MEDICAL CONTESTED CASE HEARING 16064

DECISION AND ORDER

This case is decided pursuant to 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 determines that Petitioner/Claimant is not entitled to Hyalgan injections, right knee, times 5, for the compensable injury of (Date of Injury).

STATEMENT OF THE CASE

A contested case hearing was held on March 20, 2017, to decide the following disputed issue:

> Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Hyalgan injections, right knee, times 5, is not health care reasonably required for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared and was assisted by DS, ombudsman. Respondent/Carrier appeared and was represented by WS, attorney.

EVIDENCE PRESENTED

The following witnesses testified:

For Petitioner/Claimant: JF

For Respondent/Carrier: None

The following exhibits were admitted into evidence:

Hearing Officer's Exhibits HO-1 and HO-2.

Petitioner/Claimant's Exhibits C-1 through C-5.

Respondent/Carrier's Exhibits CR-A through CR-D.

DISCUSSION

Petitioner/Claimant sustained a comminuted patella right knee fracture on (Date of Injury), when he tripped and fell during the course and scope of his employment with (Employer), Employer. GI, M.D., performed an open reduction internal fixation (ORIF) of the patella fracture on October 23, 2007, followed by a partial medial and lateral meniscectomies, chondroplasty of the

patella, and removal of hardware from the ORIF on April 9, 2010. Dr. I wrote that he initiated Supartz injections in sets of five starting on August 25, 2010, February 29, 2012, October 18, 2012, March 21, 2014, and December 7, 2015. According to the Dr. I's July 1, 2016 letter, the Supartz injections provided significant pain relief until the last series of injections which did not seem to help as long, as he had only about 3 months of relief. Dr. I stated that is why he requested Hyalgan injections, right knee, times 5 instead of Supartz injections.

Respondent/Carrier obtained a Utilization Review Authorization (URA) on the necessity for the Hyalgan injections, right knee, times 5, in light of the Official Disability Guidelines (ODG) and refused to authorize its purchase. Petitioner/Claimant appealed the denial and an IRO was appointed by the Texas Department of Insurance in accordance with Rule 133.308. After consideration of the information provided, the IRO upheld Respondent/Carrier's denial of the requested Hyalgan injections, right knee, times 5 as not reasonably necessary for treatment of the compensable injury. Dr. I thereafter filed a request for a contested case hearing as provided for by Rule 133.308(s). The contested case hearing was held on March 20, 2017.

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 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, and 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 adopted treatment guidelines by Division Rule 137.100. The 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. A decision issued by an IRO is not considered an agency decision and the Department and the Division are not

considered parties to an appeal. In a contested case hearing, the party appealing the IRO decision has the burden of overcoming the decision issued by the IRO by a preponderance of the evidence-based medical evidence. (Rule 133.308 (s).)

Dr. I requested Hyalgan injections, right knee, times 5. The request underwent a URA with Coventry Healthcare Workers Compensation Services, and it was determined that the request should be denied because medical necessity cannot be established at this time.

Dr. I requested that an IRO be appointed to review Respondent/Carrier's denial of preauthorization of the Hyalgan injections, right knee, times 5. The Division appointed Applied Assessments LLC, as the IRO. The IRO submitted the request for review of the prescription to a health care provider specializing in Orthopedic Surgery. The physician reviewer upheld the denial of the Hyalgan injections, right knee, times 5, citing his medical judgment, clinical experience and expertise in accordance with accepted medical standards and the ODG as the bases for his determination. In part, the physician reviewer wrote:

> The Official Disability Guidelines state a repeat series of injections may be warranted if there is documented significant improvement in symptoms for 6 months or more and symptom recur. The documentation submitted for review indicated the patient underwent previous Synvisc injections in the past with the latest 1 being performed on 01/04/2016. However, there was no documentation of objective functional improvement in symptoms for 6 months to warrant the need of a repeat series of injections. Therefore, the request for Hyalgan injections, right knee times 5, is upheld.

Petitioner/Claimant argues that the recommendations of the ODG regarding the Hyalgan injections, right knee, times 5 by Dr. I should not be followed because his case is outside of the norm, he should be considered an outlier, and the IRO determination should be overturned. According to Petitioner/Claimant, every case is different.

The knee section of the ODG contains the following:

> Hyalgan® (hyaluronate)
> See Hyaluronic acid injections, where a series of three to five injections of Hyalgan (hyaluronate) are recommended as an option for osteoarthritis.
>
> 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, metatarsophalangeal 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 incidence of injection-related problems has been similar to that of 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 G-F 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 expert medical evidence shows that the recommendations contained in the ODG apply to Petitioner/Claimant and that the Hyalgan injections, right knee, times 5, requested by Dr. I is not reasonably required for the compensable injury of (Date of Injury). Under the facts presented, Petitioner/Claimant has failed to prove, by a preponderance of the evidence-based medical evidence, that the determination of the IRO is incorrect.

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

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

   C. On (Date of Injury), Employer provided workers' compensable insurance with Ace American Insurance Company, Respondent/Carrier.

   D. Petitioner/Claimant sustained a compensable injury on (Date of Injury).

   E. The IRO determined that Petitioner/Claimant should not have Hyalgan injections, right knee times 5 for the compensable injury of (Date of Injury).

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

3. Applied Assessments, LLC was appointed as the IRO to review Respondent/Carrier's denial of Hyalgan injections, right knee times 5 for the compensable injury of (Date of Injury).

4. The IRO upheld Respondent/Carrier's denial of prescription for Hyalgan injections, right knee times 5 for the compensable injury of (Date of Injury).

5. The preponderance of the evidence-based medical evidence is not contrary to the IRO's determination that Hyalgan injections, right knee times 5 do not constitute reasonable and necessary health care for the compensable injury of (Date of Injury).

6. Hyalgan injections, right knee times 5 is not reasonably required health care for the compensable injury of (Date of Injury).

DECISION

Petitioner/Claimant is not entitled to Hyalgan injections, right knee times 5, for the compensable injury of (Date of Injury).

ORDER

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

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

CT CORPORATION SYSTEM
1999 BRYAN STREET, SUITE 900
DALLAS, TX 75201-3136

Signed this 21st day of March, 2017.

Early Moye
Hearing Officer