

# MATUTECH, INC.

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## Notice of Independent Review Decision

**DATE OF REVIEW:** August 26, 2009

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

3 Euflexxa injections to the left knee

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

Certified, American Board of Orthopaedic Surgery

**REVIEW OUTCOME**

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

- Utilization reviews (08/03/09, 08/13/09)
  
- Utilization reviews (08/03/09, 08/13/09)
- Office visits (03/08/07 - 06/30/09)
- Diagnostics (03/08/07 – 06/27/07)
- Procedures (06/21/07 – 11/11/08)
- Therapy (07/10/07 – 08/27/07)
  
- Utilization reviews (08/03/09, 08/13/09)
- Reviews (02/03/09)
- Office visits (03/08/07 - 06/30/09)
- Diagnostics (03/08/07 – 06/27/07)
- Procedures (06/21/07 – 11/11/08)
- Therapy (07/10/07 – 08/27/07)

ODG criteria have been utilized for the denials.

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a xx-year-old male who was boarding an airplane and twisted his left knee while getting into the seat hitting it on arm rest of the seat on xx/xx/xx.

**2007:** On March 8, 2007, , D.O., saw the patient for pain and swelling in the left knee. Examination revealed moderate contusion of the left knee along the anterior, lateral, and posterior aspects with some swelling and crepitus. Dr. diagnosed pain in the joint involving the lower leg and obtained a magnetic resonance imaging (MRI) of the left knee. MRI revealed: (1) Significant bone contusion of the lateral tibial plateau, suspicion for a non-displaced, non-depressed fracture through the lateral tibial plateau, and overlying inflammation. (2) Mild simple joint effusion. (3) 4mm globular region of signal within the posterior horn of the medial meniscus extending into the inferior articular surface, consistent with a tear versus contusion. (4) Mild intra-substance degeneration throughout the remainder of the medial meniscus.

, M.D., an orthopedic surgeon, recommended full time hinged brace and allowed walking without ambulatory aids. Later, due to extreme swelling from the knee to the calf, a venous Doppler of the left lower extremity was obtained which was unremarkable. Subsequently, the patient noted increased pain in the left knee after working in the gym. Dr. suspected persistent lateral meniscus tear.

On June 21, 2007, Dr. A performed left knee arthroscopic partial lateral meniscectomy, chondroplasty of the lateral tibial surface, and arthroscopic resection of symptomatic medial synovial plica.

Postoperatively, the patient complained of swelling and tenderness in the left calf. Venous Doppler was positive for a small nonocclusive thrombus within the posterior tibial vein. He was evaluated at emergency center for a noncardiac chest pain and was treated with Lovenox and Coumadin. , M.D., evaluated the patient for possible blood clot in the left leg. The prothrombin time was monitored regularly and the warfarin was increased.

From July through August, the patient attended physical therapy (PT) rehabilitation.

In August, Dr. noted continued patellofemoral crepitus and discomfort in the left knee, mild. He administered a steroid injection into the left knee. In September, he administered a series of Euflexxa injections into the left knee with some moderate improvement in the knee pain.

**2008:** In March, Dr. noted reoccurrence of the left knee arthritic pain and performed another steroid injection into the left knee for short-term relief of the symptoms. Due to advanced nature of arthritis, Dr. felt the patient would require knee replacement in the future; however, it would be best to postpone the surgery for as long as possible. On April, 8, 2008, November 4, 2008, and November 11, 2008, Dr. performed Euflexxa injections x3 into the knee, with minimal improvement. In December, Dr. noted the Euflexxa injections had not

particularly decreased the discomfort and the patient had occasional crepitus, which limited his ability to perform any activities. Dr. prescribed Celebrex.

On November 14, 2008, the request for peroneal nerve decompression with fibular osteotomy was authorized.

**2009:** In February, , M.D., performed a required medical evaluation (RME) and noted: *Dr. administered three Euflexxa injections in September 2007, with no significant improvement. In a designated doctor evaluation (DDE) , D.O., placed the patient at maximum medical improvement (MMI) on October 16, 2007, with 0% whole person impairment (WPI) rating. In October 2008, Dr. noted new problem of left foot numbness that began a month ago. He suspected left leg sciatica due to disc herniation. MRI of the lumbar spine revealed mild disc desiccation at T12-L1, L1-L2, and L4-L5. Electromyography/nerve conduction velocity (EMG/NCV) of the lower extremity revealed mild-to-moderate slowing of the peroneal nerve across the fibular head consistent with mild to moderate peroneal nerve palsy on the left. In a peer review, , M.D., opined that three Euflexxa injections were medically necessary. Dr. rendered the following opinions: (1) The extent of injury appeared to be primarily to his left knee. There was no documentation to support a neurological condition related to the peroneal nerve neither any indication that he had sustained a lumbar spine injury. Hence, the extent of injury would include the potential for a posttraumatic synovitis and arthritis of the knees since there did appear to be some cartilage damage and possible tibial plateau fracture of the lateral plateau. The patient also had excision of meniscal tissue, which could alter the stresses across the compartment of the knee. (2) The current treatment had been primarily to treat the knee itself. The MRI of the lumbar spine and EMG/NCV did not appear to be related to the knee injury itself. (3) The treatment with over-the-counter non-steroidal anti-inflammatory medications and follow-up on an every six-month basis had been appropriate along with the use of hyaluronic acid-type injection. He had a series of three, with the third not being as effective; therefore, additional injection therapy was not indicated based on the Official Disability Guidelines (ODG) criteria. The patient might need intermittent follow-up and could require an occasional steroid injection in the future since he developed significant recurrent effusion. It was unlikely that he would go on to a significant degree of posttraumatic arthritis.*

In February, Dr. noted the Euflexxa injections were quite helpful in reducing the left knee pain. He recommended repeating the injections in May and every six months thereafter. In June, he noted recurrence of pain due to arthritis. Repeat Euflexxa injections were ordered and peroneal nerve decompression due to the ongoing symptoms of pain, numbness and weakness was recommended.

On August 3, 2009, D.O., a physical medicine and rehabilitation specialist, denied the request for three Euflexxa injections to the left knee with the following rationale: *"Patient sustained an injury dated xx/xx/xx, from a direct trauma. Patient complained of knee pain. He underwent knee surgery (partial lateral meniscectomy). He had previous Euflexxa injection in the past that alleviated his discomfort. Based on the submitted clinical information, the complete physical examination of the patient was not presented for review. The documentation of failure of conservative management for the patient including PT progress notes, adequate pain medications, and injections were not provided for review. The*

*date and the duration of the effect of the previous injection was not provided for review. The necessity of the request was not established.”*

On August 13, 2009, [redacted], D.O., an orthopedic surgeon, denied the appeal for three Euflexxa injections to the left knee with the following rationale: *“Based on the clinical information submitted for this review and using the evidence-based peer review guidelines referenced below, this request for three Euflexxa injections on the left knee is not medically necessary. The clinician’s notes in December indicate the claimant did not realize much improvement from the prior Euflexxa injections. ODG would suggest a three series of injections over a five year period if there is relief for six-to-nine months from the symptoms. The request is not indicated.”*

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.**

The patient sustained an injury to the left knee. At time of arthroscopy for partial lateral meniscectomy, the surgeon noted “mild traumatic” arthritis of the lateral tibial plateau, but there is no description of a high-shouldered focal chondral defect surrounded by otherwise-intact articular cartilage and there is no rationale as to how the tibial plateau sustained a direct trauma; thus, the description in the operative record is more consistent with diffuse degenerative chondromalacia. That being considered, and despite the etiology of the chondromalacia (be it traumatic or degenerative), there is no ODG indication for continued use of Euflexxa, a synthetic HA preparation.

Per the ODG, no more than 3 series of injections should be given within 5 year period. The medical record indicates that the claimant had a series of 3 injections on 3 occasions (9/07, 4/08, and 10/08). Furthermore, on 12/23/08 it was noted that the claimant “feels Euflexxa injections did not help.” Thus, the determinations of the previous reviewers appear to have adequate support for the denial of another series of injections.

Hyaluronic acid injections	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. ( <a href="#">Karlsson, 2002</a> ) ( <a href="#">Leopold, 2003</a> ) ( <a href="#">Day, 2004</a> ) ( <a href="#">Wang, 2004</a> ) ( <a href="#">Aggarwal, 2004</a> ) ( <a href="#">Arrich, 2005</a> ) ( <a href="#">Karatosun, 2005</a> ) ( <a href="#">Blue Cross Blue Shield, 2005</a> ) ( <a href="#">Petrella, 2005</a> ) 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. ( <a href="#">Lo-JAMA, 2004</a> ) These more recent studies did not. ( <a href="#">Reichenbach, 2007</a> ) ( <a href="#">Jüni, 2007</a> ) The response to hyaluronan/hylan products appears more durable than intra-articular corticosteroids in treatment of knee osteoarthritis. ( <a href="#">Bellamy-Cochrane, 2005</a> ) 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. ( <a href="#">Bellamy-Cochrane2, 2005</a> ) ( <a href="#">Bellamy, 2006</a> ) 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. ( <a href="#">Modawal, 2005</a> ) 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
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	<p>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 Genzyme Corp. (FDA, 2009)</p> <p><b>Criteria for Hyaluronic acid or Hylan:</b>  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:</p> <ul style="list-style-type: none"> <li>· 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).</li> <li>· Are not candidates for total knee replacement or who have failed previous knee surgery for their arthritis, such as arthroscopic debridement.</li> <li>· Younger patients wanting to delay total knee replacement. (Wen, 2000)</li> <li>· Repeat series of injections: If relief for 6-9 months and symptoms recur, may be reasonable to do another series. Recommend <b>no more than 3 series of injections over a 5-year period</b>, 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)</li> </ul>
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**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**