MEDICAL CONTESTED CASE HEARING NO 09215
M6-09-18040-01

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 June 22, 2009 to decide the following disputed issue:

1. Is the preponderance of the evidence contrary to the decision of the IRO that the claimant is not entitled to arthrocentesis, aspiration and/or injection of the left knee for the compensable injury of _____?

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

BACKGROUND INFORMATION

Claimant sustained a compensable left knee injury on _____. Claimant has undergone six surgeries for her knee and has developed osteoarthritis. The medical records indicate that the claimant is a candidate for a total knee replacement, but due to her young age her doctors have been administering hyaluronic acid injections, also known as Synvisc injections, to avoid having to do a total knee replacement. Claimant started receiving Synvisc injections in November 2004 and has received seven series of three injections. The injections were performed in November 2004, April 2005, November 2005, April 2006, September 2006, October 2007 and April 2008. The claimant's treating doctor, Dr. S, referred the claimant to Dr. B who requested another series of three injections in December 2008.

After Dr. B requested pre-authorization for the proposed procedure, two utilization reviews were conducted. The first utilization review doctor opined that the proposed procedure was not medically necessary because the claimant had already received four previous sets of injection treatment within less than five years. The doctor concluded that the request was not reasonable and necessary in accordance with the Official Disability Guidelines (ODG). The second utilization review also denied authorization of the requested treatment and provided the same reason as the first utilization review.

Following the second denial, a request for review by an IRO was made. The IRO reviewer, a board certified orthopedic surgeon, upheld the denial of the left knee Synvisc injection. In its explanation for its denial the IRO provides the following analysis and explanation:

"There is simply not enough information available to allow the Reviewer to recommend this as medically necessary. It is unclear if steroid injections have been tried and failed. It is unclear that more than two series of Synvisc injections have been provided since 2007. If, indeed, there has been failure of traditional steroid injections in addition to the oral medications documented and if

indeed the October 2007 and April 2008 series were the only series provided it is possible that this person could become a candidate. However, the Reviewer simply cannot provide an answer to those questions based on the limited data provided."

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. Section 401.011(22-a) defines "health care reasonably required" 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: (A) evidence-based medicine; or (B) if that evidence is not available, generally accepted standards of medical practice recognized in the medical community. Section 401.011(18-a) defines "evidence-based medicine" as 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 in making decisions about the care of individual patients.

The Division of Workers' Compensation has adopted treatment guidelines under Division Rule 137.100. That rule requires that health care providers provide treatment in accordance with the current edition of the Official Disability Guidelines (ODG), and treatment provided pursuant to those guidelines is presumed to be healthcare reasonably required as mandated by the above-referenced sections of the Texas Labor Code. The initial inquiry, therefore, in any dispute regarding medical necessity, is whether the proposed care is consistent with the ODG.

With regard to Hyaluronic acid injections, the ODG provides as follows:

> Recommended as an option for osteoarthritis. 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)

Criteria for Hyaluronic acid or Hylan:
A series of three to five intra-articular injections of Hyaluronic acid (or just three injections of 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)

Claimant's requesting doctor, Dr. B, a board certified orthopedic surgeon, provided a narrative report dated March 23, 2009 to support his request for the Synvisc injections. Dr. B's report indicates that at age forty the claimant is far too young to have knee replacement surgery and the

Synvisc injections are being done to avoid a knee replacement. Dr. B also states that the Synvisc injections continue to be effective for the claimant and that traditional short term anti-inflammatories have been ineffective. Dr. B recognizes that the ODG recommends no more than three series of injections over five years, but states that these are only guidelines. Dr. B also provides literature from the makers of Synvisc, Genzyne Corp., to show the effectiveness of the medication. The ODG indicates that the claimant is to have no more than three series over a five year period and the claimant has had seven series of three. Dr. B does not provide any evidence based medicine to support the necessity of an eighth series of three injections.

The claimant's treating doctor, Dr. S, testified at the Medical Contested Case Hearing. Dr. S's testimony concerning the necessity of the injections was similar to Dr. B's narrative. Dr. S also felt that the claimant was too young to have a knee replacement, that the treatment continued to be effective with no adverse effects, and he felt that the ODG is just guidelines. Dr. S stated that he felt that the claimant's care fell outside of the guidelines and that she should be allowed to have the injections because she had six knee surgeries performed. Dr. S stated that he has to prescribe large dosages of medication to control her pain whenever the injections wear off because there is no cartilage in the claimant's knee and the grinding of bone on bone is extremely painful. Dr. S stated that his opinion was based on his training and experience as a doctor. He did not provide any evidence based documentation to outweigh the presumption of reasonableness found in the ODG.

The party appealing the IRO decision, has the burden of overcoming the IRO decision by a preponderance of evidence-based medical evidence. The IRO decision in this case is based on the ODG and noted that the Claimant's medical records failed to establish the necessary criteria as prescribed in the ODG. The Petitioner/Claimant failed to meet her burden in this matter. The preponderance of evidence based medicine is not contrary to the decision of the IRO that the claimant is not entitled to a arthrocentesis, aspiration and/or injection of the left knee for the compensable injury of _____.

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. The Texas Department of Insurance, Division of Workers' Compensation has jurisdiction in this matter.

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

   C. On _____, Claimant was the employee of (Employer).

   D. Claimant sustained a compensable injury on _____.

   E. The Independent Review Organization determined that the claimant should not have the to arthrocentesis, aspiration and/or injection of the left 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. An arthrocentesis, aspiration and/or injection of 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 an arthrocentesis, aspiration and/or injection of the left knee is not health care reasonably required for the compensable injury of _____.

DECISION

Claimant is not entitled to an arthrocentesis, aspiration and/or injection of 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 **LIBERTY MUTUAL FIRE INSURANCE COMPANY** and the name and address of its registered agent for service of process is:

CT CORPORATION SYSTEMS
360 NORTH ST. PAUL STREET
DALLAS, TEXAS 75201

Signed this 1st day of July, 2009.

Jacquelyn Coleman
Hearing Officer