MEDICAL CONTESTED CASE HEARING NO. 18003

## DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and the Rules of the Texas Department of Insurance, Division of Workers' Compensation. For the reasons discussed herein, the Administrative Law Judge determines that the preponderance of the evidence is not contrary to the decision of the IRO that right knee Hyalgan injections times five is not health care reasonably required for the compensable injury of (Date of Injury).

## ISSUE

On February 7, 2018, William M. Routon II, a Division administrative law judge, held a contested case hearing to decide the following disputed issue:

(1) Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that the claimant is not entitled to right knee Hyalgan injections times five for the compensable injury on (Date of Injury)?

## PARTIES PRESENT

The petitioner/claimant appeared and was assisted by DS, ombudsman. The carrier/respondent appeared and was represented by CE, attorney. In attendance on behalf of the employer was KI.

## BACKGROUND INFORMATION

The claimant works at a maximum security corrections facility. He was injured on (Date of Injury) as he ran to respond to provide assistance after a code was called. The claimant testified that he felt his right knee pop, and he experienced swelling in the knee. The claimant has, since the date of injury, had injections in his knee, which did not help, physical therapy, pre and post surgery, and knee surgery in October, 2016, which also did not really help, the claimant testified. The claimant testified that he currently wears a knee brace on the right knee, and has only been able to return to work on light duty. The claimant testified that his treating doctor, SF, M.D., has requested the Hyalgan injections times five to try to get his knee more mobile, and to delay a probable future full knee replacement.

In reviewing request for the Hyalgan injections, the first utilization review doctor, an orthopedic surgeon, denied the request. He explained that the Official Disability Guidelines (ODG) criteria for hyaluronic acid injections indicate that they are recommended as an option for severe knee osteoarthritis, in patients who are over 50 years old and who have not responded adequately to conservative treatment, and to potentially delay total joint replacement. He further noted that there was insufficient evidence that the injections will help other knee conditions such as

chondromalacia patella, the condition, in addition to a knee strain, accepted by the carrier in this case. The reviewer noted that the claimant was only (years) years of age, and that there was a lack of documentation of severe knee osteoarthritis.

The second utilization review doctor, also an orthopedic surgeon, also denied the request, largely for the same reasons as the first reviewer. He noted, in addition to the lack of a diagnosis of severe osteoarthritis and the claimant's age, that there was a lack of documentation of pain from the claimant's right knee interfering with activities of daily life, and a lack of documentation of the failure of conservative care.

An IRO reviewer, identified as being board certified in orthopedic surgery, upheld the utilization reviewers' denial of the five Hyalgan injections in an August, 2017 report. The IRO reviewer, like the utilization reviewers, noted that the hyaluronic injections are recommended as an option for individuals with severe osteoarthritis and who have not responded to conservative care. He also pointed out that chondromalacia patella was not an indication for the injections. He opined that the claimant did not meet the ODG requirements for the injections, including being much younger than the 50 years of age minimum.

## DISCUSSION

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence-based medicine or, if evidence-based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence-based medicine if that evidence is available. Evidence-based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the Official Disability Guidelines

(ODG), and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308 (s), "A decision issued by an IRO is not considered an agency decision and neither the Department nor the Division are considered parties to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

On the date of this medical contested case hearing, the ODG provides the following with regard to right knee Hyaluronic acid injections:

Recommended as an option for severe knee osteoarthritis (OA) for patients who have not responded adequately to conservative treatment (exercise, NSAIDs, corticosteroid injections), in order to potentially delay total joint replacement. Higher quality studies have shown the magnitude of improvement to be modest at best. While medial and/or lateral compartment OA is a recommended indication, there is insufficient evidence for other conditions including patella-femoral arthritis, chondromalacia patella, patella-femoral syndrome (kneecap pain), or osteochondritis dissecans.

**Criteria for Hyaluronic acid injections:**

(1) Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative non-pharmacologic (e.g., exercise) and pharmacologic treatments, or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 3 months;
(2) Documented symptomatic severe osteoarthritis of the knee, which may include the following: Bony enlargement; Bony tenderness; Crepitus (noisy, grating sound) on active motion; Less than 30 minutes of morning stiffness; No palpable warmth; Over 50 years of age.
(3) Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease;
(4) Failure to adequately respond to aspiration and injection of intra-articular corticosteroids;
(5) Generally performed without fluoroscopic or ultrasound guidance;
(6) Are not currently candidates for total knee replacement or who have failed previous knee surgery for their arthritis, unless younger patients wanting to delay total knee replacement. (*Wen, 2000*)
(7) Repeat series of injections: If documented significant improvement in symptoms for 6 months or more, and symptoms recur, may be reasonable to do another series. No maximum established by high-quality scientific evidence; see *Repeat series of injections* above.
(8) Hyaluronic acid injections are NOT recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, patellofemoral arthritis, patellofemoral syndrome (patellar knee pain), plantar nerve entrapment syndrome, or for use in joints other than the knee (e.g., ankle, carpo-metacarpal joint, elbow, hip,

metatarsophalangeal joint, shoulder, or temporomandibular joint) since the effectiveness of hyaluronic acid injections for these indications has not been established.

***Risk versus benefit:*** Complications related to HA injections appear to be rare, certainly much less than 1%. The incidence of injection-related problems has been similar to that of other knee injections, even saline controls. A meta-analysis of 29 studies with 4,866 patients demonstrated that US-approved viscosupplements were safe and efficacious, with only 0.2% overall adverse events. (*Strand, 2015*) Early single case reports of pseudo-sepsis or flare reactions suggesting that such transient responses might be more common with certain HA products, has not been subsequently substantiated. Most manufacturers list the possibility of temporary post-injection site pain, arthralgia, stiffness, effusion, swelling, and warmth. Theoretically, multiple sequential injections could result in a slightly higher chance of infection or injection-site complaints. Although the magnitude of benefit for HA remains controversial, the possibility of delaying or preventing need for riskier total knee replacement remains compelling.

Hyaluronic acids (HA) are naturally occurring connective tissues materials that help cushion and lubricate joints. Intra-articular injection of avian-derived or synthetic HA, also called viscosupplementation, can decrease OA symptoms in some but not all patients; with sustained improvements in pain and functional outcomes, and few adverse events. (*Karlsson, 2002*) (*Leopold, 2003*) (*Day, 2004*) (*Wang, 2004*) (*Aggarwal, 2004*) (*Arrich, 2005*) (*Karatosun, 2005*) (*Blue Cross Blue Shield Association, 2014*) (*Petrella, 2005*) Compared with lower molecular-weight HA products, higher molecular-weight HA may be more efficacious (*Lo, 2004*), although several older studies could not detect differences. (*Reichenbach, 2007*) (*Jüni, 2007*) When response to HA products occurs, it appears more long-lasting than intra-articular corticosteroids for knee OA. (*Bellamy, 2005*) Viscosupplementation is a reasonably effective treatment for OA of the knee with beneficial improvement in pain, function and patient global assessment, at different post injection periods, especially between 5 and 13 weeks. No major safety issues were detected. (*Bellamy, 2005*) (*Bellamy, 2006*) HA compared to placebo for knee OA had similar overall results, but HA showed somewhat superior improvement in knee pain and function, with no differences noted between 3 or 6 consecutive injections. (*Petrella, 2006*)

The combined use of HA injections with a home exercise program should be considered for management of moderate-to-severe pain in patients with knee OA. (*Stitik, 2007*) Refractory pain without response to oral medications can be treated with intra-articular injections. HA is associated with delayed onset of analgesia but a more prolonged duration of action than corticosteroid injections. (*Zhang, 2008*) HA is thought to restore synovial fluid viscoelasticity, which is typically depleted with OA. Hyaluronic acids have been modified to form ultra-high molecular weight hylans, in order to increase viscosity as well as decrease clearance from the joint. (*Jüni, 2007*) Hylan G-F 20 has been shown to be a safe and effective treatment for knee OA. (*Conrozier, 2008*) (*Huskin, 2008*) (*Zietz, 2008*) Comparison of clinical effectiveness, functional outcome, and patient satisfaction following hylan G-F 20 vs. sodium hyaluronate

noted that both products offered significant pain reduction, but it was achieved earlier and sustained for a longer period with the hylan G-F 20, although adverse events were slightly higher with hylan G-F 20. (*Raman, 2008*) (*Reichenbach, 2007*) In 2009 the FDA approved Synvisc-One™ (hylan G-F 20), the first single-injection viscosupplement for OA knee pain in the U.S. (*FDA, 2009*) A meta-analysis concluded that up to week 4, intra-articular corticosteroids appear to be relatively more effective for pain relief than HA, but then the two approaches have similar efficacy until beyond week 8, where HA is better. (*Bannuru, 2009*) In patients who are candidates for TKR, surgery can be delayed with HA injections. (*Waddell, 2007*)

*Recent research:* AHRQ Comparative Effectiveness Research reported that published knee OA clinical trials comparing injection of viscosupplements vs. placebo have yielded inconsistent results. Higher quality larger trials have generally found less clinical improvement in pain and function than smaller poor quality studies. It was concluded that any clinical improvement attributable to HA is small at best and probably not clinically meaningful. Evidence also appeared to be insufficient to demonstrate clinical superiority for the higher molecular weight products. (*AHRQ, 2011*) Another meta-analysis of 89 RCTs including 12,667 patients concluded that HA had minimal effects on pain and function with knee OA, but did increase risk for adverse reactions. They also suggested publication biases in favor of HA treatment. (*Rutjes, 2012*)

The California Technology Assessment Forum (CTAF) concluded that HA for knee OA did not meet their criteria of safety, efficacy and improvement in health outcomes regarding progression of disease or delay to knee replacement. (*CTAF, 2012*) The *AAOS Guidelines for Treatment of Osteoarthritis of the Knee*, does not recommend HA for patients with symptomatic OA, based on "strong" evidence. Fourteen HA studies were analyzed, and it was noted that a few individual trials found statistically significant treatment effects, but when combined in a meta-analysis, the evidence did not meet their "minimum clinically important improvement" (MCII) thresholds. It was conceded that there might be some subgroup of responders who could be helped by HA, but that subgroup has not yet been identified. (*AAOS, 2013*) In contrast, another AHRQ meta-analysis of 137 HA studies with 33,243 participants concluded that viscosupplementation was the "best" pharmacologic intervention for knee OA, with an effect size of 0.63. Interestingly, intra-articular placebo effect proved to be significantly better than oral placebo, and any intra-articular treatment, even placebo, proved more effective than any oral medications. The apparent superiority of intraarticular injections may not reflect a true placebo effect, but instead may be a pain relief phenomenon from injecting any fluid into the knee. HA results were better than injected placebo or corticosteroids. (*Bannuru, 2015*)The American Medical Society for Sports Medicine (AMSSM) recommends HA for appropriate knee OA patients, based on a very large network meta-analysis. They criticized the AAOS MCII methodology, stating lack of validation and higher than appropriate cut-off values, even suggesting that such a position increases the number of surgical procedures. (*Trojian, 2016*) The American College of Rheumatology (ACR) and Osteoarthritis Research Society (ORS) make no official recommendation regarding HA. The

U.K. National Institute for Health and Care Excellence (NICE) does not recommend HA. (*Johal, 2016*)

*Repeat series of injections:* A systematic review of the efficacy and safety of repeat courses of HA for knee OA concluded that it can be safe and effective. (*Pagnano, 2005*) Another study concluded that repeated cycles of intra-articular sodium hyaluronate was efficacious during 54-month follow-up, continuing to delay TKR. (*Turajane, 2009*) An RCT of effectiveness and safety of repeat courses of hylan G-F 20 also provided support for repeat treatments. (*Raynauld, 2005*) A lower quality study recommended no more than 3 series of injections over a 5-year period, because effectiveness may decline. (*Spitzer, 2008*) Although the scientific evidence remains weak, considering the cost and risks associated with TKR, it makes sense to repeat a series of injections for those with good pain relief for 6 months or longer, since they are likely to respond well again.

> *After meniscectomy or ACL reconstruction:* An RCT found there was no benefit of HA injection following arthroscopic meniscectomy, at least during the first 6 weeks after surgery, and concluded that routine use of HA after knee arthroscopy cannot be recommended. (*Baker, 2012*) This finding was confirmed in another RCT involving 90 patients followed for 180 days, with the authors concluding that HA injection at the end of the surgical procedure is not a successful strategy to provide either faster functional recovery or symptomatic improvement after meniscectomy. (*Filardo, 2016*) A similar RCT of 60 ACL reconstruction procedures also demonstrated that the early postoperative injection of HA did not lead to significant improvement in subsequent clinical scores. (*Di Martino, 2016*)

The claimant relies on a January 3, 2018 causation letter from SC, PA-C, who apparently worked in conjunction with Dr. F. In that letter, C set out the claimant's treatment history, which documented substantial conservative care, including injections and physical therapy, as well as surgery. It stated that the claimant had failed conservative treatment and “that what was left” to try was the injections. C noted that they were trying to put off any need for a total knee arthroplasty. While C’s letter addresses some of the reasons for denial of the injections by the utilization and IRO doctors, it was prepared after the IRO review and so was not in existence when that review was performed. In addition, C’s letter still does not address the criteria raised by the reviewers that the claimant was not diagnosed with osteoarthritis but instead with chondromalacia patella, and the claimant was only (years) years old, well below the 50 year old guideline set by the ODG.

Based on a careful review of the evidence presented in the hearing, the claimant failed to meet his burden of overcoming the IRO decision by a preponderance of the evidence-based medicine. The IRO decision in this case is based on the ODG and the evidence revealed that the claimant failed to meet all of the necessary criteria for the right knee Hyalgan injections prescribed in the

ODG. The preponderance of the evidence-based medicine is not contrary to the decision of the IRO and, consequently, the claimant is not entitled to the right knee Hyalgan injections.

The Administrative Law Judge considered all of the evidence admitted. The Findings of Fact and Conclusions of Law are based on an assessment of all of the evidence whether or not the evidence is specifically discussed in this Decision and Order.

## FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue is proper in the (City) Field Office of the Workers' Compensation Division of the Texas Department of Insurance.

   B. On (Date of Injury), the claimant was the employee of (Employer), Employer.

   C. On (Date of Injury), the employer provided workers' compensation insurance as a Self-Insurer.

   D. On (Date of Injury), the claimant sustained compensable injuries of a right knee strain and right knee chondromalacia.

   E. The IRO determined that the claimant is not entitled to right knee Hyalgan injections times five.

2. The carrier delivered to the claimant a single document stating the true corporate name of the carrier, and the name and street address of the carrier's registered agent, which document was admitted into evidence as Administrative Law Judge's Exhibit Number 2.

3. Right knee Hyalgan injections times five is not health care reasonably required for the compensable injury of (Date of Injury).

## CONCLUSIONS OF LAW

1. The Workers' Compensation Division of the Texas Department of Insurance has jurisdiction to hear this case.

2. Venue is proper in the (City) Field Office.

3. The preponderance of the evidence is not contrary to the decision of the IRO that right knee Hyalgan injections times five is not health care reasonably required for the compensable injury of (Date of Injury).

## DECISION

The claimant is not entitled to right knee Hyalgan injections times five for the compensable injury on (Date of Injury).

## ORDER

The carrier [is, is not] liable for the benefits at issue in this hearing. The claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **(EMPLOYER), SELF INSURED** and the name and address of its registered agent for service of process is:

**(NAME)**
**(ADDRESS)**
**(CITY), TX (ZIPCODE)**

Signed this12th day of February, 2018.

William M. Routon II
Administrative Law Judge