



CLAIMS EVAL

*Utilization Review and
Peer Review Services*

Notice of Independent Review Decision-WC

DATE OF REVIEW: 4-17-12

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Five in office left knee Supartz injections

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

American Board of Orthopaedic Surgery-Board Certified

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 or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- 4-22-11 MRI of the left knee.
- 11-7-11 MD., office visit.
- 11-30-11 MD., office visit.
- 1-18-12 MD., office visit.
- 1-30-12 UR notes Physician Advisor completed a peer to peer.
- 2-23-12 UR The Physician Advisor completed a peer to peer phone conversation.
- 4-9-12 MD., performed a Prospective Review response.

PATIENT CLINICAL HISTORY [SUMMARY]:

4-22-11 MRI of the left knee shows a joint effusion is present. Osteoarthritic changes are noted. The thickening and signal changes seen in the medial collateral ligament may be indicative of a partial tear. This should be correlated with the clinical findings. The increased signal seen in the proximal tibia is most likely the result of a bone contusion.

11-7-11 MD., the claimant is a female who presents for recheck of the left knee. The DOI was xx/xx/xx. Her medications include: Celebrex. The MRI was denied. She is still having some soreness from mechanical knee symptoms. She is also having some sciatic pain on the left side. On exam, the claimant has pes anserinus bursitis with tenderness to palpation over the pes anserinus bursa. The claimant also has some medial joint line tenderness noted today clinically. Impression: Left knee pes anserinus bursitis as well as medial joint line pain. The evaluator performed a steroid injection at the pes anserinus bursa as well as the medial joint line. The claimant will be placed on light duty.

11-30-11 MD., the claimant has failed conservative management. She has failed NSAID's, Supartz injections as well. The evaluator recommended left knee arthroscopy, arthroscopic evaluation of medial compartment and possible partial meniscectomy versus chondroplasty.

1-18-12 MD., the claimant is seen for postop visit. The claimant will be seen in two weeks for repeat evaluation. She will be off work until followup and get Supartz approval.

1-30-12 UR notes Physician Advisor completed a peer to peer with Dr. 1-26-12. They discussed the case/clinical records as follows: patient failed Supartz and cortisone injections over the past 6 months. This was used as justification for arthroscopic chondroplasty which was just done a week or 2 ago. A request for a repeat Supartz series is not justified without conventional post operative management such as therapy, NSAIDs, and perhaps a cortisone shot. Only if arthritis is firmly established and she has failed other pharmacologic treatments would consideration of another series of shots after surgery be justified. They agreed that she would most likely improve with a more standard post op regimen at this time.

2-23-12 UR--The Physician Advisor completed a peer to peer phone conversation with PA on 02/22/12. They discussed case/clinical records and denial rationale. A request for a repeat Supartz series is no justified without conventional post operative management such as therapy, non steroidal anti-inflammatories, and perhaps a cortisone shot. Only if arthritis is firmly established and she has failed other pharmacologic treatments would consideration of another series of shots after surgery be justified.

4-9-12 MD., performed a Prospective Review response. In response to a request for reconsideration for approval for five in-office left knee Supartz injections at Bone & Joint as requested by Dr. on 02/23/12, the Physician Advisor stated, "Deny: the Physician Advisor completed a peer to peer phone conversation with PA on 02/22/12. They discussed case/clinical records and denial rationale. A request for a repeat Supartz series as therapy, non steroidal anti-inflammatories, and perhaps a cortisone shot. Only if arthritis is firmly established and she has failed other pharmacologic treatment would consideration of another series of shots after surgery be justified." Further the Physician Advisor added "On 1/12/12 and 1/26/12, there was a documented denial by another peer review physician of a request for Supartz injection." In addition for the previous rationale for the previous denial, "the clinical notes of 2/16/12 and 2/26/12 had no discernible mention of any treatment with Supartz. There was no discernible entry relating specifically to the rationale on which the previous denials were based. The requestor has not furnished documentation which fulfills the ODG criteria for the requested service. Based on these facts, the request as submitted is not deemed to be r/n. the claimant had a previous chondroplasty, thus, making it unlikely that the requested injections would be efficacious. DENIAL STANDS." TASB maintains its position that the proposed treatment of outpatient left knee Supartz injections x5 at Beaumont Bone and Joint as requested by Dr. is not medically reasonable and necessary for the treatment of the compensable injury. Review of documentation

indicates that the claimant, who is a female, sustained a slip and fall injury while working as an for Department on xx/xx/xx. Significant past medical/surgical history is positive for prior left knee surgery in 2010, carpal tunnel of the bilateral hands, hysterectomy, bilateral feet, tonsillectomy and gallbladder. Claimant has a height of 5'3" and a weight of 216 pounds. Compensable injury is limited to the left knee. The carrier has disputed osteoarthritic changes in the left knee. Based on the diagnosis of left knee pain, initial treatment included diagnostic studies, Lidocaine/Celestone and Supartz x5 injections, which provided only some benefit and lasted about a month. Additional treatment included nine sessions of physical therapy. MRI of the knee on 04-22-11 documented joint effusion with osteoarthritic changes noted, thickening of the medial collateral ligament and increased signal in the proximal tibia, most likely the result of an ulnar contusion. It is documented that the claimant failed conservative management. Therefore, a left knee arthroscopy was recommended. Medical notes from the provider dated 01/18/12 reported the claimant s/p left knee arthroscopy with chondroplasty patella, trochlea and medial femoral condyle. Incisions were clean, dry and intact without signs or symptoms of infection. As reported by the Physician Advisor, clinical notes of 2/16/12 and 2/26/12, did not furnish documentation which fulfills the ODG criteria for the requested Supartz injections treatment. According to the Lower Extremity Treatment Guideline, treatment of a work related injury must be adequately documented and evaluated for effectiveness. In addition, treatment recommendations should be in accordance with the Official Disability Guidelines and Return to Work Guidelines. Per the Official Disability Guidelines, indications for Hyaluronic injections are indicated for patients who experience significantly symptomatic osteoarthritis but have not responded adequately to standard non pharmacologic and pharmacologic treatments or are intolerant of these therapies. Also, these injections are indicated for patients who are not candidates for total knee replacement or who failed previous knee surgery for their arthritis, such as arthroscopic debridement. It is documented that the provider agreed with the Physician Advisor during the denials, that the claimant most likely will improve with a more standard post op regimen. Additionally, ODG Criteria further indicates that response to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants) should be documented. The claimant had a recent left knee arthroscopy with chondroplasty. Documentation regarding ongoing progress in the recovery process by appropriate re-evaluations, objectively measured and demonstrated functional gains, reduction in pain, and increasing the patient's tolerance to daily activities while continuing with her home exercise program was not submitted. Therefore, the performance of outpatient left knee Supartz injections x5 at Bone & Joint as requested by Dr. in this patient who most likely will improve with conventional standard post op management after her recent surgery is not supported and is not medically reasonable or necessary at this time.

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

AFTER HAVING REVIEWED THE ENTIRETY OF THE SUBMITTED RECORDS, INCLUDING THE MOST RECENT CLINICAL RECORD DATED 1-18-12, THERE IS INCOMPLETE DOCUMENTATION OF A LACK OF PROGRESS FROM ROUTINE

POSTOPERATIVE CARE AFTER THE ARTHROSCOPIC SURGERY. THEREFORE, DESPITE A DIAGNOSIS OF OSTEOARTHRITIS OF THE AFFECTED KNEE, A LACK OF RESPONSE TO PHARMACOLOGIC AND NONPHARMACOLOGIC TREATMENTS HAS NOT BEEN DOCUMENTED TO SUPPORT THE UTILIZATION OF VISCOSUPPLEMENTATION AT THIS TIME BASED ON THE APPLICABLE ODG CRITERIA. THEREFORE, THE REQUEST FOR FIVE IN OFFICE LEFT KNEE SUPARTZ INJECTIONS IS NOT REASONABLE OR MEDICALLY NECESSARY.

ODG-TWC, last update 2-15-12 Occupational Disorders of the Knee – Supartz (Hyaluronic acid Injections):

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 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.

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)**