MEDICAL CONTESTED CASE HEARING NO. 16054

DECISION AND ORDER

This case is decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder. For the reasons discussed herein, the Hearing Officer determines that Claimant is not entitled to Synvisc injection for the right knee for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

On January 26, 2017, a medical contested case hearing was held to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to Synvisc injection for the right knee for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by KW, ombudsman.

Respondent/Carrier appeared and was represented by KM, attorney.

BACKGROUND INFORMATION

Claimant served as a police officer for (City). He injured his right knee on (Date of Injury), when he was in pursuit of a felony suspect and stepped out of his patrol car. Claimant testified he has had physical therapy, medications, steroids, injections and surgery for medial and lateral meniscus tears. At this point, his surgeon, JB, M.D., is requesting Claimant undergo Synvisc injections to try and hold off Claimant undergoing a total knee replacement. Carrier's utilization review doctors disagreed with the medical reasonableness for this procedure. Claimant requested an independent medical review. The IRO doctor upheld Carrier's denial of the treatment. Claimant requested this medical contested case hearing, disputing the IRO's determination.

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 Official Disability Guidelines provides the following with regard to Synvisc injections for the right knee:

> Synvisc is a brand of hylan supplied by Genzyme Corporation. See Hyaluronic acid injections, where a series of three injections of hylan or one of Synvisc-One hylan are recommended as an option for osteoarthritis.

The Official Disability Guidelines provides the following with regarding 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, metatarso-phalangeal 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 incidences of injection-related problems have been similar to 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 GF-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: 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*)

Brands of hyaluronic acid: There are several brands of viscosupplements on the market, and there is a general lack of reliable evidence that any specific brand is superior to others. However, some clinically important reductions in pain have been noted, after closer review of systematic reviews and meta-analyses, using higher-molecular weight and cross-linked formulations. Synvisc and Synvisc-One are cross-linked with molecular weight 5-6M (million Daltons). Monovisc (1-2.9M), and Gel-One (N/A) are also cross-linked. Euflexxa (2.4-3.6M), Orthovisc (1-2.9M), Supartz (0.6-1.2M), and Hyalgan (0.5-0.7M) are not cross-linked. Hyalgan and Supartz may be less expensive than others, but actual costs vary with specific fee schedules and purchasing arrangements. (*Johal, 2016*) Recommendations involve only a single Synvisc-One, Gel-One, or Monovisc injection; with a series of 3-5 weekly intra-articular injections of Hyalgan or Supartz, 3-4 of Orthovisc, and 3 of Synvisc or Euflexxa. (FDA labeling) Euflexxa or Monovisc, both synthetics, may be recommended where there is an allergy contraindication to the other avian-derived formulations (eggs, feathers or poultry). (*Huskin, 2008*) (*Zietz, 2008*) (*Wobig, 1999*) (*Raman, 2008*)

The IRO doctor opined Claimant did not meet the requirements under the ODG. His opinion consistently discussed the lack of clinical documentation supporting the reasonableness for the Synvisc injection under the ODG. He noted the clinical documentation did not identify Claimant had symptoms of pain interfering with functional activities. He noted Claimant's gait and station

were normal as of August 04, 2016, which was the latest physical examination in the available records. He noted the records did not identify the extent to which Claimant participated in nonpharmcological treatment, such as exercise. He noted there was an indication that Claimant had undergone some physical therapy, but there was no specification as to the frequency and duration of sessions, nor what Claimant's functional outcome was following physical therapy. He noted the recent exam did not document the medications Claimant was taking to determine if he was utilizing any forms of nonsteroidal anti-inflammatory drugs or other pain relieving medications. The IRO doctor lastly noted Claimant's most recent MRI showed Claimant also has chondromalacia patella, which is a condition the ODG specifically mentions as a condition that should not be treated with Synvisc injections.

Claimant's surgeon, Dr. B, wrote a letter dated August 16, 2016. This appears to be a letter supporting Claimant's disability, as opposed to the need for the Synvisc injection or documentation supporting how the criteria of the ODG have been met or how the ODG are not applicable to Claimant's specific condition. Dr. B's letter touches upon a few of the criteria noted above, but he does not address each element, specifically Criterion #2 - documented symptomatic severe osteoarthritis of the knee. This is especially important because the MRI of November 03, 2016, indicated Claimant has mild to moderate severity osteoarthritis in the medial and lateral compartments of the knee, as well as high grade chondromalacia within the posterior aspect of the weightbearing lateral femoral condyle, and moderate-grade chondromalacia within the weightbearing medial femoral condyle and within the patellofemoral compartment. He also noted Claimant underwent cortisone injections that had only a mild short-term, improvement.

The Designated Doctor who was appointed to address MMI, impairment rating and return to work, JK, D.C., also opined Claimant would benefit from hyaluronic acid injections as Claimant has not responded to aspiration, and pain is interfering with his functional activities. However, she did not address the severity of Claimant's osteoarthritis and diagnosed tricompartmental chondromalacia.

Additionally, Carrier's post-Designated Doctor required medical examination doctor, PO, M.D., agreed Claimant should try the Synvisc injections. He noted the acceleration of chondromalacia in the lateral and medal compartments of Claimant's knee, noting this was not unusual in patients who undergo meniscectomies. He pasted the ODG criteria above into his report and stated the ODG supports these injections. Dr. O's concern is that hyaluronic acid may delay a knee replacement, but in Claimant's age bracket with the amount of degenerative processes already in Claimant's knee and large knee effusion that has not responded to cortisone injections, Claimant will be facing a knee replacement in the future. While Dr. O opined Claimant was a candidate for these injections, he also noted the latest MRI showed subtle grade chondromalacia within the weightbearing medial femoral condyle and within the patellofemoral compartment with mild patellofemoral spurring present. One contraindication to undergoing these injections, per the

ODG, is that hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae.

Claimant failed to provide evidence based medical evidence contrary to the decision of the IRO or expert medical opinion that shows how the ODG does not apply in this case. Specifically, Claimant did not have a doctor who addressed these criteria: (2) Documented symptomatic severe osteoarthritis of the knee; (4) Failure to adequately respond to aspiration and injection of intra-articular corticosteroids; and (8) Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, and patellofemoral arthritis.

Even though all the evidence presented was not discussed, it was considered. The Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

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

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

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

   D. On (Date of Injury), Claimant sustained a compensable injury.

   E. The Independent Review Organization orthopedic surgeon determined Claimant should not have Synvisc injections for the right knee.

2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

3. Synvisc injection for the right knee is not health care reasonably required for the compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, 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 Synvisc injection for the right knee is not health care reasonably required for the compensable injury of (Date of Injury).

4.

DECISION

Claimant is not entitled to Synvisc injection for the right knee for the compensable injury of (Date of Injury).

ORDER

Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is the **(CARRIER)** and the name and address of its registered agent for service of process is

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

Signed this 27th day of January, 2017.

KEN WROBEL
Hearing Officer