MAXIMUS Federal Services

Case Number:	CM15-0129973		
Date Assigned:	07/16/2015	Date of Injury:	05/02/2012
Decision Date:	08/14/2015	UR Denial Date:	06/29/2015
Priority:	Standard	Application Received:	07/06/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: New Jersey, Alabama, California
Certification(s)/Specialty: Neurology, Neuromuscular Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 58-year-old female who sustained an industrial injury on 5-2-12 with current complaints of cervical, lumbar and right knee pain. The diagnoses are headaches, cervical disc disease, cervical facet syndrome, status post right shoulder arthroscopy with residual, bilateral wrist sprain-strain, lumbar disc disease, lumbar facet syndrome, and bilateral knee internal derangement. In an orthopedic agreed medical examination dated 3-18-15, the physician notes constant right knee pain rated at 6 at best and 8 at worst, out of 10. Pain is increased with activity and she experiences constant clicking, popping, grinding, locking and giving way and occasional swelling. Left knee pain is intermittent and rated 4-5 out of 10. Knee range of motion on the right and left is flexion 135 and extension 0. In a follow up evaluation dated 6-11-15, a primary treating physician notes subjective complaints of cervical and lumbar pain rated at 5 out of 10 and that her right knee has gotten worse. She takes her medications regularly, tolerates them well and states they are helping with her pain. Objective exam notes a heel-toe walk exacerbates her antalgic gait on the right. There is moderate right knee and mild left knee pain, medially and posteriorly. A knee exam notes; Patellar Compression is positive on the right and left and McMurray's Test is positive on the right and left. Lower extremity reflexes are 1+ on the right knee and 2+ on the left. The treatment plan includes a right Synvisc injection for a series of three to be done two to three weeks apart as well as a random urinary drug-screening test to ensure compliance with current medical regimen and also to ensure she is not receiving medications from multiple prescribing physicians or illicit drugs. X-rays of bilateral knees, dated 4-8-14 reveal; mild degenerative change, no destructive pathologic process and no calcification in the soft tissues. The impression is mild degenerative change. An MRI of the right knee dated 7-10-14 revealed posterior horn of the medial meniscus myxoid change; anterior and

posterior horns of the lateral meniscus myxoid change; osteochondral lesion at the lateral facet of the patella with thinning of adjacent retro patellar cartilage, representing grade 4 chondromalacia patella; anterior cruciate ligament mucinous degeneration; mild joint space narrowing, medial and lateral femorotibial joints. Work status is that she is not working. A 3-12-15 progress report notes a treatment plan to continue Motrin and Tramodol. A 5-18-15 treatment plan notes she is to continue her home exercises and stretches as directed by a physical therapist and refill Motrin 800 mg twice a day. Previous treatment includes rest, ice, Ibuprofen, 2 cervical epidural injections-which helped for one to two weeks, a right knee injection, and a lumbar injection - which helped for 1 week. The requested treatment is for Synvisc Injection to the right knee, for a quantity of 3 and a Toxicology-Urine Drug Screen.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Synvisc Injection right knee quantity 3: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Knee and leg chapter, Hyaluronic Acid Injections.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Hyaluronic acid injections, http://www.worklossdatainstitute.verioiponly.com/odgtwc/knee.htm#Hyaluronicacidinjections .

Decision rationale: According to ODG guidelines, Hyaluronic acid injections Recommended as a possible option for severe osteoarthritis for patients who have not responded adequately to recommended conservative treatments (exercise, NSAIDs or acetaminophen), to potentially delay total knee replacement, but in recent quality studies the magnitude of improvement appears modest at best. See recent research below. 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) (Jƒni, 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. (Juni, 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) In patients who are candidates for TKR, the need for TKR can be delayed with hyaluronic acid injections. (Waddell, 2007) There is no documentation that the patient failed conservative therapies. There is no documentation that the patient is suffering from osteoarthritis or severe osteoarthritis that did not respond to conservative therapies. Therefore, the medical necessity for Synvisc Injection right knee quantity 3 is not established.

Toxicology - Urine Drug Screen: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, drug testing. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Urine drug testing (UDT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, steps to avoid misuse/addiction Page(s): 77-78; 94.

Decision rationale: According to MTUS guidelines, urine toxicology screens are indicated to avoid misuse/addiction. "(j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs". There is no evidence that the patient have aberrant behavior for urine drug screen. There is no clear evidence of abuse, addiction and poor pain control. There is no documentation that the patient has a history of use of illicit drugs. Therefore, the request for Urine drug screen is not medically necessary.