Becket Systems

An Independent Review Organization
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Description of the service or services in dispute:

XXXX , quantity 10, to apply patch to skin every 72 hours

Description of the qualifications for each physician or other health care provider who reviewed the decision: Board Certified Anesthesiology

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

- ☐ Overturned (Disagree)
- ☑ Upheld (Agree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)

XXXX who was diagnosed with lumbosacral plexus disorder. (G54.1). XXXX reported that XXXX lower back. This caused severe pain in XXXX pelvis.

XXXX for the pelvic pain that had started on XXXX. XXXX had been diagnosed with pelvic floor dysfunction by XXXX. XXXX reported XXXX. XXXX sought care approximately one week later and obtained a lumbar MRI because the doctor thought it was low back complications. XXXX was referred to XXXX for surgical consultation, where it was determined that XXXX did not have back abnormalities, and they were not able to determine the cause of pain. Initially, XXXX was prescribed compounded suppositories and was referred to special physical therapy but was not able to financially afford to continue. Since that time, XXXX had a lapse in care and was not on any treatments at the time. XXXX reported that the pain was an anterior pelvic pain that radiated from the scrotum to the anus. The pain was sharp, throbbing, shooting, cramping, stabbing, tingling and severe in nature. XXXX denied any radicular pain down either lower extremity. XXXX reported associated symptoms of muscle spasm. Sleep was disturbed due to pain. XXXX reported that activities of daily living, household chores, work, falling asleep, and staying asleep were affected by the pain. Screening and opioid assessment for patients with pain (SOAPP) score was XXXX, which indicated XXXX to be a low risk for opioid abuse. The physical examination revealed pain upon

palpation below the coccyx and coccydynia. The diagnoses were pelvic and perineal pain, long-term (current) use of opiate analgesic, and encounter for therapeutic drug level monitoring.

Treatment to date consisted of medications (compound suppositories, XXXX), and physical therapy (one session due to financial constraints).

Per a utilization review determination letter dated XXXX, the request for XXXX. Rationale: The clinical report dated XXXX noted no pain and reported only subjective findings of pain to palpation over the coccyx. XXXX had not recently tried or failed prescription medications. The use of XXXX would only be considered as a second to third line option for the treatment of severe uncontrolled pain, which was not evident, no risk for the medications were noted. Given those issues which did not meet guideline recommendations, the request could not be certified."

A utilization review determination letter dated XXXX, revealed that the appeal / reconsideration request dated XXXX, was denied by XXXX who upheld the initial adverse determination and could not recommended certification of the procedure / treatment as medically necessary for the following reasons: "Guidelines indicate that XXXX patches are not recommended for routine musculoskeletal pain. The use of XXXX would only be considered as a 2nd to 3rd line option for pain of a non-musculoskeletal nature. Therefore, on appeal, the request is non-certified. The original denial is upheld."

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The patient has an injury dated back to XXXX. The residual complaint appears to be anococcygeal pain or perineal pain. Visual analog scores are not recorded for this pain not evidence of functional impairment. The SOAP score is XXXX. Treatment has included suppositories. The actual etiology of the patient's pain is not clear. A surgical consult with a colorectal surgeon has not been conducted. A coccygeal nerve block was recommended, but is pending a MRI, which has not yet been performed. Two prior UR consultations are accurate in their assessment of the patient's condition. XXXX are indeed only indicated when other agents have been deemed ineffective. The patient currently takes another opioid orally, i.e. XXXX. Given the documentation available, the requested service(s) is considered not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines
- ☐ DWC-Division of Workers Compensation
- ☐ Policies and 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 and Treatment Guidelines

ODG® 2018 Official Disability Guidelines® (23nd annual edition) & ODG® Treatment in Workers' Comp
(16th annual edition) Pain Chapter Updated 06/19/18

CRITERIA FOR USE OF OPIOIDS

Therapeutic Trial of Opioids

1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:
(a) Are there reasonable alternatives to treatment, and have these been tried?
(b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?
(c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? Specific questions about current use of alcohol, illegal drugs, other prescription drugs, and over-the-counter drugs should be asked. Obtaining a history of personal and/or family substance abuse issues is important. See Substance abuse (tolerance, dependence, addiction). See Opioids, screening for risk of addiction. (Webster, 2008) (Ballyantyne, 2007)
(d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase: (1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories. There are better treatments for this type of pathology. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008)
(e) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.
2) Steps to Take Before a Therapeutic Trial of Opioids:
(a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.
(b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.
(c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.
(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.

(e) Pain related assessment should include history of pain treatment and effect of pain and function.
(f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.
(g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)
(h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
(i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.
(j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.
3) Initiating Therapy
(a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.
(b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.
(c) Only change 1 drug at a time.
(d) Prophylactic treatment of constipation should be initiated.
(e) If partial analgesia is not obtained, opioids should be discontinued.
4) On-Going Management. Actions Should Include:
(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
(b) The lowest possible dose should be prescribed to improve pain and function.
(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain
patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)
(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (Webster, 2008)
(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).
(g) Continuing review of overall situation with regard to nonopioid means of pain control.
(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)
5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):
(a) Every 2 weeks for the first 2 to 4 months
(b) Then at approximate 1 ½ to 2-month intervals
Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)
6) When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. The patient should not be abandoned.
(a) If there is no overall improvement in function, unless there are extenuating circumstances (b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain and lack of improved function despite high doses of opiates- e.g. > 100 mg/day morphine equivalents)
(c) Decrease in functioning
(d) Resolution of pain
(e) If serious non-adherence is occurring
(f) The patient requests discontinuing
(g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.
(h) Many physicians will allow one "slip" from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.
(i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (Weaver, 2002)
(j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

(k) Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence with difficultly weaning. See Opioids for chronic pain.
7) When to Continue Opioids
(a) If the patient has returned to work
(b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)

Appeal Information

You have the right to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.