

MEDICAL CONTESTED CASE HEARING NO 12008
M6-11-32927-01

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, 2011 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 one Synvisc injection to the right knee for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Provider appeared by telephone. Respondent/Carrier appeared and was represented by MS, attorney. The Claimant did not appear and her appearance was excused.

BACKGROUND INFORMATION

The Claimant sustained a compensable injury to her right knee on (Date of Injury) while working for (Employer). Later, after a graft from her left knee during a surgical procedure for her right knee, her left knee became problematic and has been treated as a part of the compensable injury. The Claimant, who is 46 years old, has undergone four knee surgeries, two on the right and two on the left, according to the testimony of Dr. M, who is a board certified orthopedic surgeon and is the requestor of the injection at issue herein. She initially saw Dr. M on September 23, 2010 for persistent bilateral knee pain, right much greater than left. Dr. M noted on September 23, 2010 that the Claimant would eventually need a total knee arthroplasty (TKA) surgery on the right. On October 28, 2010, Dr. M performed the most recent surgery upon the Claimant's right knee, which involved an arthroscopy, medial meniscectomy, removal of loose bodies, and synovectomy. After the October 28, 2010 surgery, the Claimant's right knee symptoms were greatly improved, and she reported to Dr. M on December 8, 2010 that she had no right knee pain. Dr. M also noted on that date that she had full range of motion (ROM) of both knees, but that her left knee pain was persistent. On January 18, 2011, Dr. M noted that the Claimant was having discomfort in the anterior part of her right knee, and he diagnosed her right knee condition as symptomatic patellofemoral arthrosis. He recommended a Synvisc #1 injection to the Claimant's right knee. The Claimant previously had five Synvisc injections to her right knee performed by Dr. Ernest Roman between September 6, 2007 and October 4, 2007.

The request for the Synvisc injection at issue herein was denied by two Carrier utilization review agents (URAs), and the denials were upheld by an IRO. The IRO physician reviewer, who is also board certified in orthopedic surgery, reasoned that the Claimant does not meet the criteria in the Official Disability Guidelines (ODG) to have the requested injection since there was no evidence of significant improvement following the initial series of injections 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. 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 in making decisions about the care of individual patients. 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 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 [is] considered [a party] 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."

ODG Recommendations:

HYALURONIC ACID INJECTIONS (including injections of Synvisc-One hylan)

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 [sic] 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 [sic] of the knee. Synvisc-One is the only single-injection viscosupplement approved for the treatment of OA knee pain in the United States, from Genzyme 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) 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)

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.

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 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.

Dr. M's testimony showed that the Claimant has significant osteoarthritis/post-traumatic arthritis in her right knee that will eventually lead to a TKA surgery when she is older. He opined that the Claimant meets the ODG criteria to have the Synvisc injection performed since she has significantly symptomatic arthritis in the knee which does not respond to over-the-counter medications, and because she is too young now to have the TKA surgery performed. The two Carrier URA denials for this procedure were based on the lack of documentation of post-operative rehabilitation following the Claimant's October 28, 2010 surgery. In response thereto, Dr. M testified at the hearing that the Claimant did undergo post-operative physical therapy that began on October 29, 2010 and continued for four weeks, but by three months post-operatively she was suffering from right knee pain. He also testified, in response to the IRO denial, that the Claimant's prior Synvisc injections were successful for several months, although they only provide temporary relief.

The medical records in evidence document the performance of the prior injections upon the Claimant's right knee, but the records have very little information reflecting their effect upon the Claimant's symptoms. A record dated September 18, 2007 from her treating doctor at the time, Dr. G, D.C., states that the Claimant had undergone two injections and reported "a little relief" from them. Another record dated December 5, 2007 from Dr. K, who is an orthopedic surgeon who was affiliated with the same facility as Dr. R, noted that the Synvisc injections to the Claimant's right knee had "helped somewhat...". After a review of the entire record, it is determined that the medical evidence admitted into the record does not establish that the series of Synvisc injections to the Claimant's right knee in 2007 provided significant improvement in her symptoms for at least six months.

The evidence in the record demonstrates that the Claimant does not meet the last criterion in the ODG for the performance of a repeat Synvisc injection. On this basis, Dr. M did not establish that the preponderance of the evidence-based medical evidence is contrary to the IRO decision

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

Even though all the evidence presented may not have been discussed in detail, 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 to hear this case, and venue was proper in the (City) Field Office.
 - B. On (Date of Injury), Claimant sustained a compensable right knee injury while in the course and scope of her employment with (Employer).
 - C. The IRO upheld the Carrier's denial in deciding that the Claimant is not entitled to one Synvisc injection to the right knee for the compensable injury of (Date of Injury).
2. Respondent delivered to Petitioner a single document stating the true corporate name of Respondent, and the name and street address of Respondent's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 1.
3. Claimant does not meet all of the requirements of the ODG for one Synvisc injection to the right knee and Petitioner did not present evidence-based medical evidence sufficient to overcome the determination of the IRO.
4. One Synvisc injection to the right knee is not health care reasonably required for Claimant's 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 was 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 one Synvisc injection to the right knee for Claimant's compensable injury of (Date of Injury).

DECISION

Claimant is not entitled to one Synvisc injection to the right knee for her 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 **AMERICAN CASUALTY COMPANY OF READING, PENNSYLVANIA**, and the name and address of its registered agent for service of process is:

**C T CORPORATION SYSTEM
350 N. ST. PAUL STREET
DALLAS, TX 75201**

Signed this 16th day of August, 2011.

Patrice Fleming-Squirewell
Hearing Officer