

Notice of Independent Review Decision

September 26, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Supartz Injections (Supartz viscosupplementation injection to painful knee)

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician is a member of the Texas Medical Board. The physician has a private practice of Physical Medicine & Rehabilitation, Electro Diagnostic Medicine & Pain Management in Texas. The physician has published in medical journals. The physician is a member of his state and national medical societies.

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)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Upon independent review, the reviewer finds that the previous adverse determination should be upheld.

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INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records Received: 1 document received totaling 17 pages via fax 09/18/12 Texas Department of Insurance IRO request and Letter of authorization, 1 document totaling 39 pages received via fax 09/20/12 URA response to disputed services including administrative and medical records.

- Preauthorization request dated 08/08/12.
- Preauthorization denial letter with rationale dated 08/13/12.
- Preauthorization appeal dated 08/29/12.
- Preauthorization appeal denial letter with rationale dated 09/06/12.

PATIENT CLINICAL HISTORY [SUMMARY]:

Within the information provided to the IRO, the patient clinical history summary indicates that this individual is described as a man. The injury is not further described. The patient was noted to have undergone steroid injection in April 2012 and 08/02/12. There is mention of some degenerative change noted in the knee, but no copies of imaging reports are provided.

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

As stated within the denials, it is indicated that the *ODG* does recommend viscosupplementation for knee degenerative arthritis. The information provided from the healthcare providers does not indicate treatment the patient has received for the knee pain, response to treatment, response to therapies, or other alternative treatment approaches that have been tried. The *ODG* does not recommend Supartz injections as medically reasonable and necessary given the limited amount of clinical information provided to support the request.

ODG -TWC

ODG Treatment

Integrated Treatment/Disability Duration Guidelines

Knee & Leg (Acute & Chronic)

Hyalgan®	See Hyaluronic acid injections .
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<p>Hyaluronic acid injections</p>	<p>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) (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. (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. (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</p>
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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](#))

Recent research: 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 repeated 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](#))

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:

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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.

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

- 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)**