

<b>Case Number:</b>	CM15-0098707		
<b>Date Assigned:</b>	06/01/2015	<b>Date of Injury:</b>	04/28/2006
<b>Decision Date:</b>	06/30/2015	<b>UR Denial Date:</b>	04/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/21/2015

### 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 60 year old female who sustained an industrial injury on 04/28/2006. Diagnoses include discogenic lumbar condition with Magnetic Resonance Imaging showing disc disease at L4-L5 and L5-S1, cervical sprain with no real Magnetic Resonance Imaging done, nerve studies showing carpal tunnel syndrome moderate and bilateral ulnar nerve involvement on the left, internal derangement of the knee bilaterally, impingement syndrome of the shoulder on the left, status post decompression followed by repeat surgery where labral tear was done, shoulder sprain on the right treated with observation, based on chronic pain, the injured worker has an element of depression, sleep and stress. Treatment to date has included diagnostic studies, medications, injections, status post left knee arthroscopic basis meniscectomy medially and laterally 01/16/2014, arthroscopy surgery on the left knee in 2007, and right knee in 2009, knee braces a cane for ambulation, and cortisone injections. There is documentation noted in a physician progress note dated 12/03/2014 that x rays were done on the left knee on the last visit and revealed minimal articular surface to the left medially. A physician progress note dated 04/13/2015 documents the injured worker complains of severe pain in both knees and she is not sleeping at night. She has swelling in both knees. She also has neck and bilateral shoulder pain which comes and goes. She can do full extension and flexion at 120 degrees bilaterally. There is tenderness along the joint both medially and laterally with positive anterior drawer test 1+ bilaterally. The treatment requested was for Norco 10/325mg #120, Cymbalta 30mg #30, and Protonix 20mg #60, Voltaren gel 1% 100g, three tubes, and Celebrex 200mg #30 for

inflammation, and x rays of bilateral knees. Treatment requested is for Protonix 20mg #60, and Sodium hyaluronate injection 20mg/2ml & Hyalgan; series of 5 for the bilateral knees, #10.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Sodium hyaluronate injection 20mg/2ml & Hyalgan; series of 5 for the bilateral knees, #10:**  
Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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), too 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) (Juni, 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 visco-supplementation 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 [REDACTED], from [REDACTED]. (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 is suffering from osteoarthritis or severe osteoarthritis that did not respond to conservative therapies. There is no rationale for recommending 5 consecutive injections of the knees bilaterally without documentation of efficacy of previous injections. Therefore, the medical necessity for Sodium hyaluronate injection 20mg/2ml & Hyalgan; series of 5 for the bilateral knees, #10 is not medically necessary.

**Protonix 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 102.

**Decision rationale:** According to MTUS guidelines, Protonix is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. There is no documentation that the patient is at an increased risk of GI bleeding. Therefore the prescription of Protonix 20mg #60 is not medically necessary.