MEDICAL CONTESTED CASE HEARING NO. 14072

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 Hearing Officer determined that Claimant/Petitioner is not entitled to right knee synvisc injection series of three with one week between injections for the compensable injury of (Date of Injury). The Hearing Officer also determined that Claimant/Petitioner did not timely appeal the IRO decision in this case.

STATEMENT OF THE CASE

On July 1, 2014, Gerri Thomas, a Division hearing officer, held a contested case hearing to decide the following disputed issues:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the Claimant is not entitled to right knee synvisc injection series of three with one week between injections?
2. Did the Claimant/Petitioner timely appeal the IRO decision?

PARTIES PRESENT

Claimant/Petitioner appeared and was assisted by JBT, ombudsman. Carrier/Respondent appeared and was represented by PP, attorney.

OFFICIAL NOTICE

Official notice was taken of the calendar for March 2014 and April 2014.

DISCUSSION

Timeliness of Appeal

Rule 133.308(s)(1)(A) states, to wit:

> The written appeal must be filed with the division's Chief Clerk of Proceedings no later than the later of the 20th day after the effective date of this section **or** 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the division. Requests that are timely submitted to a division location other than the division's Chief Clerk of Proceedings, such as a local field office of the division, will be considered timely

> filed and forwarded to the Chief Clerk of Proceedings for processing; however, this may result in a delay in the processing of the request.

Id (emphasis added). Essentially, the Rule actually provides for two separate deadlines for the filing of an appeal of the IRO decision with the later in time applying.

In this particular case, the IRO decision was issued and sent to the parties on March 12, 2014. The applicable deadline for the filing of the appeal of the IRO decision in this case was 20 days from the date the IRO decision was sent to the parties, which was April 6, 2014; however, that was a Sunday. As a result, the appeal of the IRO decision in this case was due Monday, April 7, 2014. Claimant/Petitioner filed his appeal of the IRO decision with the Division on April 8, 2014. There are no other applicable provisions and/or Division Rules providing for extensions of and/or good cause exceptions to the 20-day deadline for appealing the IRO decisions. Since the Claimant/Petitioner did not comply with the 20-day deadline contained in the applicable Division Rules, the appeal of the IRO decision was untimely.

Medical Necessity

Evidence Based Medicine (EBM)

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 Hyaluronic acid injections:

> Recommended as a possible option for severe osteoarthritis for patients who have not responded adequately to recommended conservative treatments (exercise, NSAIDs or acetaminophen), to potentially delay total knee replacement, but in recent quality studies the magnitude of improvement appears modest at best. See *Recent research* below. While osteoarthritis of the knee is a recommended indication, there is insufficient evidence for other conditions, including patellofemoral arthritis, chondromalacia patellae, osteochondritis dissecans, or patellofemoral syndrome (patellar knee pain). Hyaluronic acids are naturally occurring substances in the body's connective tissues that cushion and lubricate the joints. Intra-articular injection of hyaluronic acid can decrease symptoms of osteoarthritis of the knee; there are significant improvements in pain and functional outcomes with few adverse events. (Karlsson, 2002) (Leopold, 2003) (Day, 2004) (Wang, 2004) (Aggarwal, 2004) (Arrich, 2005) (Karatosun, 2005) (Blue Cross Blue Shield, 2005) (Petrella, 2005) Compared with lower-molecular-weight hyaluronic acid, this study concluded that the highest-molecular-weight hyaluronic acid may be more efficacious in treating knee OA. (Lo-JAMA, 2004) These more recent studies did not. (Reichenbach, 2007) (Jüni, 2007) The response to hyaluronan/hylan products appears more durable than intra-articular corticosteroids in treatment of knee osteoarthritis. (Bellamy-Cochrane, 2005) Viscosupplementation is an effective treatment for OA of the knee with beneficial effects: on pain, function and patient global assessment; and at different post injection periods but especially at the 5 to 13 week post injection period. Within the constraints of the trial designs employed no major safety issues were detected. (Bellamy-Cochrane2, 2005) (Bellamy, 2006) Intra-articular viscosupplementation was moderately effective in relieving knee pain in patients with osteoarthritis at 5 to 7 and 8 to 10 weeks after the last injection but not at 15 to 22 weeks. (Modawal, 2005) This study assessing the efficacy of intra-articular injections of hyaluronic acid (HA) compared to placebo in patients with osteoarthritis of the knee found that results were similar and were not statistically significant between treatment groups, but HA was somewhat superior to placebo in improving knee

pain and function, with no difference between 3 or 6 consecutive injections. (Petrella, 2006) The combined use of hyaluronate injections with a home exercise program should be considered for management of moderate-to-severe pain in patients with knee osteoarthritis. (Stitik, 2007) Patients with moderate to severe pain associated with knee OA that is not responding to oral therapy can be treated with intra-articular injections. Intra-articular injections of hyaluronate are associated with delayed onset of analgesia but a prolonged duration of action vs injections of corticosteroids. (Zhang, 2008) Treatment with hylan or hyaluronic acids is thought to restore synovial fluid viscoelasticity, which is depleted in patients with OA. Hyaluronic acids were modified to form high molecular weight hylans, to increase viscosity and decrease clearance from the joint. (Jüni, 2007) Data of the literature demonstrate that hylan GF-20 is a safe and effective treatment for decreasing pain and improving function in patients suffering from knee osteoarthritis. (Conrozier, 2008) (Huskin, 2008) (Zietz, 2008) In one trial comparing the clinical effectiveness, functional outcome and patient satisfaction following intra articular injection with two viscosupplementation agents - Hylan G-F-20 and Sodium Hyaluronate in patients with osteoarthritis (OA) of the knee, both treatments offered significant pain reduction, but it was achieved earlier and sustained for a longer period with Hylan G-F 20. From this study, it appeared that the clinical effectiveness and general patient satisfaction are better amongst patients who received Hylan G-F 20, although the numbers of treatment related adverse events were higher (39 vs. 30) in the Hylan G-F 20 group. As with all injections, care must be given to watch for any possible adverse events, and particularly with the use of Hylan over Hyaluronic acid. (Raman, 2008) (Reichenbach, 2007) On 02/26/09 the FDA granted marketing approval for Synvisc-One™ (hylan G-F 20), a product intended for the relief of pain associated of the knee. Synvisc-One is the only single-injection viscosupplement approved for the treatment of OA knee pain in the United States, from Genzyne Corp. (FDA, 2009) A meta-analysis of clinical trials concluded that, from baseline to week 4, intra-articular corticosteroids appear to be relatively more effective for pain than intra-articular hyaluronic acid, but by week 4, the 2 approaches have equal efficacy, and beyond week 8, hyaluronic acid has greater efficacy. (Bannuru, 2009) In patients who are candidates for TKR, the need for TKR can be delayed with hyaluronic acid injections. (Waddell, 2007)

Recent research: AHRQ Comparative Effectiveness Research reported that, in people with osteoarthritis of the knee, published clinical trials comparing injections of viscosupplements with placebo have yielded inconsistent results. Higher quality and larger trials have generally found lower levels of clinical improvement in pain and function than small and poor quality trials. They conclude that any clinical improvement attributable to viscosupplementation is

likely small and not clinically meaningful. They also conclude that evidence is insufficient to demonstrate clinical benefit for the higher molecular weight products. (AHRQ, 2011) According to a meta-analysis based on 89 randomized trials including 12,667 patients, hyaluronic acid injections produced minimal or nonexistent effects on pain and function in patients with knee osteoarthritis (OA), but did increase the risks for serious adverse events and local adverse reactions. They also identified unpublished trials, suggesting publication bias in favor of the treatment. The best they could say is that the use of this therapy depends on individual patient features and response to the treatment, while randomized controlled trials give only the mean value for therapy, which may not be generalizable to every patient. (Rutjes, 2012) The California Technology Assessment Forum (CTAF) concluded that treatment of knee OA with injections of intra-articular HA does not meet CTAF criteria for safety, efficacy and improvement in health outcomes for progression to knee replacement or progression of disease. (CTAF, 2012) The latest AAOS Guidelines for Treatment of Osteoarthritis of The Knee, says they cannot recommend using HA for patients with symptomatic OA of the knee, based on strong evidence. According to the authors, fourteen studies assessed intraarticular (HA) injections. Although a few individual studies found statistically significant treatment effects, when combined together in a meta-analysis, the evidence did not meet the minimum clinically important improvement thresholds. There might be a subgroup of responders who would be helped by intraarticular HA, but that subgroup has not been identified, and studies have been done comparing products but not done showing that viscosupplementation actually works in a subgroup. (AAOS, 2013)

Repeat series of injections: This systematic review on the efficacy and safety of repeat courses of hyaluronan therapy in patients with OA of the knee concluded that repeat courses of the hyaluronans are safe and effective in the treatment of pain associated with OA of the knee. (Pagnano, 2005) This study concluded that repeated cycles of intra-articular sodium hyaluronate treatment was efficacious during a 54-month follow-up period in continuing to delay time to TKR in patients with knee osteoarthritis. (Turajane, 2009) This RCT on effectiveness and safety of repeat courses of hylan G-F 20 in patients with knee osteoarthritis provided support for repeat treatments. (Raynauld, 2005) On the other hand, this lower quality study recommended no more than 3 series of injections over a 5-year period, because effectiveness may decline, this is not a cure for arthritis, but only provides comfort and functional improvement to temporarily avoid knee replacement. (Spitzer, 2008) Overall, the scientific evidence for use of these is weak, but there may be continued improvement in some cases that otherwise would have resulted in TKA. Considering the cost of TKA and risk of complications, it may make sense to repeat a series of injections. While it is hard

to predict which patients will respond based upon imaging or clinical indicators, those who got relief and then had recurrence more than six months later are likely to do well again.

After meniscectomy: This RCT found there was no benefit of hyaluronic acid injection after knee arthroscopic meniscectomy in the first 6 weeks after surgery, and concluded that routine use of HA after knee arthroscopy cannot be recommended. (Baker, 2012) Also see Criteria below: Patients should not have failed previous knee surgery for their arthritis, such as arthroscopic debridement.

Brands of hyaluronic acid: There are several brands of viscosupplement on the market, but there is a lack of reliable evidence that any one brand is superior to other brands for medically necessary indications. Euflexxa may be recommended where there is allergy contraindication to ingredients in the others (eggs, feathers or poultry). The Euflexxa and Orthovisc brands may be less costly, and other brands, Hyalgan, Supartz, Synvisc (Hylan G-F 20), and Synvisc One, may be more costly, but this is dependent on specific fee schedules and purchasing techniques. Recommendations include a series of three to five intra-articular injections of Hyaluronic acid (Hyalgan or Supartz), or just three injections of Hylan or Euflexxa, or three to four injections Orthovisc, or one of Synvisc-One hylan, in the target knee with an interval of one week between injections. (FDA labeling) (Huskin, 2008) (Zietz, 2008) (Wobig, 1999) (Raman, 2008)

Criteria for Hyaluronic acid injections:

· Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative nonpharmacologic (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;

· 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 of synovium; Over 50 years of age.

· Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease;

· Failure to adequately respond to aspiration and injection of intra-articular steroids;

· Generally performed without fluoroscopic or ultrasound guidance;

· 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)

· 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.

· Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, or 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, and temporomandibular joint) because the effectiveness of hyaluronic acid injections for these indications has not been established.

Claimant/Petitioner sustained a compensable injury on (Date of Injury), when he attempted to climb down off the trailer of his 18-wheeler and lost his grip causing him to fall backwards and twist his right knee. Pre-authorization was requested for right knee synvisc injection series of three with one week between injections. The IRO Reviewer upheld the previous denials, and Claimant/Petitioner appealed.

Carrier/Respondent argued the opinion of the IRO Reviewer was correct. Claimant/Petitioner testified concerning the mechanism of injury, his course of treatment including physical therapy and corticosteroid injections, and his continuing pain and limitations; however, there was insufficient explanation through the use of evidence-based medical evidence as to how Claimant/Petitioner met the requirements of ODG for the requested injections. Claimant/Petitioner also did not establish the necessity of the requested injections at issue through other evidence-based medical evidence. As such, insufficient evidence-based medical evidence existed to explain that the requested injections were medically reasonable and necessary. Therefore, the preponderance of the evidence is not contrary to the decision of the IRO that Claimant/Petitioner is not entitled to right knee synvisc injection series of three with one week between injections.

The Hearing Officer 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. The Texas Department of Insurance, Division of Workers' Compensation has jurisdiction to hear this matter.

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

C. On (Date of Injury), Claimant/Petitioner was the employee of (Employer), Employer.

D. On (Date of Injury), Employer provided workers' compensation insurance with New Hampshire Insurance Company, Carrier/Respondent.

E. On (Date of Injury), Claimant/Petitioner sustained a compensable injury.

F. The Independent Review Organization determined Claimant/Petitioner should not have the requested treatment of right knee synvisc injection series of three with one week between injections.

G. Claimant/Petitioner filed his appeal of the decision of the IRO on April 8, 2014.

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

3. Claimant/Petitioner's appeal of the IRO decision was not filed within the 20-day deadline contained in Division Rule 133.308(s)(1)(A).

4. Right knee synvisc injection series of three with one week between injections 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 the Claimant is not entitled to right knee synvisc injection series of three with one week between injections.

4. Claimant/Petitioner did not timely appeal the IRO decision in this case.

DECISION

Claimant/Petitioner is not entitled to right knee synvisc injection series of three with one week between injections for the compensable injury of (Date of Injury). Claimant/Petitioner did not timely appeal the IRO decision in this case.

ORDER

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

The true corporate name of the insurance carrier is **NEW HAMPSHIRE INSURANCE COMPANY**, and the name and address of its registered agent for service of process is:

CORPORATION SERVICE COMPANY
211 EAST 7th STREET, STE. 620
AUSTIN, TX 78701-3218

Signed this 1st day of July, 2014.

Gerri Thomas
Hearing Officer