections. The authors noted that further well-designed studies were required to determine the role of hyaluronic acid intra-articular treatment for rotator cuff pathology.(38) **(EG 2)**

For temporomandibular joint disorders, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** An umbrella review of 18 systematic reviews of temporomandibular joint disorder comparing intra-articular hyaluronic acid (with or without arthrocentesis or arthroscopy) with sham therapy, platelet-rich plasma, or corticosteroid injections concluded that, while studies showed positive results in terms of safety and effectiveness, the studies were of low quality and heterogeneous, and more randomized clinical trials are needed to confirm the efficacy of hyaluronic acid injections for pain relief and joint function.(39) **(EG 1)** A systematic review of 6 randomized controlled trials of intra-articular hyaluronic acid injection after arthrocentesis or arthroscopy concluded that, while 3 of the studies showed significant benefits in reducing postoperative pain and 2 showed improved mandibular functionality, more randomized controlled trials with larger sample sizes and longer follow-up periods are needed to evaluate the effectiveness of intra-articular hyaluronic acid injections after minimally invasive procedures.(40) **(EG 1)**

For tendinopathy of the lateral epicondyle, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** Systematic reviews of multiple therapies found some evidence that hyaluronic acid injection was more effective than placebo at relieving pain, but there was only a small number of studies and no evidence comparing the effectiveness of hyaluronic acid injection with that of corticosteroids for this condition.(41)(42) **(EG 1)**

For trigger finger, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A randomized controlled trial of 39 affected digits found that ultrasound-guided injection of either hyaluronic acid derivative or steroid resulted in comparable resolution of triggering at 3 months, although the patients who received steroid injection improved more in visual analog scale assessment of finger pain and range of motion. The authors concluded that both agents may exhibit significant therapeutic activity and that larger randomized studies are needed.(43) **(EG 1)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(44); 42 CFR 422.101(45)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(46); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(47); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(48)

Medicare Coverage Determinations: Medicare Coverage Database(49)

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Codes

HCPCS: J7318, J7320, J7321, J7322, J7323, J7324, J7325, J7326, J7327, J7328, J7329, J7331, J7332

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