

Vanguard MedReview, Inc.

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Notice of Independent Review Decision

March 7, 2015, Amended April 6, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medications Lidoderm Patches, Celebrex

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

This reviewer is a Board Certified Anesthesiologist with over 6 years of experience.

REVIEW OUTCOME:

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

Overturned (disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured at work on xx/xx/xx when he slipped while carrying a heavy object down an incline.

11/10/2014: Office Note. **HPI:** Patient has responded well with flexeril for muscle spasm. Patient with concomitant muscle spasms with failed back surgery syndrome, reviewed patient's case review. In patient's case muscle relaxants are not primary treatment modality, it is an adjuvant. ODG guidelines 2011 support use of muscle relaxants as adjuvant modality. **Assessment:** Low back pain ICD 724.2 Lumbar radiculopathy ICD 724.4 Lumbar disc displacement without myelopathy IDC 722.10. Muscle spasms ICD 728.85 Post laminectomy syndrome ICD 722.83. Lumbar spinal stenosis 724.02 chronic pain syndrome.

11/13/2014: Appeal Note. Reviewed denial note dated November 11, 2014 and find denial of treatment completely inappropriate. Furthermore physician reviewing the case is not qualified to review this case as he is not in pain management or

interventional pain management; physician has not had any formal training in pain medicine nor does have fellowship training or board certification. Patient has failed back surgery syndrome and he made extremely poor recommendations especially immediate sensation of MS Contin MSSR utilization on patient who is on chronic narcotics and will go into withdrawals which can compromise patient's overall health. records address "4 A's" of treatment with medications as described by ODG guidelines, treatment index; he limits addition, 2014 pain chapter, opioids Criteria for use. is demonstrating good judgment in the use of his medications. He is using the medications as prescribed without adverse side effects. He states that the medications allow him to maintain his quality of life, activities of daily living and level of function. For medications allow him to maintain his quality of life, ADL's, and level of function. The patient has been counseled regarding the usage and side effects of medication and has been advised to keep them in a safe place and to avoid alcohol with his current medication regimen. Patient reports that without treatment his pain affects mood, ADL's, function, social interactions and leisure. No aberrant behaviors. Denies adverse reactions. Patient reports that since his last visit pain is stable. Patient has failed back surgery syndrome with two level interbody fusion with instrumentation and adjacent level progressive. Patient has undergone periodic drug testing to document compliance.

01/21/2015: Appeal Note. has been repeatedly denied his medication, MS Contin/MSSR, Lyrica, Flexeril, Lidoderm Patches, and Celebrex. These medications are "Y" on the formulary list from the ODG guidelines. Patient reports that since his last visit pain is stable with medications. Patient with concomitant muscle spasms with failed back surgery syndrome and has been stable on flexeril, reviewed patients case review. In patient's case muscle relaxants are not primary treatment modality, it is an adjuvant. ODG guidelines 2011 support use of muscle relaxants as adjacent. denies any adverse side effects with current medication regimen. does not demonstrate any aberrant behaviors and is demonstrating good judgment in the use of his medications. He is using the medications as prescribed without adverse side effects. He states that the medications allow him to maintain his quality of life; ADL's and level of function. He has been counseled regarding the usage and side effects of medication and has been advised to keep them in a safe place and avoid alcohol. Additionally, patient has failed back surgery syndrome with tow-level interbody fusion with instrumentation and adjacent level progressive disease at L3-4 which likely in the future will require additional surgical intervention; despite of this patient continues to function at home and continues his ADL's. He has undergone periodic drug testing to document compliance.

02/12/2015: UR. The patient is a male who was injured when he slipped while carrying a heavy object down an incline on xx/xx/xx. He was managed as a case of lumbar radiculopathy, lumbar disc displacement without myelopathy, muscle spasms, post laminectomy syndrome, lumbar spinal stenosis, and chronic pain syndrome. A request was made for MS Contin/MSSR, Lyrica, and Flexeril. Treatments rendered to date include medications, ESI, PT and surgery. MRI on 8/20/08 unofficial report revealed a multilevel disc bulge with posterior protrusion and extrusion indenting the anterior thecal sac. He underwent an L4-S1

arthrodesis on 08/2010. As per the UR determination dated 11/11/14, the patient was on Nucynta, Lyrica, Flexeril, morphine sulfate 30mg, and Celebrex 200mg. As per the appeal note dated 1/21/15, the requesting provider stated that the patient was stable with medications. The patient was reported to have concomitant muscle spasms with failed back surgery syndrome and was "stable" on Flexeril. The requesting provider also indicated that "in patient's case muscle relaxants are not primary treatment modality." The patient denied any adverse effects with current medication regimen and he does not demonstrate aberrant behaviors. He was noted to be demonstrating good judgment in the use of his medications and that the medications allow him to maintain his quality of life, activities of daily living, and level of function. He reported that without treatment, the pain affects his mood, activities of daily living, function, social interactions, and leisure. For the requested MS Contin/MSSR, ODG recommends that there should be an ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, clear objective functional gains that the patient obtains from use of MS Contin were not provided, such as an objective improvement in ADL's or pain assessment including the current pain; the least reported pain over the period since last assessment; average pain intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent evidence of monitoring for medication compliance, such as a pill count, pain contract, or a urine drug screen was also not clearly provided. The prescribed dose and dosing frequency was not provided, as well as the amount of MS Contin being requested. Furthermore, routine long-term opioid therapy is not recommended by ODG. Thus, the medical necessity of the requested MS Contin is not substantiated. However, abrupt discontinuation of the aforementioned medication has been associated with withdrawal symptoms. Detoxification is a consideration for this medication. For the requested Lyrica, ODG states that it has been documented to be effective in treatment of diabetic neuropathy and post herpetic neuralgia, has FDA approval for both indications, and is considered first line treatment for both. However, there was no recent clinical evaluation of the patient to include a history and physical examination to support the presence of neuropathic pain for which continued use of Lyrica is warranted. In addition, the dose and dosing frequency of Lyrica was not provided for review as well as the amount being requested. Thus the medical necessity of the requested Lyrica is not substantiated. As for the requested Flexeril, ODG states that the efficacy of muscle relaxants appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. The duration for which the patient is on Flexeril was not provided for review, as it is not recommend to be used for longer than 2 to 3 weeks. Furthermore, ongoing muscle spasms were not documented to warrant continued use of Flexeril. The patient's response to prior Flexeril use was likewise not provided. Thus, the medical necessity of the requested Flexeril is not substantiated. Based on the clinical information provided, the medical necessity of the requested medications is not established at this time.

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

Claimant is a male who was injured when he slipped while carrying a heavy object down an incline on xx/xx/xx. Claimant diagnosed with lumbar radiculopathy, lumbar disc displacement without myelopathy, muscle spasms, post laminectomy syndrome, lumbar spinal stenosis, and chronic pain syndrome.

Treatment has included medications, ESI, PT and surgery.

As per the UR determination dated 11/11/14, the patient was on Nucynta, Lyrica, Flexeril, morphine sulfate 30mg, and Celebrex 200mg. Claimant noted to be stable on these medications and that muscle relaxants are not being used as primary treatment modality. Both Celebrex and lidoderm patches are approved for this patient at this time as they are both appropriate modalities for this claimant. Per ODG, lidoderm patches are approved for patients with neuropathic pain, who have other first line medications (such as Lyrica) and are acceptable for short term use with a specific treatment plan. All of these criteria are met by this claimant and therefore this request for Medications Lidoderm Patches, Celebrex is certified.

Per ODG:

<p>Lidoderm® (lidocaine patch)</p>	<p>Not recommended until after a trial of a first-line therapy, according to the criteria below. Lidoderm® is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized neuropathic pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. For more information and references, see Topical analgesics. [Lidoderm ranked #2 in amount billed for WC in 2011. (Coventry, 2012)]</p> <p>Criteria for use of Lidoderm patches:</p> <ul style="list-style-type: none"> (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day). (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period.
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	<p>(h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued.</p> <p>(i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued.</p>
Celebrex® (celecoxib)	<p>Celebrex® is the brandname for celecoxib, and it is produced by Pfizer. Celecoxib is a non-steroidal anti-inflammatory drug (NSAID) that is a COX-2 selective inhibitor, a drug that directly targets COX-2, an enzyme responsible for inflammation and pain. See Anti-inflammatory medications. See NSAIDs (non-steroidal anti-inflammatory drugs) for specific patient decision-making criteria. Unlike other NSAIDs, celecoxib does not appear to interfere with the antiplatelet activity of aspirin and is bleeding neutral when patients are being considered for surgical intervention or interventional pain procedures.</p>

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
- AHCPR- 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 JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)