

May 21, 2004

MDR Tracking #: M2-04-1201-01

IRO #: 5251

___ has been certified by the Texas Department of Insurance as an Independent Review Organization. The Texas Worker's Compensation Commission has assigned this case to ___ for independent review in accordance with TWCC Rule 133.308 which allows for medical dispute resolution by an IRO.

___ has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, all relevant medical records and documentation utilized to make the adverse determination, along with any documentation and written information submitted, was reviewed.

The independent review was performed by a matched peer with the treating doctor. This case was reviewed by a licensed Medical Doctor board certified and specialized in Orthopedic Surgery. The reviewer is on the TWCC Approved Doctor List (ADL). The ___ health care professional has signed a certification statement stating that no known conflicts of interest exist between the reviewer and any of the treating doctors or providers or any of the doctors or providers who reviewed the case for a determination prior to the referral to ___ for independent review. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

CLINICAL HISTORY

This review is in regard to the medical necessity for Synvisc injections, a series of three, for treatment of left knee pain for an injury sustained ___. A preauthorization request dated 3/17/03 was denied for the reviewing physician opined that it was doubtful that Synvisc injection would be of any benefit due to the significant findings on x-rays. An appeal upheld the denial reporting that the criteria was not met for the arthritic condition due to bone on bone contact and no medical evidence to indicate benefit would be effectively gained from any additional injections of Synvisc. A request submitted 6/12/03 was for repeat MRI, which was denied given the fact that the previous MRI and arthroscopic surgery had been performed, repeat MRI was unlikely to yield any diagnostic benefit and was not medically necessary. An appeal letter submitted 1/12/04 by the requesting physician, ___, revealed the patient had not responded to conservative care or treatment, he continued to work, the knee remained painful, he was at MMI and there was no reason to return for continued conservative management of his knee injury, implying 'if no further treatment was going to be approved.'

The medical records submitted for perusal indicate that this patient has an arthritic knee, has had several relapses of recurrent knee 'attacks' that have required emergency treatment with intraarticular injections with persistent internal derangement. He has had previous arthroscopic surgery by ___ and recent MRI reported from June show no further pathology for surgery.

This patient has considerable underlying degenerative disease primary to the medial compartment. The physician has been trying for approximately one year to repeat Synvisc injections that have been reported to have been beneficial in previous series. He opined that despite the bone on bone arthrosis there was benefit in the past, but in an obese 51-year-old gentleman he was hesitant to perform joint replacement surgery due to the increased risk of that form of treatment. An unloader brace has been shown to be beneficial and over several different months repeated corticosteroid injections have been performed for acute flares.

A DME from ___ performed on 11/21/03 recapitulated the injury from ___ where the patient had worked for 30 years and fell after slipping on a slurry in the floor of a vat. He had had knee surgery approximately 3 years prior with known degenerative disease. He had recovered and was able to continue to work. The recapitulation continued that multiple injections had been performed. Synvisc was denied, an unloader brace was fitted. Vioxx was being used to treat his arthritis and there were repeated flares requiring ongoing treatment. The opinion was that the patient was MMI on 11/21/03 and there was no recommendation for surgery, although a total joint replacement in the future was expected.

A variety of clinic notes were submitted regarding the attending physicians treatment and conservative care. An MRI dated 1/28/03 showed a joint effusion, severe osteoarthritic changes of the medial compartment and no meniscal tear. Critical information of when the first Synvisc series was performed is unknown and it is unclear the objective improvement resulting from that regarding increased activity, decreased medication, etc. Provided that the information submitted by the requesting physician is true and correct, this patient benefited from a series of viscosupplementation in the past, is gainfully employed and continues to suffer from advanced compartmental changes, but does not have end stage arthritis in regard to all three compartments.

REQUESTED SERVICE

A series of three Synvisc injections to the left knee are requested for this patient.

DECISION

The reviewer disagrees with the prior adverse determination.

BASIS FOR THE DECISION

The rationale for this decision includes the report of success; the literature is supportive of a repeat series based on the efficacy of the initial series. There is a significant amount of literature circulated by different producers of hyaluronic acid that includes Supartz, Hyalgan, Synvisc, Orthovisc, and Neovisc. The literature provided by detail representatives are somewhat critical of their competitors but overall it is the consensus that this is a good alternative for treatment of arthritic knees that have not responded to basic conservative efforts, including analgesics, exercise and/or weight reduction, etc, but are not advanced enough to require joint replacement surgery in this category, which this

patient appears to be labeled. Recent literature has suggested that viscosupplementation does not have an advantage over corticosteroid use, and this gentleman appears to respond to corticosteroid use as far as intraarticular injections. However, the steroid is a drug and has a risk that, with repeated steroid injections, can cause further damage to the knee in addition to systemic issues regarding diabetic concerns, avascular necrosis, osteoporosis, etc.

The viscosupplementation, in particular Synvisc, is classified as a prosthesis with the FDA and is not considered a drug and does not have the same risk of the corticosteroid. A recent study suggested the efficacies are the same, but the risk panel probably is improved by the viscosupplementation with the only real risk being allergy to the hyaluronic acid or inadvertent introduction of infection due to the injection itself. The critical decision for recommending this to be reasonable and necessary is the report that this patient had a series in the past and had a significant improvement with that form of treatment. Being a motivated worker, ___ continues to work with his medication and bracing, has been determined not to be a candidate for joint replacement surgery, and has exhausted all other forms of modalities. It is appropriate to offer a repeat series to provide continued ongoing care for this patient's painful condition. It is noted that a pseudoseptic reaction can occur with Synvisc, postulated due to the cross linkage of the compound. This may or may not be a real phenomenon but it is an understood event, but not a strong contraindication to the use of this product. If after the first injection there is a reaction, then the series should be aborted. Otherwise it is considered reasonable to proceed as requested.

___ has performed an independent review solely to determine the medical necessity of the health services that are the subject of the review. ___ has made no determinations regarding benefits available under the injured employee's policy.

As an officer of ___, Inc, dba ___, I certify that there is no known conflict between the reviewer, ___ and/or any officer/employee of the IRO with any person or entity that is a party to the dispute.

___ is forwarding by mail and, in the case of time sensitive matters by facsimile, a copy of this finding to the treating doctor, payor and/or URA, patient and the TWCC.

Sincerely,

YOUR RIGHT TO REQUEST A HEARING

Either party to medical dispute may disagree with all or part of the decision and has a right to request a hearing.

If disputing a spinal surgery prospective decision, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **10 (ten)** calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

If disputing other prospective medical necessity (preauthorization) decisions, a request for a hearing must be in writing, and it must be received by the TWCC Chief Clerk of Proceedings within **20** (twenty) calendar days of your receipt of this decision (28 Tex. Admin. Code 142.5(c)).

This decision is deemed received by you 5 (five) days after it was mailed or the date of fax (28 Tex. Admin. Code 102.5(d)). A request for a hearing and a **copy of this decision** must be sent to:

Chief Clerk of Proceedings / Appeals Clerk
P.O. Box 17787
Austin, Texas 78744
Fax: 512-804-4011

The party appealing this decision shall deliver a copy of its written request for a hearing to other party involved in this dispute.

I hereby certify, in accordance with TWCC Rule 102.4 (h), that a copy of this Independent Review Organization decision was sent to the carrier, requestor, claimant (and/or the claimant's representative) and the TWCC via facsimile, U.S. Postal Service or both on this 21st day of May 2004.