MEDICAL CONTESTED CASE HEARING NO. 11043
M6-10-28518-01

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.

ISSUES

A contested case hearing was held on October 18, 2010 to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to viscous supplementation treatment of one injection a week for three weeks in the left knee for the compensable injury of _____?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by SL, ombudsman.
Respondent/Carrier was represented by RJ, attorney.

BACKGROUND INFORMATION

On _____, Claimant sustained a compensable injury to his left knee and left elbow. As a result of the compensable injury, Claimant has not had any surgery and continues to experience pain to his left knee. Claimant testified that he was given prescription medication, which did give him some relief, but that the Carrier has recently denied refilling his medication. Claimant's treating physician has requested viscous supplementation to treat his bursitis and chondromalacia. The request for the viscous supplementation has been denied by the Carrier and referred to an IRO who upheld the Carrier's denial.

The IRO reviewer, Board Certified in Orthopedic Surgery, concluded that per the Official Disability Guidelines (ODG) the requested treatment is not appropriate for the Claimant's diagnoses and that further conservative treatment has not been exhausted.

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 (t), "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."

Under the *ODG*, the proposed treatment of "viscosupplementation" is discussed under the sub-heading of hyaluronic acid injections and states as follows:

> Recommended as an option for osteoarthritis. 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)

Criteria for Hyaluronic acid or Hylan:
A series of three to five intra-articular injections of Hyaluronic acid (or just three injections of Hylan, or one of Synvisc-One hylan) in the target knee with an interval of one week between injections. (Huskin, 2008) (Zietz, 2008) (Wobig, 1999) (Raman, 2008)
Indicated for patients who:
· Experience significantly symptomatic osteoarthritis but have not responded adequately to standard nonpharmacologic and pharmacologic treatments or are

intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications).
· Are not candidates for total knee replacement or who have failed previous knee surgery for their arthritis, such as arthroscopic debridement.
· Younger patients wanting to delay total knee replacement. (Wen, 2000)
· Repeat series of injections: If relief for 6-9 months and symptoms recur, may be reasonable to do another series. Recommend 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)

The *ODG* specifically states that "[w]hile 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)." In his medical necessity letter dated May 14, 2010, Claimant's treating physician notes that "patient not only has bursitis, he also has chondromalacia of the patellofemoral joint that is very symptomatic…The patient does not have degenerative joint disease." He further opines in that letter that "viscous supplementation has been used for the treatment of pain caused by chondromalacia successfully in the past…" However, the IRO reviewer provided a detailed review of Claimant's medical records and noted that other conservative measures had not been considered prior to recommending viscous supplementation. The IRO further noted that the requested treatment of viscous supplementation was not appropriate for the Claimant's diagnosis. Claimant's treating physician's opinion is merely his opinion and does not rise to the level of evidence based medicine. The treating physician fails to discuss the *ODG* nor does he cite any studies showing that viscous supplementation used for chondromalacia have been successful. Claimant has failed to provide evidence based medical evidence contrary to the decision of the IRO.

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 _____, Claimant was the employee of (Employer).

   C. On _____, Claimant sustained a compensable injury.

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. The IRO determined that the requested services were not reasonable and necessary health care services for the compensable injury of _____.

4. Claimant failed to present evidence based medicine contrary to the IRO decision.

5. Viscous supplementation treatment of one injection a week for three weeks in the left knee is not health care reasonably required for the compensable injury of _____.

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 Claimant is not entitled to viscous supplementation treatment of one injection a week for three weeks in the left knee for the compensable injury of _____.

DECISION

Claimant is not entitled to viscous supplementation treatment of one injection a week for three weeks in the left knee for the compensable injury of _____.

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 **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, SUITE 620
AUSTIN, TEXAS 78701-3232

Signed this 21st day of October, 2010.

Teresa G. Hartley
Hearing Officer