po box 519
schertz, tx 78154
p: 800.292.3051
f: 888.972.7053

IRO Certificate No: X

Notice of Workers' Compensation Independent Review Decision

X

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
X

INFORMATION PROVIDED TO THE IRO FOR REVIEW:
X

PATIENT CLINICAL HISTORY [SUMMARY]:
This case involves a now X. The diagnosis of the patient is documented as lumbar spondylosis without myelopathy or radiculopathy; lumbar vertebrogenic low back pain; long term (current) use of opiate analgesic; and lumbar radiculopathy. Magnetic resonance imaging (MRI) Lumbar on X. The visualized portion of the X.
On X, the patient was seen for follow up of X low back pain radiated down the bilateral legs with pain scale of X. Physical exam revealed X. MRI lumbar X. There was a disc bulge at X. Previous treatments were X.

In the Notice of Adverse Determination dated X, the requested X was not authorized. The patient has a history of an occupational claim on X. The mechanism of injury was identified as the claimant X. The claimant had a follow up visit on X with complaints of low back pain radiated down X bilateral legs. MRI demonstrated X was noted.

In the Letter of Medical Necessity on X, the provider requested prior authorization for X. The patient's primary problem is X. Modic changes may be described as endplate changes associated with X. Modic changes are an objective biomarker that X. The intercept procedure, not just the device, received its initial FDA clearance in X. That clearance means the procedure is safe and effective in the eyes of the FDA. The FDA set forth the indications for use: 1) X; 2) X; 3) X. The patient had an MRI performed on X which revealed X. Modic type 1 and 2 endplate changes are accepted as a biomarker of vertebrogenic pain.

In the First Preauth Appeal Request Denial on X, the request was still determined not medically necessary. The X is not generally recommended. The guideline indicates that additional literature study is needed to support this treatment. According to the report, there are more concerning radicular symptoms noted in progress notes.

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

The Official Disability Guideline does not recommend X. Not recommended. Despite promising early reports, further trials with longer-term outcomes and less risk of bias are required. If approved despite non-recommendation, there should be at least X.

According to the U.S. Food and Drug Administration (FDA), FDA approval alone is not a basis for coverage. X. However, the FDA regulates X. Three product codes are used to represent these devices: X. Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

In a cited reference titled "X", it states that "To date, there are few documented significant adverse events, and it appears that X." In addition, "Despite the positive long-term clinical outcomes demonstrated to date, outcomes of patients undergoing X are needed."

In another cited article titled "The Effectiveness of X: A Systematic Review, it states that "X is a novel treatment which may be considered for patients reporting X." In addition, "Further, high-quality non industry funded studies are needed to confirm these findings."

In this case, the claimant has a history of occupational claim on X. The treating provider recommended the X. MRI lumbar revealed X. There was a X. X was present at X.

The requested procedure is not supported by the current literature, as there is insufficient evidence to establish the safety and efficacy of X. A review of full-text clinical practice guidelines and position statements offers weak support for the X. Long-term, non-industry-funded prospective trials should be pursued to confirm the results of currently published clinical studies. The X for CPT codes X is considered not medically necessary. Therefore, the prior determination for the requested X is upheld.

SOURCE OF REVIEW CRITERIA:

☐ ACOEM – American College of Occupational & Environmental Medicine UM Knowledgebase

☐ AHRQ – 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 Judgment, Clinical Experience, and Expertise in Accordance with Accepted Medical Standards
☐ Mercy Center Consensus Conference Guidelines
☐ Milliman Care Guidelines
☒ ODG- Official Disability Guidelines & Treatment Guidelines
☐ Presley Reed, the Medical Disability Advisor
☐ Texas Guidelines for Chiropractic Quality Assurance & Practice Parameters
☐ TMF Screening Criteria Manual
☐ Peer Reviewed Nationally Accepted Medical Literature (Provide a Description)
☐ Other Evidence Based, Scientifically Valid, Outcome Focused Guidelines (Provide a Description)

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

ATTESTATIONS:
X.

X