

Notice of Independent Review Decision

DATE OF REVIEW: SEPTEMBER 16, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Left knee; Hyalgan injection (in office)

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

The doctor performing this review is a board certified orthopedic surgeon who is currently licensed and practicing in the state of Texas.

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Type of Document Received	Date(s) of Record
Adverse Determination	08/06/2013
Appeal Acknowledgement Letter	08/14/2013
Pre-Authorization Appeal	08/20/2013
Operative Report	03/05/2013
MRI of the Knee W/O Contrast	11/08/2012
Prospective Review Response	09/12/2013
Office Visit	07/31/2013
Impairment Rating report	07/15/2013
Office Visit	07/03/2013
DWC073	07/03/2013
Pre-Auth request for physical therapy	06/13/2013
Office Visit	05/29/2013
Post Op Visit from Orthopaedic	04/29/2013
Post Op Visit from Orthopaedic	03/25/2013
Office Visit from Orthopaedic	03/06/2013



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Office Visit from Orthopaedic	01/21/2013
Office Visit from Orthopaedic	01/07/2013
Office Visit from Orthopaedic	12/05/2012
Physical Therapy Notes from Physical Therapy	04/24/2013

EMPLOYEE CLINICAL HISTORY [SUMMARY]:

The injured worker is a male, injured xx/xx/xx, in a slip and fall incident. The claimant was diagnosed with joint pain in the leg. MRI dated 11/12/2012 reported a small focal tear in the mid portion of the medial collateral ligament. A possible flap tear or free edge horizontal tear involving the posterior horn of the medial meniscus. Intrasubstance degeneration in the posterior root attachment was noted. The injured worker underwent a left knee partial meniscectomy, chondroplasty of the lateral femoral condyle, patella and trochlea and medial femoral condyle and medial tibial plateau on 02/08/2013. The injured worker received 12 to 15 postoperative physical therapy sessions. He was seen by an Impairment Rating Doctor, DC on 07/22/2013 and was placed at MMI as of 07/01/2013 and assigned a 1% whole person impairment rating. He returned to his treating physician and a preauthorization request was made for an in office left knee Hyalgan Injection on 08/06/2013. This was denied by the carrier as the ODG knee and leg chapter requires lower levels of care of anti-inflammatory medications and cortisone injections in the knee. There is no documentation of lower levels of care of non-steroid anti-inflammatory medications or cortisone injections. The treating provider appealed this decision on 08/14/2013 and the denial was upheld based again on the ODG's.

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

After review of the injured workers file, there is no documentation of lower levels of care as required in the ODG. In addition, the injured worker does not have documented severe osteoarthritis as per the criteria of the ODG.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:



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- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)

OFFICIAL DISABILITY GUIDELINES:

Criteria for Hyaluronic acid injections:

· Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative nonpharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 3 months;



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- Documented symptomatic severe osteoarthritis of the knee according to American College of Rheumatology (ACR) criteria, which requires knee pain and at least 5 of the following:
 - (1) Bony enlargement;
 - (2) Bony tenderness;
 - (3) Crepitus (noisy, grating sound) on active motion;
 - (4) Erythrocyte sedimentation rate (ESR) less than 40 mm/hr;
 - (5) Less than 30 minutes of morning stiffness;
 - (6) No palpable warmth of synovium;
 - (7) Over 50 years of age;
 - (8) Rheumatoid factor less than 1:40 titer (agglutination method);
 - (9) Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³);
- Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease;
- Failure to adequately respond to aspiration and injection of intra-articular steroids;
- Generally performed without fluoroscopic or ultrasound guidance;
- Are not currently candidates for total knee replacement or who have failed previous knee surgery for their arthritis, unless 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.
- Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, or patellofemoral arthritis, patellofemoral syndrome (patellar knee pain), plantar nerve entrapment syndrome, or for use in joints other than the knee (e.g., ankle, carpo-metacarpal joint, elbow, hip, metatarso-phalangeal joint, shoulder, and temporomandibular joint) because the effectiveness of hyaluronic acid injections for these indications has not been established.

FULL INSERT FROM ODG

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](#)) ([Jüni, 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. ([Sitik,](#)



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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](#)) 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](#))

Recent research: 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](#)) According to a meta-analysis based on 89 randomized trials including 12,667 patients, hyaluronic acid injections produced minimal or nonexistent effects on pain and function in patients with knee osteoarthritis (OA), but did increase the risks for serious adverse events and local adverse reactions. They also identified unpublished trials, suggesting publication bias in favor of the treatment. The best they could say is that the use of this therapy depends on individual patient features and response to the treatment, while randomized controlled trials give only the mean value for therapy, which may not be generalizable to every patient. ([Rutjes, 2012](#)) The California Technology Assessment Forum (CTAF) concluded that treatment of knee OA with injections of intra-articular HA does not meet CTAF criteria for safety, efficacy and improvement in health outcomes for progression to knee replacement or progression of disease. ([CTAF, 2012](#)) The latest AAOS Guidelines for Treatment of Osteoarthritis of The Knee, says they cannot recommend using HA for patients with symptomatic OA of the knee, based on strong evidence. ([AAOS, 2013](#))

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.



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After meniscectomy: This RCT found there was no benefit of hyaluronic acid injection after knee arthroscopic meniscectomy in the first 6 weeks after surgery, and concluded that routine use of HA after knee arthroscopy cannot be recommended. ([Baker, 2012](#)) Also see Criteria below: Patients should not have failed previous knee surgery for their arthritis, such as arthroscopic debridement.

Brands of hyaluronic acid: There are several brands of viscosupplement on the market, but there is a lack of reliable evidence that any one brand is superior to other brands for medically necessary indications. Euflexxa may be recommended where there is allergy contraindication to ingredients in the others (eggs, feathers or poultry). The Euflexxa and Orthovisc brands may be less costly, and other brands, Hyalgan, Supartz, Synvisc (Hylan G-F 20), and Synvisc One, may be more costly, but this is dependent on specific fee schedules and purchasing techniques. Recommendations include a series of three to five intra-articular injections of Hyaluronic acid (Hyalgan or Supartz), or just three injections of Hylan or Euflexxa, or three to four injections Orthovisc, or one of Synvisc-One hylan, in the target knee with an interval of one week between injections. (FDA labeling) ([Huskin, 2008](#)) ([Zietz, 2008](#)) ([Wobig, 1999](#)) ([Raman, 2008](#))