

# P&S Network, Inc.

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## Notice of Independent Review Decision

**DATE OF REVIEW:** May 20, 2008      **AMENED DECISION:** 05/22/08

**IRO CASE #:**

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

This case was reviewed by a PM&R Physician, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

Viscosupplementation injections x 3 from 03/21/08 to 05/21/08

**REVIEW OUTCOME**

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

**Upheld (Agree)**

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o March 17, 2008 Request for viscosupplementation, Dr.
- o March 21, 2008 Denial of request for viscosupplementation injections x 3
- o April 1, 2008 Letter of Appeal for viscosupplementation from Dr.
- o April 4, 2008 Denial of reconsideration for viscosupplementation injections x 3
- o April 21, 2008 Request for IRO

**PATIENT CLINICAL HISTORY [SUMMARY]:**

According to the medical records submitted for review, the patient is a XX-year-old employee who sustained an industrial injury to the left knee on XX/XX/XX. He is status post left knee arthroscopy, medial and lateral meniscoplasty and patellar chondroplasty November of 2006. The patient has residual osteoarthritis, a common sequella to meniscoplasty. The patient underwent 5 injections of hyaluronic acid with the last injection provided on August 9, 2007.

The patient reported benefit from the injections until he became symptomatic again in approximately February of 2008, 6 months after his last hyaluronic injection. Updated plain films show tricompartmental osteoarthritis. A repeat series of 3 injections to be performed under video fluoroscopy was requested on March 17, 2008 for the increased symptoms.

Request for viscosupplementation x 3 was not certified in review on March 21, 2008 with rationale that current guidelines state the number of injections should be limited to three. It was noted that the patient has had 5 injections.

The provider responded on April 1, 2008 with a letter of appeal. The provider makes reference to Medicare guidelines which support "this therapeutic intervention in 6-month increments if objective and subjective symptomatology persist. It was stated that, while the patient received good benefit from prior injections, he has again begun experiencing knee pain and ambulation difficulties as related to his osteoarthritis and, therefore, viscosupplementation injections x 3 are again recommended per guidelines.

On April 4, 2008 the request for reconsideration was denied in review with rationale that the request did not meet medical necessity guidelines.

On April 21, 2008, request was made for an IRO.

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

The medical records document a patient with post-op arthritis following arthroscopic intervention with procedures of medial and lateral meniscoplasty and patellar chondroplasty. Approximately 8 months post-op, the patient's knee symptoms increased and he was provided 5 weekly hyaluronic injections which resolved his exacerbation for over 6 months, until February of 2008. At that time he returned to his provider and a second series of injections was requested.

The patient benefitted from viscosupplement injections for over 6 months. His symptoms increased above baseline again in February of 2008. Repeat radiographs show a degree of tricompartmental osteoarthritis consistent with a Grade II Kellgren-Lawrence grading system.

The Official Disability Guidelines recommend viscosupplementation as an option for osteoarthritis. 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. The number of injections should be limited to three. 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.

Viscosupplementation has been shown to relieve pain in many patients who cannot get relief from nonmedicinal measures or analgesic drugs. The technique has been used in Europe and Asia for several years, but the U.S. Food and Drug Administration did not approve it until 1997, and then only for treating osteoarthritis of the knee. Several preparations of hyaluronic acid are now commercially available. It is very expensive and clinical trials have not yet proven that it is cost-effective. The number of injections is usually 3 [for Synvisc] or 5 [for Hyalgan] depending on the formulation used. The literature generally states that the beneficial effect lasts from several months up to a year.

The Official Disability Guidelines statement that the number of injections should be limited to three can be interpreted as referring to a period of effective benefit and not a lifetime cap. Per the provider's letter of appeal, Medicare guidelines allow hyaluronic injections in 6 month increments if objective and subjective symptomatology persists.

While it is true that Medicare guidelines state, "at least six months has elapsed since the end of the prior series of injections", as a requirement for candidates for these injections, Medicare also requires that, "there is explicit documentation that at least three months of conservative therapy have been tried, including pharmacologic therapy (e.g., aspirin or NSAIDs), exercise, and physical therapy, and the patient has failed to respond satisfactorily." The patient reported increased knee symptoms in approximately February of 2008 and conservative treatment of 3 months would not have been exhausted until the end of April 2008 per Medicare guidelines. ODG also states, 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. While the medical records indicate the patient takes medications of Celebrex 200 mg and Tramadol 50 mg on a continuing basis, there is not reported, conservative measures attempted prior to the request for injections. The medical records fail to document the patient's self-management measures or exhaustion of 3 months of conservative treatment as described by the cited guidelines. Therefore, my determination is to agree with the previous non-certification of the request for viscosupplementation injections x 3 from 03/21/08 to 05/21/08.

The IRO's decision is consistent with the following guidelines:

**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

\_\_\_X\_\_\_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)

\_\_\_X\_\_\_OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME (Medicare/Blue Cross-Blue Shield Guidelines)

The Official Disability Guidelines: 5-7-08:

Recommended as an option for osteoarthritis. 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. The number of injections should be limited to three. (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)

Blue Cross/Blue Shield of Tennessee (Riverbend Government Benefits Administrator):

Viscosupplementation will be considered medically necessary when ALL of the following criteria have been met:

1. The patient is symptomatic with interference in functional activity (e.g., ambulation, prolonged standing, ability to sleep) because of the knee involvement.
2. There is a clinical diagnosis of osteoarthritis of the knee which is supported by radiological evidence and, where necessary, by laboratory tests to rule out other conditions.
  - a. knee pain associated with radiographic evidence of osteophytes in the knee joint, sclerosis in bone adjacent to knee or joint space narrowing;
  - b. morning stiffness of less than 30 minutes in duration or crepitus on motion of the knee.
3. The patient does not have end-stage degenerative joint disease. Cartilage must be present as demonstrated by x-ray.
4. There is explicit documentation that at least three months of conservative therapy have been tried, including pharmacologic therapy (e.g., aspirin or NSAIDs), exercise, and physical therapy, and the patient has failed to respond satisfactorily.
5. Surgical knee replacement is not a planned treatment option at the time the intra-articular viscosupplementation is administered. (The use of injections in an attempt to avoid knee replacement is reasonable; the use of injections in a patient for whom knee replacement is anticipated within the next year or two is not medically necessary.)
6. The pain and local joint symptoms cannot be attributed to other forms of joint disease, i.e. to other diagnoses or conditions.
7. The product is approved by the FDA for intra-articular injection.
8. If the first series of HA injections produce relief, then a second series may be reasonable if symptoms return. This one-time, repeat series of injections will be considered medically necessary only when:

- a. At least six months has elapsed since the end of the prior series of injections, AND
- b. The patient demonstrated clinical improvement with the initial series, as evidenced by significant improvement in pain and functional capacity objectively documented in the record AND/OR a significant reduction in the dose of NSAIDs taken or a reduction in the number of intra-articular steroid injections to the knees during the six month period following injection, again objectively documented in the medical record.

Limitations of Coverage: (see - <http://www.rgbagov.com/publications/lcd/lcd-files/23488.html>)