

Case Number:	CM14-0120713		
Date Assigned:	08/06/2014	Date of Injury:	07/27/2013
Decision Date:	09/11/2014	UR Denial Date:	07/15/2014
Priority:	Standard	Application Received:	07/31/2014

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. The expert reviewer is Board Certified in : Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 male who sustained an industrial injury on July 27, 2013. The mechanism of injury was twisting of the right knee and the patient sustained chronic knee pain. Conservative therapies have included physical therapy, pain medications including Celebrex, and hinged knee brace. MRI of the right knee on 9/2013 revealed medial meniscal tear, full thickness chondral loss of the medial femoral condyle, severe chondromalacia of the lateral femoral condyle, and interstitial tear of the ACL. The injured worker is noted to have declined cortisone injection because cortisone injections in other joints have not worked. The disputed issue is a request for a series of Synvisc knee injections.

IMR ISSUES, DECISIONS AND RATIONALES

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

Series of Synvisc Injections, Left knee: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Criteria for Hyaluronic acid injections.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee Chapter, Viscosupplementation.

Decision rationale: Hyaluronic acid injections of the knee are not specifically addressed by the CA MTUS or ACOEM Guidelines. Instead, the Official Disability Guidelines are cited, which specify the following for hyaluronic injection: "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) (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 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."In this case, the radiologic finding demonstrate that at least a component of the pain is attributed to osteoarthritis. The MRI of the right knee on 9/2013 revealed medial meniscal tear, full thickness chondral loss of the medial femoral condyle, severe chondromalacia of the lateral femoral condyle, and interstitial tear of the ACL. The injured worker is noted to have declined cortisone injection because cortisone injections in other joints have not worked, specifically in the wrist. The Official Disability Guidelines does not actually state that corticosteroid injections are part of the standard pharmacologic treatment of symptomatic osteoarthritis. The patient has

documentation of other standard pharmacologic treatments including anti-inflammatory and nonpharmacologic treatments such as activity restriction and physical therapy. Therefore viscosupplementation is appropriate in this case and is medically necessary.