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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:

x☐ Overturned Disagree

☐ Partially OverturnedAgree in part/Disagree in part

Upheld Agree

INFORMATION PROVIDED TO THE IRO FOR REVIEW: • X
PATIENT CLINICAL HISTORY [SUMMARY]: X who was injured on X. The biomechanics of the injury was not available in the medical records. The diagnosis was vertebrogenic low back pain. No office visit notes or diagnostic reports were available for the review. Treatment to date consisted of X. Per a utilization review adverse determination letter dated X by X, MD, requests for X were not certified. Rationale: “ODG regarding the request X states, "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." In this case, the patient has complaints of low back pain. An MRI of the lumbar spine report dated X, revealed I.X. 2.X. 3.X. 4.X. Mild X at X. X with a X. However, guidelines consider this procedure is currently investigational or experimental. By definition the procedure requires further investigation by higher powered study such as randomized control trials or cohort studies or multicenter data analysis to firmly establish the short-term and long-term efficacy of this treatment as it pertains to this patient's pain, as well as several other patient prototypes. Additionally, risk stratification must be investigated. As such, this request is not medically necessary. Therefore, the request for X is not certified.” An appeal letter on behalf of X was provided on X, for wrongful denial for X. This procedure addresses vertebrogenic pain by addressing a gap in the treatment algorithm for patients suffering from chronic low back pain. The peer-reviewed literature clearly supported the request. X had tried and X without relief as documented by X, MD in the original letter of medical necessity and the medical records previously submitted and attached at the time. Per a peer review dated X by X, MD, request for X were not medically necessary. Rationale: “ODG by X. This procedure is not currently recommended as a treatment for low back pain due to a need for additional research. A

successful peer-to-peer call with X, NP, was made. The peer discussed and noted the ODG guidelines regarding the X. The peer noted pain when sitting. The peer said low back pain radiates to the legs, and a X was also planned. The X excluded patients with radicular pain or radiculopathy. The request is not shown to be medically necessary. Therefore, the request for X non-certified and upheld." Per a letter dated X, a review by an Independent Review Organization (IRO) was requested for X, due to the prior denials for X. X was based upon X years of basic science research linking X. This linkage resulted in the X. The clinical records that would be forwarded demonstrated X had X and met the medical necessity and reasonableness criterion, as determined by X, MD and set forth in greater detail in the enclosed letter of medical necessity. The X had been FDA cleared since X demonstrated the procedure was safe and effective. Since then, the peer-reviewed literature had expanded to where there were more than X. For a technology not to be considered investigational, insurers frequently utilized the following criteria: 1.X. 2.X. 4.X. 5.X. The X meets all five criteria, which helps explain why it has medical society support X. There are also numerous insurers that had positive policies including the X. X primary problem was chronic low back pain (CLBP) due X on X MRI, as determined by X, MD X. X. The FDA clearance included that patients must meet the following criterion to be medically necessary: pain for more than X months, X. It was requested that this review be performed by a X. This denial was inconsistent with benefits provided for which premiums had been paid. To provide relief of X ongoing symptoms these benefits were to provide medically necessary procedures, which would include the X. For reasons set forth herein, the denial of the X was unwarranted and unsupported by X ongoing medical status and ongoing peer-reviewed literature. X had a history of X. X had multiple treatments including: X. Medications included: X. The pain had a significant impact upon X. Nothing had provided significant sustainable relief. The severity

of pain on X. X had an MRI performed on X at X. The MRI demonstrated X. As such, X chronic low back pain was from the X. The attachments which supported this request were to be considered. It was requested to overturned the prior denials and afford X the relief of their chronic low back pain. The X requested by X, MD was an X. Objective assessment of the science supporting the X demonstrated it was the right procedure for X at this time and it was safe and effective, consistent with X, MD determination that the X was medically reasonable and necessary to solve X chronic low back pain. Thoroughly reviewed provided records. Noted that patient has had X. Patient appears to have vertebrogenic pain based on subjective findings. Earlier it appeared the patient may have more radicular pain and attempted X without relief. Imaging findings are consistent with possible vertebrogenic pain including X. Patient meets cited ODG criteria from peer reviews for requested X.X,X is medically necessary and certified

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

Thoroughly reviewed provided records. Noted that patient has had X. Patient appears to have vertebrogenic pain based on subjective findings. Earlier it appeared the patient may have more radicular pain and attempted X. Imaging findings are consistent with possible vertebrogenic pain including X. Patient meets cited ODG criteria from peer reviews for requested X. 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

☒ ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

☐ 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

☐ 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)