

MEMORANDUM

January 22, 2018

To: Medical Advisory Committee

From: Juerg Kunz

Subject: Request for technology review: Low-dose irradiation and constrained revision for severe, idiopathic arthrofibrosis following total knee arthroplasty.

The division received a request to exclude low-dose irradiation and constrained revision for severe, idiopathic arthrofibrosis following total knee arthroplasty from compensability:

The City/CIS also asserts that the proposed treatment is unscientific, unproven as to its effectiveness, or experimental pursuant to OAR 436-010-0030 (sic). Please consider this a request to initiate review under this process.

The division was able to locate only one relevant article published in the scientific literature: Farid YR, Thakral R, Finn HA. Low-dose irradiation and constrained revision for severe, idiopathic, arthrofibrosis following total knee arthroplasty. *The Journal of Arthroplasty*. 2013 Sep;28(8):1314-20.

Furthermore, the division received two independent medical reports where physicians were asked whether the disputed treatment should be considered unscientific, unproven, or experimental:

Paul L. Tesar, MD (Orthopedic Surgery), and Patrick L. Radecki, MD, PMR (Neurophysiology) responded as follows:

We have reviewed Dr. Finn's article in the *Journal of Arthroplasty*. This is a small series of patients in which he used preoperative low-dose radiation in an attempt to decrease scar formation. This type of study is hypothesis generating and further studies are necessary to prove or disprove the hypothesis. There is no definitive evidence that this treatment works. There is potential harm that may occur. This is not the standard of care but is experimental, and we would recommend against this treatment at this time. One needs further evidence that this treatment is successful before recommending it to a patient. As physicians, we always want to help the patient and when we do not have a good treatment, we should be careful not to recommend improved remedies. As a

physician, we should do no harm.

Raymond R North, MD (Orthopedic Surgery), responded as follows:

The proposed treatment in my opinion is not unscientific or experimental and the proof of the effectiveness is discussed as follows:

Henry A Flynn, M.D. the senior author and others published a high quality peer reviewed scientific article titled: Low-Dose Radiation and Constrained Revision for Severe Idiopathic Arthrofibrosis Following Total Knee Arthroplasty in the Journal of Arthroplasty 28(2013) pages 1314-1320 which is a credible publication of the highest order of cases done at the Bone and Joint Replacement Center, Weiss Memorial Hospital, Chicago, Illinois.

This well recorded retrospective series of 14 patients had been followed at the time of publication with a mean follow up of three years which is enough time to identify a failure of treatment. Four patients needed one combined non-invasive mechanical treatment with manipulation under anesthesia and three required two manipulations under anesthesia to prevent failure with recurrent severe arthrofibrosis. Fifty percent of the cohort needed combined biological and non-invasive mechanical treatment strategies.

Only one of the 14 did not reach satisfactory improvement for an improvement percentage of 92 percent.

This is the only series of treatment in the world's literature known to me documenting successful severe arthrofibrosis treatment in total knee replacements.

The combined biological and mechanical treatment strategies needed and uncommon prevalence of this entity do not make it reasonable to expect a randomized double blind study of the highest order of scientific evidence for scientific acceptance or proof.

On the other hand, this study is considered a higher level scientific evidence than single case reviews or expert opinion based on unpublished experience.

It is unlikely someone would volunteer under informed consent to have a procedure of this magnitude and potential severity of failure without granting proceeding with a minimally invasive MUA to ensure a satisfactory end result.

Dr. Finn's scientific paper was reporting on cases that were done between 2003 and 2009 and presumably he has additional experience and possibly modified his treatment protocol.

Prophylactic irradiation is, an accepted treatment for heterotopic ossification after total hip arthroplasty and keloid or hypertrophic scar formation after skin incisions as a biologic strategy in entities that have failed treatment with invasive mechanical surgical strategies.