MAXIMUS Federal Services

Case Number:	CM15-0024563		
Date Assigned:	02/17/2015	Date of Injury:	01/17/2007
Decision Date:	03/31/2015	UR Denial Date:	01/19/2015
Priority:	Standard	Application Received:	02/09/2015

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, Michigan, 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 64 year old female, who sustained an industrial injury on 1/17/07. She has reported injury to multiple body parts. The diagnoses have included exacerbation of cervical degenerative disc disease, bilateral upper extremity overuse syndrome, bilateral carpal tunnel syndrome, bilateral carpal tunnel releases, right wrist de Quervain's tenosynovitis status post release, right elbow lateral epicondylitis, left knee medial and lateral meniscal tear, status post partial medial and lateral menisectomy left knee and right total knee replacement. Treatment to date has included left knee arthroscopy, bilateral carpal tunnel release, oral medications and physical therapy. X-ray of left knee and right knee were performed revealing patellar spurring of left knee with deformity medial patella and total knee replacement of right knee.Currently, the injured worker complains of left knee pain. Progress note dated 12/2/14 revealed medication improved the knee pain. Physical exam noted positive tenderness parapatellarly and posteriorly with quadriceps atrophy and tenderness of medial joint line.On 1/19/15 Utilization Review non-certified Visco supplementation left knee using ultrasound, noting the lack of documentation to support failed treatment. The MTUS, ACOEM Guidelines and ODG were cited.On 1/22/15, the injured worker submitted an application for IMR for review of Visco supplementation left knee using ultrasound.

IMR ISSUES, DECISIONS AND RATIONALES

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

Visco supplementation, left knee using ultrasound guidance with Hyalgan: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, 12th Edition (web), 2014, Hyaluronic Acid

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) (Jni, 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. (Jni, 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. There is no rational behind Therefore, Visco supplementation, left knee using ultrasound guidance with Hyalgan is not established.