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Notice of Independent Review Decision

Amendment X

IRO REVIEWER REPORT

Date: X; Amendment X

IRO CASE #: X

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: X

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

REVIEW OUTCOME:

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

☒ Overturned Disagree

☐ Partially Overturned Agree in part/Disagree in part

☐ Upheld Agree

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- X

PATIENT CLINICAL HISTORY [SUMMARY]:

X who sustained an injury on X. X was X. The diagnoses included vertebrogenic low back pain, vertebral endplate pain, chronic pain syndrome, BMI 32.0-32.9 in adults. X was seen by X, MD on X for chronic low back pain. X complained of right greater than left low back pain that radiated on the posterior aspect of X right lower extremity terminating at the foot. The pain started working as a X. X experienced X in the second and third toes. X reported X radicular component of pain was equal to any axial component. X described X pain as a X. X relieves the pain somewhat and X increased the pain. X had been dealing with the symptoms for X years and they had been worsening over the past X months. X saw Dr. X and was told X was not a X. X was told many years back, X had X, but treated it X. X mentioned that X medication regimen was providing X with approximately X reduction of overall pain and an improvement in X functional capacity. X body mass index was 32.12 kg/m^2. On examination, X sat uncomfortably in the chair. X relieved X pain X increased X pain. There was X. X was intact to X in the lower extremities except decreased over X right second and third toes. X was intact to X. X was negative bilaterally. It was noted that X had chronic low back pain that may have a significant component related to the X. Authorization for an X was placed. An MRI of the lumbar spine on X was X. Treatment to date included X. Per Adverse Determination by X, MD on X, the request for X was non-certified. Rationale: “Per ODG, "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." The patient is a X-year-old who sustained an injury on X. This procedure is not currently recommended as a treatment for low back pain due to a need for additional research. Moreover, the patient has not had a recent trial of X. The request is not shown to be medically necessary. The requested X is denied.” In an appeal letter dated X, X, MD wrote, “I am filing an appeal on behalf of my patient, X, for wrongful denial for X. This procedure X. X has X. As such, I strongly disagree with your decision. Your claim of requiring X. This procedure improves the quality of

life of patients suffering from vertebrogenic low back pain. The X, not just the device received X. That clearance means the procedure is safe and effective. Many companies consider technology to be investigational if the X. We have previously submitted a bibliography reference document along with an executive summary of the science that supports the X. We have again included it with this document. The X meets all of the above criterion used to evaluate whether or not a device is investigational. Workers Compensation X will pay for other spinal ablations that do not have the strength of this scientific support. Those ablations if successful, will be repeated every X months due to the myelin sheath present. The X is unique, as it is predominantly nonmyelinated and will not regrow and regenerate, as such the results are sustainable. The peer reviewed publications of two and five year follow support this ascertain. It is my position this denial is inconsistent with benefits provided to the patient and for which premiums have been paid. These benefits provide the patient with access to medically necessary procedures which provide relief of their current symptoms. For reasons set forth above, I believe the denial of the X is unwarranted and unsupported by the patient's current medical status and current peer-reviewed literature. Given the previously submitted history, physical examination and the radiologic findings, the X is medically necessary and supported by strong science. I would like to perform this procedure at X on X." Per Appeal Determination Denial by X, MD on X, the request for X was non-certified. Rationale: "Per the ODG by MCG, X is not recommended. Despite promising early reports, further trials with longer-tem1 outcomes and less risk of bias are required. Additionally, it was noted that the claimant has X. There is no evidence of recent trials and failure of traditional conservative measures that are guidelines supported. X are no exceptional clinical findings noted in the medical records that would support going beyond the guideline recommendations." In the letter dated X, X, MD wrote, "I am filing a request for the treatment proposed for my patient X, to be reviewed by an Independent Review Organization (IRO). I feel prior denials for X. X is founded on X years of basic science research linking Modic to chronic low back pain. It is an objective biomarker for indicated patients, unparalleled level I clinical evidence, that demonstrates sustained clinical improvements in function and pain with longitudinal follow up. The procedure has an excellent safety profile. Stating this treatment has not demonstrated effectiveness, safety and efficacy and as such should be considered investigational or experimental is inappropriate considering

the documentation previously submitted. TASB Risk Management Fund appears to have neglected the review of the typical criteria that are used to determine if a technology is investigational or experimental. The science supporting the X meets all the following: X. X to address chronic low back pain, identified by Modic changes; fulfills a treatment gap for patients with chronic low back pain. Workers Compensation X decision does not reflect the recent medical research. My patient and I request this denial be overturned, and the procedure authorized. My patient's primary problem is X. X may be described as X. X are an objective X. The X, and not the device received its initial FDA clearance in X. That indication means the procedure is safe and effective and with the clearance the indications for use were defined: X. I am requesting that this review be performed by a board-certified physician with background in X procedures that is familiar with the X, to ensure a fair review for my patient. It is my position this denial is inconsistent with benefits provided to the patient and for which premiums have been paid. To provide relief of their current symptoms these benefits provide the patient with access to medically necessary procedures, which would include the X. For reasons set forth herein, I believe the denial of the X is unwarranted and unsupported by the patient's current medical status and current peer-reviewed literature. Summary of Patient History: X is a X Years old. X has a history of low back pain beginning over X months ago. X has had multiple treatments including X. Medications have included: X. The pain has had a significant impact upon ADL such as: sitting. Nothing has provided significant sustainable relief. X had an MRI performed on X at X. The MRI demonstrated X. As such, X chronic low back pain is coming from the vetebrogenic change at X am requesting you consider the supportive documentation and benefits that the X provides for a specific subset of patients suffering from chronic low back pain. All available information needed to review my patient's clinical picture and approve the X has been provided. I ask the IRO to overturn the prior denials and afford my patient the relief of their chronic low back pain. Addressing a patient's chronic low back pain identified by X. It is my contention if the science is reviewed objectively, there is no basis by which the insurer can support the claim that the X is not a covered benefit, not medically necessary, or could be construed as experimental or investigational. Thank you for performing a thorough review of the submitted information.” Patient with X. X has X . Note that peer review took issue with no recent X. No appeal letter has refuted this statement. Provider now requesting X. Though this is not a commonly

covered/accepted treatment option, in select patients who have tried more traditional treatment options,an “experimental therapy” such as X is warranted. There are multiple randomized controlled trials to support the use of X , but not enough evidence to be widely accepted in guidelines such as the cited ODG. X to Treat Chronic Vertebrogenic Pain (X) is medically necessary and certified

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

Patient with X. X has X. Note that peer review took issue with no recent X. No appeal letter has refuted this statement. Provider now requesting X. Though this is not a commonly covered/accepted treatment option, in select patients who have tried more traditional treatment options,an “experimental therapy” such as X is warranted. There are multiple randomized controlled trials to support the use of X, but not enough evidence to be widely accepted in guidelines such as the cited ODGX to Treat Chronic Vertebrogenic Pain (X) is medically necessary and certified

Overturned

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

☐ 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

☐ OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)

☐ PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

☐ PRESLEY REED, THE MEDICAL DISABILITY ADVISOR

☐ TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS

☐ TMF SCREENING CRITERIA MANUAL