

Hyaluronic Acid, Intra-Articular Injection

ACG: A-0306 (AC)

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Clinical Indications for Procedure

- 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)

Alternatives to Procedure

- Alternatives include(20)(21)(32):
 - 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.(6)(7)(8)(9) **(EG 2)**

Inconclusive or Non-Supportive Evidence

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.(10) **(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.(11) **(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 and meta-analysis found 4 randomized studies and 5 other studies (with a total of 354 patients), and while a small statistically significant benefit was observed with hyaluronic acid derivatives, the placebo effect of injection itself accounted for 87% of observed efficacy.(12) **(EG 1)** A systematic review and meta-analysis identified 6 randomized trials (240 participants) of the use of hyaluronic acid for the treatment of ankle osteoarthritis and concluded that it is unclear if it offers a benefit or harm as compared with placebo due to the low quality of the evidence.(1) **(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.(13) **(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.(14) **(EG 1)** A randomized controlled trial of 357 patients with mild to moderate hip osteoarthritis compared a single intra-articular injection of hyaluronic acid with saline placebo and found, at 26-week follow-up, significant improvement in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) walking, pain, and function scores with both interventions, with no significant difference seen between the groups.(15) **(EG 1)** A multicenter study randomized 85 patients to fluoroscopically guided injection of either placebo or hyaluronic acid. During a 3-month follow-up period, improvement in pain as well as all secondary endpoints were not significantly different between placebo and active treatment groups.(16) **(EG 1)** A subsequent randomized trial with 77 patients receiving either standard care or ultrasound-guided injection with either saline, hyaluronic acid, or steroid found that, over 8 weeks, the steroid arm had significant clinical response, the saline arm had the next-best response, and the remaining 2 groups had minimal but equivalent responses.(17) **(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 that 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.(2)(18) **(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.(19) **(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.(20) **(EG 2)** Another specialty society guideline recommends education, exercise programs, and nonselective NSAIDs for the nonsurgical management of hip osteoarthritis.(21) **(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)** A systematic review and meta-analysis of 25 randomized controlled trials evaluated the effectiveness of hyaluronic acid injection to treat knee osteoarthritis and found, in the 24 studies (8997 patients) that evaluated pain intensity, that hyaluronic acid was associated with a statistically significant, though not clinically relevant, improvement in pain (measured by visual analog scale) as compared with placebo (eg, saline, preparations with negligible concentrations of hyaluronic acid, or no intervention). The authors noted that the findings were limited by the chosen data evaluation methodologies and possible lack of generalizability to fragile populations with more comorbidities; further well-designed studies were recommended.(22) **(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.(23) **(EG 1)** A network meta-analysis that included 11 randomized controlled trials (3391 patients) found a small but statistically significant improvement with regard to pain and function for knee arthritis patients treated with intra-articular hyaluronic acid as compared with those treated with intra-articular corticosteroids or placebo. However, the authors stated that further high-quality studies are needed to address the uncertainties regarding clinical benefit from hyaluronic acid injections, especially in active adults from 40 to 60 years of age.(3) **(EG 1)** A systematic review and network meta-analysis of 137 studies and 33,243 participants found that intra-articular hyaluronic acid was significantly better than both placebo and intra-articular corticosteroids for treatment of pain and better than placebo for treatment of stiffness; of note, the intra-articular delivery method was found to have a significant effect, an effect that is unobservable in a traditional meta-analysis.(24)(25) **(EG 1)** A systematic review and network meta-analysis of 5 studies (with a total of 712 participants) indicated that the efficacy of intra-articular hyaluronic acid is not significantly different from that of NSAIDs at follow-up of 12 weeks.(26) **(EG 1)** A systematic review and meta-analysis of 6 randomized controlled trials (310 patients) evaluating the efficacy of intra-articular hyaluronic acid after knee arthroscopy found that compared with usual care (femoral nerve block, intra-articular opioids, or anti-inflammatory medications), hyaluronic acid was associated with improved pain on motion and worsened WOMAC scores; there was no difference in pain scores between the groups at 2 weeks, 6 weeks, or 12 weeks post procedure.(27) **(EG 1)** Meta-analyses, systematic reviews, and review articles have reported that evidence for clinical benefit of intra-articular hyaluronic acid is hindered by variable quality of trials, potential publication bias, a large placebo effect, and unclear clinical significance of some of the reported improvements; at best, it would appear that hyaluronic acid exhibits modest effectiveness, and at worst, it may not differ significantly from placebo.(28)(29)(30) **(EG 1)** A systematic review of 18 randomized trials found that the use of intra-articular hyaluronic acid in the elderly population was associated with few serious adverse events and a small statistically significant improvement in function, but no conclusion could be made regarding delay or avoidance of total knee replacement. The authors recommended additional randomized studies with larger numbers of patients.(4) **(EG 1)** A double-blind randomized controlled study of 196 patients with mild to moderate knee arthritis found that 3 intra-articular injections of hyaluronic acid (at weekly intervals) resulted in significant improvement in pain and functional scores at 6 months; however, there was no significant difference from treatment with placebo.(31) **(EG 1)** A systematic review of 19 randomized controlled trials (4485 patients) concluded that evidence does not support the routine use of intra-articular hyaluronic acid for osteoarthritis of the knee because patient benefit, as assessed by outcomes involving pain relief and functional improvement, was not clinically important.(5) **(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.(32) **(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.(21) **(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.(20) **(EG 2)** Other specialty 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 in which patients such therapy may be most useful.(33)(34) **(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.(35) **(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.(36) **(EG 1)** For shoulder impingement, randomized controlled trials have not demonstrated clinical benefit as compared with corticosteroid injections or placebo.(37)(38) **(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.(39) **(EG 2)**

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 urged that additional large randomized controlled trials be undertaken.(40) **(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.(41) **(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.(42) **(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)** A systematic review found 19 acceptable papers, of which 8 were randomized studies; while positive outcomes of hyaluronic acid injection were noted in all studies, superiority of hyaluronic acid therapy was noted only against saline injection, while outcomes were comparable with those obtained with oral appliances or corticosteroid injections. The authors indicate that significant additional study is required to better identify appropriate indications and dosing regimens.(43) **(EG 2)** A systematic review of randomized trials concluded that there was no statistical difference in the effectiveness of hyaluronic acid compared with intra-articular corticosteroid injection for this condition.(44) **(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.(45)(46) **(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.(47) **(EG 1)**

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Codes

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

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Last Update: 9/21/2023 5:20:18 AM
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