



PROFESSIONAL ASSOCIATES

NOTICE OF INDEPENDENT REVIEW

NAME OF PATIENT:
IRO CASE NUMBER: M2-05-2193-01
NAME OF REQUESTOR:
NAME OF PROVIDER: Shawn Henry, M.D.
REVIEWED BY: Board Certified in Orthopedic Surgery
IRO CERTIFICATION NO: IRO 5288
DATE OF REPORT: 09/12/05 (REVISED 09/15/050)

Dear Ms. ____:

Professional Associates has been certified by the Texas Department of Insurance (TDI) as an independent review organization (IRO) (#IRO5288). Texas Insurance Code Article 21.58C, effective September 1, 1997, allows a patient, in the event of a life-threatening condition or after having completed the utilization review agent's internal process, to appeal an adverse determination by requesting an independent review by an IRO.

In accordance with the requirement for Texas Workers' Compensation Commission (TWCC) to randomly assign cases to IROs, TWCC has assigned your case to Professional Associates for an independent review. The reviewing physician selected has performed an independent review of the proposed care to determine if the adverse determination was appropriate. In performing this review, the reviewing physician reviewed relevant medical records, any documents utilized by the parties referenced above in making the adverse determination, and any documentation and written information submitted in support of the appeal. determination, and any documentation and written information submitted in support of the appeal.

This case was reviewed by a physician reviewer who is Board Certified in the area of Orthopedic Surgery and is currently listed on the TWCC Approved Doctor List.

I am the Secretary and General Counsel of Professional Associates and I certify that the reviewing physician in this case has certified to our organization that there are no known

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conflicts of interest that exist between him and any of the treating physicians or providers or any of the physicians or providers who reviewed this case for determination prior to referral to the Independent Review Organization.

REVIEWER REPORT

Information Provided for Review:

A patient history from Harris Methodist Occupational Health Network dated 03/11/04 and signed by an unknown provider (the signature was illegible)

X-rays of the lumbar, dorsal, and cervical spine dated 03/11/04 and interpreted by Robert Gloyna, M.D.

Subsequent visits at Harris Methodist Occupational Health Fort Worth dated 03/12/04, 03/15/04, 03/16/04, 03/18/04, 03/24/04, 03/25/04, 03/26/04, 03/30/04, 04/02/04, 04/05/04, 04/07/04, 04/09/04, 04/14/04, 04/15/04, 04/16/04, 04/19/04, 04/20/04, 04/23/04, 05/28/04, 05/03/04, 05/07/04, and 05/21/04

An MRI of the lumbar spine dated 03/30/04 and interpreted by Dr. Tommy Moore (credentials were not provided)

An acute pain evaluation dated 04/27/04 from Felipe Garcia, Jr., M.D.

A progress note from Dr. Garcia dated 05/06/04

A procedure note for trigger point injections dated 05/07/04 from Dr. Garcia

An MRI of the cervical spine dated 05/07/04 and interpreted by Eric Bennos, M.D.

A follow-up evaluation with Dr. Garcia dated 05/14/04

A referral from Dr. Garcia dated 05/19/04 for Dr. Danshaw

An evaluation with Craig Danshaw, D.O. dated 05/24/04

A referral to Dr. Danshaw dated 05/28/04 for a lumbar epidural steroid injection (ESI)

A procedure note for a caudal block dated 06/09/04 from Dr. Danshaw

An electrodiagnostic study dated 06/11/04 from Dr. Garcia

Another procedure note for a second caudal block dated 06/30/04 from Dr. Danshaw

Follow-up evaluations with Dr. Garcia dated 07/14/04, 08/17/04, 09/15/04, 10/06/04, and 12/21/04

A third caudal block dated 07/21/04 from Dr. Danshaw

A reevaluation dated 08/18/04 from Dr. Danshaw

A procedure note for a cervical epidural block at C6-C7 dated 09/01/04 from Dr. Danshaw

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An operative report dated 09/22/04 for a second cervical epidural block at C6-C7 with Dr. Danshaw

An evaluation from Texas Back Institute dated 10/07/04 from an unknown provider (no name or signature was available).

A history and physical examination by Shawn Henry, D.O., dated 10/13/04

A third cervical epidural block at C6-C7 dated 10/20/04 from Dr. Danshaw

A peer-to-peer review dated 11/03/04 from Dr. Henry

A lumbar discogram with post discogram CT scan dated 11/09/04 and interpreted by Prabhakar Kesada, M.D.

Prescription refill request dated 11/15/04 from Dr. Garcia

A follow-up progress note dated 11/18/04 from Dr. Henry

Additional refill request dated 12/27/04 from Dr. Garcia

A TWCC-73 form signed by Dr. Henry on 12/28/04

A preauthorization determination dated 01/05/05 from Tina Hawes, L.V.N., at St. Paul Travelers Insurance.

Another prescription refill dated 01/13/05 from Dr. Garcia

Follow-up visits with Dr. Henry on 01/26/05, 03/24/05, and 05/05/05

A follow-up evaluation with Dr. Garcia dated 03/29/05

A preauthorization determination dated 05/17/05 from Melissa Ellington at St. Paul Travelers Insurance

Additional follow-up evaluations with Dr. Henry on 05/18/05, 06/16/05, 07/01/05, and 08/01/05

An appeal denial letter dated 06/16/05 from Ms. Hawes at St. Paul Travelers Insurance

A letter from Kristi Davis, from Medical Bill Repricing Unit, at St. Paul Travelers Insurance

An evaluation with Dr. Garcia dated 08/09/05

Clinical History Summarized:

From 03/12/04 through 05/21/04, the patient had office visits at Harris Occupational Health Fort Worth with an unknown provider for her neck and back pain. She fell down six stairs at work, which resulted in pain and tightness in the posterior cervical region. An MRI of the lumbar spine on 03/30/04 revealed a left sided L4-L5 definite disc protrusion/herniation. On 04/27/04, Dr. Garcia evaluated the patient. His impressions were tension headaches, cervical dystonia with possible disc pathology, and lumbosacral radiculopathy on the left. Zolofit was started and a cervical MRI with trigger point injections were scheduled, as well as massage therapy. The patient received trigger point injections in the bilateral C2 paraspinals and bilateral trapezius on 05/07/04. The patient received caudal blocks on 06/09/04, 06/30/04, and 07/21/04 from Dr.

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Danshaw. She then underwent cervical epidural blocks at C6-C7 on 09/01/04, 09/22/04, and 10/20/04. On 09/15/04, Dr. Garcia referred the patient to Dr. Henry for a surgical evaluation. On 10/13/04, Dr. Henry evaluated the patient and recommended a discogram, which was performed on 11/09/04. On 11/18/04, the patient's discogram and post discogram CT scan were reviewed and the patient opted for surgical fusion with Dr. Henry. On 10/21/04, Dr. Garcia prescribed the patient Wellbutrin, as she was very tearful and had a lot of fear and anxiety. She was sent to Bruce Bollinger, M.D. for a second opinion at her request. On 01/05/05, St. Paul Travelers provided an adverse determination regarding the 360 degree fusion at L4-L5 and L5-S1. On 05/05/05, Dr. Henry noted that due to the patient's young age, her best option would be an artificial disc replacement. On 05/17/05, St. Paul Travelers provided an adverse determination regarding the Charite/Arthroplasty at L4-L5 and L5-S1. Dr. Henry had a peer-to-peer review on 06/15/05 with Dr. Stinson (credentials were not provided), who noted that at that point, artificial disc replacement was only approved for one level by the F.D.A. On 06/16/05, St. Paul Travelers again denied the Charite Arthroplasty at L4-L5 and L5-S1. On 08/01/05, Dr. Henry noted they would continue to appeal the artificial disc replacement surgery and on 08/09/05, Dr. Garcia agreed with the recommended surgery and also noted the patient's thoracic spine was starting to bother her.

Disputed Services:

Charite/Arthroplasty at L4-L5 and L5-S1

Decision:

I disagree with the requestor. The proposed Charite/Arthroplasty at L4-L5 and L5-S1 would not be reasonable or necessary.

Rationale/Basis for Decision:

I do not believe the requested surgical procedure would be reasonable and necessary. There are several reasons for this. Primarily, this would be applied in a two level application. The only scientific research of any validity has been done was the FDA IDE study, which concentrated on the cream of the crop. Those were patients without psychological abnormalities, people who had abnormalities at one level and who did not have any degeneration above the level. In addition, this study only has two years of follow-up. There is scanty scientific literature covering to the two level procedure and at this time, there is no consensus as to whether that would be

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successful. Therefore, the total disc arthroplasty would not be indicated at this time for multilevel fusions. While Dr. Henry attempted to make the argument that we use surgical procedures all of the time that are beyond the FDA approval, this was one technology that has not yet been adequately proven even within the FDA guidelines and at this time, we should not be stretching those guidelines.

In addition, there was question about the validity of the discography. This individual had marked spondylosis with a near circumferential grade IV annular fissure at L3-L4, a grade IV posterior fissure at L4-L5, and a grade II fissure at L5-S1. While the L3-L4 level was not concordant pain, it was 6/10 in severity. This would indicate that this individual has significant multilevel spondylosis and would not be indicated for fusion or total disc arthroplasty of the two lower levels.

The third objection at this time was that this patient had significant preexisting depression. This would render the results of discography inappropriate at best.

In summary, the requested surgery was neither reasonable nor necessary, as it falls outside the accepted guidelines for the use of this technology.

This review was conducted on the basis of medical and administrative records provided with the assumption that the material is true and correct.

This decision by the reviewing physician with Professional Associates is deemed to be a Commission decision and order.

YOUR RIGHT TO REQUEST A HEARING

Either party to this medical dispute may disagree with all or part of this 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/Appeals Clerk **within ten (10) calendar days** of your receipt of this decision (28 Texas Administrative Code 1133.308 (v) (1)).

If disputing other prospective medical necessity (preauthorized) decisions a request for a hearing must be in writing and it must be received by the TWCC Chief Clerk of Proceedings/Appeals Clerk **within twenty (20) calendar days** of your receipt of this decision (28 Texas Administrative Code 148.3).

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This decision is deemed received by you **five (5) calendar days** after it was mailed (28 Texas Administrative Code 102.5 (d)). A request for a hearing should be faxed to 512-804-4011 or sent to:

Chief Clerk of Proceedings/Appeals Clerk
Texas Workers' Compensation Commission
P. O. Box 17787
Austin, TX 78744

A copy of this decision should be attached to the request. The party appealing the decision shall deliver a copy of its written request for a hearing to all other parties involved in the dispute.

I hereby verify that a copy of this Independent Review Organization's decision was sent to the respondent, the requestor, TWCC and the patient via facsimile or U.S. Postal Service this day of 09/12/05 from the office of Professional Associates.

Sincerely,

Lisa Christian
Secretary/General Counsel