AccuReview

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Notice of Independent Review Decision

[Date notice sent to all parties]: September 18, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Hydrocodone/acetaminophen 10-325mg, Fentanyl 25mcg/hr patch, Gabapentin 300mg, Tizanidine 4mg

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

This physician is Board Certified Anesthesiologist with over 12 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 female with a date of injury of xx/xx/xx. She felt a pulling and stinging in her back and then a pop. The claimant is noted to have spinal pain since DOI. Pain is centered across the low back that goes into the left buttock and somewhat down the left foot with numbness in the heel. The claimant spent greater than one year at chiropractic sometimes as much as three times a week with no real improvement.

05-24-99: Office Visit. The claimant presented today after being evaluated and was diagnosed with two-level disc disease for which he feels she may benefit from ESI or possibly eventually interdiscal therapy. Claimant has past medical remarkable for fibromyalgia. Recommend ESI. Procedure: ESI was performed at L4-5 with 120mg Depo-Medrol and 4cc 1% Lidocaine.

06-01-99: Office Visit. Claimant reported significantly feeling better following the first lumbar ESI noticed a very distinct difference in both her back pain and in the foot pain. Recommend another injection today, neurological exam is unchanged. Procedure: lumbar ESI given.

08-01-00: Follow-up Note. Claimant responded to ESIs over a year ago and is seen for recurrent back pain, back spasms, and radiating leg pain that had progressively worsened particularly left leg pain. evaluated and found progression of her disease and indicated to repeat ESIs. She has no neurological deficits, particularly no weakness and non new medications. Procedure: ESI L5-S1.

10-15-01: Follow-up Note. Claimant presented with increased back pain with numbness down into the left leg. Recommend ESI today and if pain is not improved recommend surgery. Procedure: ESI given.

03-02-04: Follow-up. The claimant is not completely resolved of her symptoms. Examination revealed nearly full ROM. Her root tension signs are now absent and she continued to require periodic medications, using 2-3 Lortab a day and Ambien to sleep. She continued to work. Will refill her medications and follow up every 6 months for medication check.

01-15-05: Psychiatric Consultation. Claimant was evaluated for recent mental status changes including confusion and combativeness which began shortly after recent spinal fusion surgery on January 12, 2005. Medical and nursing staff reported waxing and waning mental status since admission with probable audio and visual hallucinations, disorientation and agitation. The claimant had been treated with multiple medications for pain, including morphine, which she does remember causing visual hallucinations after taking it postoperatively last week. She was also taking Zanaflex and Ambien as well at home. Medications: Seroquel 100mg PO BID, Rocephin 1g IV daily, Protonix 40mg daily, Norco 10mg Q4-6 hrs PRN pain, Surfak 240mg daily, Demerol 50mg IV Q4hr PRN pain, Phenergan 12.5mg IV Q4hrs PRN nausea. Home medications include Ambien, antibiotics, Zanaflex, Xanax and Prozac. Allergies to aspirin and nonsteroidal anti-inflammatory drugs. Mental status examination: Claimant is mildly irritated with constricted affect. She denies SI or HI. Her musculoskeletal strength is equal bilaterally. Diagnosis: Axis I: 1. Delirium, 2. Major depressive disorder, in remission; Axis II: deferred; Axis III: status post back surgery; Axis IV: medical stress; Axis V: GAF 30. Recommendations: Continue Seroquel 100mg PO BID, Haldol 1-2mg PO/IM Q4hrs PRN for severe agitation. Recommend hold Demerol and Phenergan at this time.

09-08-05: Follow-up Note. Claimant had lumbar fusion surgery and still experiencing significant pain, mainly back pain. She had a L3-4 posterior lumbar interbody fusion with an L2-4 postolateral fusion with instrumentation. She reported pains that are radiating down her legs, left leg worse than right with some pains going down to foot. She has buttocks pain that feels like a bee sting. She is taking 8 Norco per day and that dulls the pain. On examination, she had

markedly decreased ROM and tenderness over the hardware. Recommendations: hardware injection and L3-4 nerve blocks both diagnostically and therapeutically on the left, where the majority of the pain is located.

10-18-05: Operative Report. Preoperative Diagnosis: 1. Pseudoarthrosis, L3-4 interbody fusion with presumed pseudoarthritis, L3-4 intratransverse process arthrodesis. 2. Possible pseudoarthrosis, L2-3 intertransverse process arthrodesis. Postoperative Diagnosis: 1. Pseudoarthrosis, L3-4 interbody fusion with presumed pseudoarthritis, L3-4 intratransverse process arthrodesis. 2. Possible pseudoarthrosis, L2-3 intertransverse process arthrodesis. 3. Intact fusion posterior laterally at L2-3 on the low right side.

04-26-06: CT Lumbar Spine with Reconstructions. Impression: 1. Solid anterior interbody fusion L3-S1. There is also solid posterior fusion L2-S1. 2. Evidence for loosening of transpedicular screw on the left at L2, protruding through the superior aspect of the pedicle and the superior endplate of L2. Note that this is progressed since the prior examination. Posterior fusion is complete. 3. No spinal canal or neural foraminal stenosis at any level. Canal has been decompressed via laminectomy L2-5. 4. Bilateral transpedicular screws L2-4 with intact posterior steffee plates bilaterally.

05-24-06: Operative Report. Preoperative Diagnosis: 1. Status post L2-4 posterolateral fusion with retained painful hardware. Postoperative Diagnosis: 1. Status post L2-4 posterolateral fusion with retained painful hardware.

11-06-06: New Patient Evaluation. The claimant has a history of low back pain that started with DOI. She reported having significant amounts of pain in the upper part of her back, which radiates down her lower extremity. She also complained of significant amount of pain in the upper part of her neck, thoracic spine, and generalized arthritis, which are non-compensable areas. Her predominant complaint is low back pain, described as constant, burning, and aching in nature. She stated that the pain is usually worse with any kind of activity; not relieved by rest or by medication. She stated that the Norco seems to be helping her some, but only lasts for approximately 2-3 hours at the most. Previous Therapy: Claimant has undergone numerous physical therapy, numerous medications, and injections none of which actually helped her. Current medications: Prozac, Protonix, Synthroid, Lipitor, Clarinex, Norco approximately four a day, Zanaflex, Xanax, and Ambien CR. ROS: Positive for insomnia secondary to pain. Positive for lethargy and daytime somnolence. PE: Lumbar Spine: well-healed midline scar present with mild scar tenderness. ROM on forward flexion and extension is slightly decreased. Assessment: post laminectomy syndrome, chronic opioid usage in a controlled fashion. Plan/Recommendations: 1. Medications: placed on sustained-acting morphine like Kadian 20mg daily and continue with Norco for breakthrough pain. 2. Changed Prozac to Cymbalta 60mg daily. 3. Continue the present treatment. 4. F/U in 3-4 weeks to assess efficacy of these treatment modifications.

12-14-06: Follow up. Claimant stated that the medication has controlled her pain significantly except that she fell and hurt her right ankle and has been in significant amount of pain mostly in the back radiating down the lower extremities in an L5-S1 dermatomal distribution, significantly worse than before. She reported some amount of pain mostly in the back radiating down the lower extremity in an L4-5 dermatomal distribution. Current Medications: Prozac, Protonix, Synthroid, Lipitor, Clarinex, Zanaflex, Ambien CR and Xanax. PE: Lumbar spine: Some tenderness over L4-5 present, especially on the right side at the facet joints. Sitting SLR on the right side is positive with concordant pain to back and leg at 45 degrees. Slightly decreased sensation in an L5-S1 dermatomal distribution to light touch. Assessment: Postlaminectomy syndrome, myofascial pain, acute exacerbation of her low back pain. Plan/Recommendations: Increased Kadian to 30mg daily and continue Norco at the current dose. Start Senokot to help with her constipation. If pain is not controlled with this medication, she may benefit from right L5-S1 transforaminal ESI to reduce symptoms.

01-25-07: Follow up. Claimant stated that the Kadian did not help and she stopped using it. She stated that Norco seemed to help some, but she still has significant amount of pain around the right lower extremity in an L5-S1 dermatomal distribution, reported actually worsening over the last few weeks with noted weakness in right leg. Assessment: Postlaminectomy syndrome, acute exacerbation of her low back pain, myofascial pain. Plan/Recommendations: EMG/nerve conduction due to increased weakness and/or subjective feelings in her right leg as well as persistent pain in her right leg. Switched her to Percocet 10/325 with no more than six pills a day for breakthrough medication. Refilled Prozac and Xanax as insomnia is still her predominant complaint. Recommend starting Restoril 15mg PO QHS. F/U after EMG/nerve conduction tests.

12-03-07: New Consult. Chief complaint: lower extremity pain, numbness, tingling, weakness and low back pain. Medications: Prozac, Gabapentin, Avinza, Protonix, tizanidine, Benicar, Lipitor, Ambien, Synthroid, hydrocodone, alprazolam, Clarinex and lactulose. PE: Musculoskeletal exam: some tenderness to lumbar and cervical paraspinals. Impression: Probable lumbar failed back syndrome, symptoms involving multiple dermatomal distribution at L3-S1. Plan: Would asses with nerve conduction studies. Further recommendations to follow.

04-01-08: Operative Report. Preoperative Diagnosis: 1. post laminectomy syndrome. 2. Lumbar radiculopathy. Postoperative Diagnosis: same.

09-24-08: Operative Report. Preoperative Diagnosis: 1. post laminectomy syndrome. 2. Lumbar radiculopathy. Postoperative Diagnosis: same.

04-17-09: Follow-up Note. Claimant was hospitalized last December for pneumonia and was able to come off all her pain medications with the exception of four hydrocodone a day. The claimant has pain 24 hours a day, and four short-acting pulls give her a roller coaster effect. She gets relief from the hydrocodone

and when it wears off she is chasing pain again. She does not like the roller coaster effect. She is on Xanax and takes one or two a day. She inquired about a Duragesic patch to level out the pain; a small dose Fentanyl patch would be indicated. Recommend Duragesic 25 with usage of hydrocodone for breakthrough, keeping hydrocodone at a maximum of four per day will be safe. She had trigger point injections today. Recommend the Duragesic 25 for her chronic pain from post-laminectomy syndrome. She will take her Gabapentin, which has been somewhat beneficial for her radicular pain. She remains relatively functional at this point and actually looks better than she has. Believed that stresses she has had greatly aggravated her pain situation, which is a direct result of her post-laminectomy syndrome.

04-11-11: Follow-up Note. Claimant presented with having a lot more low back pain. She recently completed knee replacement and therefore does not have the limping that previously aggravated her LBP. PE: She has pain with extension and rotation and some pain when she bends that does radiate down her leg. This is compatible with an L5 radiculopathy, where she known to have some foraminal stenosis. Medications: Duragesic 25, taken on a timely basis with no evidence of abuse or diversion or any aberrant behavior. She is taking four hydrocodone per day, again without abuse, diversion, or any difficulties. Recommend continue medications. Recommendations: trigger point injections. Procedure: bilateral SI trigger point injections. Follow-up: prn.

06-04-13: Follow-up. Chief complaint: low back pain consistently. Takes Norco, 4 a day with Duragesic 25. Improves quality of life, ADL. Occasional sciatic. She gets pain with spasms in the back. Received Xanax from psychiatrist, Dr.; as well as Buspar. On Gabapentin for neuropathy, believes it helps. Severity of symptoms: 8/10 max; meds drop to 3/10; acuteness of symptoms: not really; interference with ADL: yes; ROS: depression/anxiety. Current medications: Duragesic, Gabapentin, Norco, Prozac. PE: very tight lower back, particularly painful over SI and L3 area, with spasm, decrease ROM. Recommendation: injections. Continue Duragesic, Gabapentin, Norco and follow-up in 3 months.

06-05-14: Office Visit. Chief complaint: back pain. She described pain as aching, sharp and burning rated 10/10 most days in spite of treatment. The pain is located in the buttocks and spine region. She ambulates with a walker and cane on occasion, but not today. No bowel or bladder abnormalities. Current medications: Fentanyl and Tizanidine. Allergies: NSAIDs and aspirin. PE: Hypertonicity in the paraspinous muscles with multiple tender points. Imaging Studies: multiple x-ray views resulted in posterolateral bone fusion and very extensive decompression as well as interbody cages. Assessment: lumbar strain, lumbalgia, lumbar radiculopathy, chronic pain syndrome, previous spinal fusion. Plan: continue seeing for her injections which she stated does help, continue ice, moist heat and anti-inflammatories.

08-04-14: UR. Reason for denial: According to the clinic note on 6/5/14, there was mention of the claimant receiving periodic trigger point injections in the lower lumbar spine and SI joint, with some improvement to the point that her

medications could be kept at the same level, and that she was on Duragesic with reportedly nice analgesic and improvement of activities of daily living without evidence of abuse or diversion. It was also noted that drug testing in the past was compatible; Norco for breakthrough pain and Gabapentin for neuropathy, as well as mention that at one point the claimant was seen by another provider for consultation for a spinal cord stimulator, but that this was never follow up on. Physical exam noted that the claimant was bent over with an antalgic gait, pain with extension and rotation, decreased sensation of the feet, and no other clearly detailed objective physical exam findings were listed. The impression was post-laminectomy pain, with recommendation for an injection bilateral L5 to S1 paralumbar containing Depo-Medrol and lidocaine, which was done at that visit, and also for prescription renewal. The retrospective request for hydrocodone/acetaminophen 10-325mg; Fentanyl 25mcg/hr patch; Gabapentin 300mg; and tizanidine 4mg. The request is not medically necessary.

08-18-14: UR. Reason for denial: The claimant is a female with a DOI on xx/xx/xx, when she injured her back in a fall. Current complaints include pain in the buttocks and spine region. She described the pain as aching, sharp and burning, rated 10/10. Physical examination on 06/05/14 noted motor to be intact in all myotomes and sensation intact in all dermatomes. There was hypertonicity in the paraspinous muscles with multiple tender points and good range of the lumbar spine. Previous treatments include multiple back surgeries, injections and medications. This is a retrospective request for hydrocodone/acetaminophen 10-325mg; Fentanyl 25mcg/hr patch; Gabapentin 300mg; and tizanidine 4mg. The request is not medically necessary.

08-21-14: Office Visit. Current Symptoms: The claimant has two components of pain: back pain that is centered around the lower back, bilateral, to SI and buttock area and chronic leg paresthesias, numbness into her legs, and pain that radiates down her right leg from the hip to just past the knee. She takes medications which significantly help her symptoms, but recently her carrier deemed it not necessary to approve them. She is on Duragesic 25; a small dose. It provides significant improvement in her chronic lower back pain and has improvement in ADL. There are no signs of abuse with this modest dose and is medically indicated to treat her chronic pain due to her work related injury and post laminectomy pain. For breakthrough, she is on Norco 10, taking up to 4 per day without evidence of abuse, no early refills. She has improvement in her pain which is directly related to her work related injury. For paresthesias and radicular symptoms, she is on Gabapentin 300mg three times a day. This medication is indicated for her radiating leg pains, numbness and paresthesias. It provides improvement and ability for her to tolerate these symptoms. She has improvement in ADL as a result of taking this medication. This medication is indicated for treatment of her post laminectomy radiating leg pain and paresthesias which is a result of her on the job injury. For back spasms, which can be prominent, she is on tizanidine. This medication significantly assists in the chronic back spasms she has. It is indicated for treatment of her job related injury and post laminectomy back spasms. It provides significant improvement and assists in her ADL. Her carrier has denied all 4 of her medications and summarily

cut them off. This put her at significant risk for medical complications as a result of abrupt discontinuation. This is irresponsible both on the part of the carrier and the peer reviewers who said they were not indicated. Severity of symptoms: 7/10 without medication; 3/10 with. Acuteness of symptoms: chronic. Interference with ADL: yes, but improved on meds. ROS: chronic anxiety/depression sue to pain; hypertension. Current medications for symptoms: Duragesic 25; Gabapentin 300; Zanaflex 4; Norco 10. Current medications for other problems: Prozac. PE: Diminished ROM; pain with SI stressing; spasms paralumbar; pain extension of hip radiate to knee (posterior); dysesthesias calf and foot. Imaging: Lumbar fusion L4 to S1; no new imaging. Diagnostic Impression: Post laminectomy pain; radicular pain; lumbar muscle spasms; radiculopathy. Results from previous procedures: improves with lumbar TPI every 3-4 months, improves spasms. Recommendation: Trigger point injections; refill medications; appeal workers compensation carrier denial of medication refills. F/U: See new pain doctor in 2-4 months; follow up.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
The previous adverse determinations are overturned. The claimant is a female with a DOI on xx/xx/xx, when she injured her back in a fall. Patient continues to have pain in the buttocks which radiates to into her legs. Pain is described as aching, sharp and burning and rates 10/10. Previous treatments include multiple back surgeries, injections and medications. Medication is clearly shown to have marked benefit and allows this patient to perform ADLs. Additionally, medications are being used in line with ODG. This is a retrospective request for Hydrocodone/acetaminophen 10-325mg, Fentanyl 25mcg/hr patch, Gabapentin 300mg, Tizanidine 4mg. After reviewing the medical records and documentation provided, the request is medically necessary and certified.

Per ODG:

Duragesic® (fentanyl transdermal system)	Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by ALZA Corporation and marketed by Janssen Pharmaceutica (both subsidiaries of Johnson & Johnson). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. Due to the significant side effects, not for use in routine musculoskeletal pain. The FDA announced it will require color changes to the writing that appears on fentanyl pain patches (Duragesic and generics) so they can be seen more easily and to emphasize that unintended exposure can cause death. This is part of an effort to prevent accidental exposure to the patches, which can cause serious harm and death in children, pets, and others. (FDA, 2013) See Fentanyl. [Duragesic ranked #9 in amount billed for WC in 2011. (Coventry, 2012)]
Gabapentin (Neurontin®)	Recommended for neuropathic pain. Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. See Anti-epilepsy drugs (AEDs) for general guidelines, as well as specific Gabapentin listing for more information and references.
Opioids for chronic pain	Not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-

	malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED). Risks of adverse effects are documented in the literature at doses as low as 50 MED. At this dose of MED, prescribing clinicians should begin to use caution in terms of any additional escalation of dose. At doses of 100 mg MED it is recommended that reassessment of use of this class of drugs should be made due to limited evidence for improved pain control and function with continued use as well as evidence of substantial adverse risks with higher MEDs. Escalation of doses beyond the 50 to 100 MED range should be done with caution, and generally under the care of pain specialists. In certain cases, addiction specialists may need to evaluate patients, with the understanding that many patients who progress to chronic opioid therapy have underlying psychiatric disease and substance abuse issues. See Opioid, dosing for details on how these values were derived based on current literature. Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making. Extreme caution is required for any opioid use in patients with the following: (1) Individuals with a high risk for misuse or diversion; (2) Individuals with evidence of substance abuse issues; (3) Individuals with a family history of substance abuse; (4) Individuals with underlying psychiatric disease. An accurate diagnosis should be established. At the minimum, screening for opioid risk and psychological distress inventories should occur before starting this class of drugs and a psychological evaluation is strongly recommended. While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective in achieving the original goals of complete pain relief and functional restoration. For patients now on high opioid doses who are not benefiting from this class of drugs there is some evidence that dose reduction does not increase pain levels or decrease function, and in fact, may provide improvement of these outcomes. (DiBenedetto, 2014) (Baron, 2006) See Weaning of medications. To prevent new patients from getting caught in this cycle, ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases. Use for specific disease states - Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain, where opioids are not recommended as a first-line therapy. (McNicol, 2013) - Chronic back pain: Opioids appear to be efficacious but should be limited for short-term pain relief in patients with acute low back pain. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. (Martell-Annals, 2007) (White, 2011) (Franklin, 2009) Failure of activity level to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicates that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing tramadol to placebo that have reported pain relief, but this did not necessarily improve function. (Deshpande, 2007) See also the Low Back Chapter for recommendations in acute pain, where opioids are not recommended except for short use for severe cases, not to exceed 2 weeks. - Headaches: Not recommended, in particular, due to the risk of medication overuse headache. (Lake, 2008) (Olesen, 2006) See Medication overuse headache. - Osteoarthritis: Not recommended as a first-line therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of

	contraindications for use of first-line medications. There is a lack of evidence to allow for a treatment recommendation for long-term use. If used on a long-term basis, the criteria for use of opioids should be followed. See Opioids for osteoarthritis for citations. The American College of Rheumatology guidelines do not recommend opioids for osteoarthritis, except in patients who should have total joint arthroplasty but cannot. (Hochberg, 2012) - Nociceptive pain: Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer). - Mechanical and compressive etiologies: rarely beneficial. Evidence for use: A major concern about the use of opioids for chronic pain is that most randomized-controlled trials are limited to a short-term period (1 to 6 months), with high rates of dropout due to adverse effects and/or lack of efficacy (as high as 60%). Studies usually exclude patients with mental health disease or substance abuse, limiting generalizability. Methodological issues result in limitations, with problems of studies including insufficiently comprehensive outcome assessment, and incomplete inclusion of adverse effects. Results suggest modest pain relief compared to placebo (approximately 30%), but there are no long-term studies to determine if pain relief is maintained. Overall, the safety of long-term use has not been adequately studied, and some nonrandomized prospective studies suggest opioid treatment may actually retard functional recovery. This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Eriksen, 2006) (Ballantyne, 2006) (Furlan, 2006) (Ballantyne, 2008) (Franklin, 2008) (Chou, 2009) (Chapman, 2010) (Papaleontiou, 2010) (Furlan, 2010) (Von Korff, 2011) (Manchikanti, 2011) Patients most likely to receive high-dose opioids: Cohort studies indicate that small proportions of patients are most likely to receive the majority of opioids (in one study 5% of patients received 70% of opioids dispensed). Patients most likely to receive high-dose opioids in cohort studies are those who have multiple pain complaints, and have mental health and substance use disorders. These are generally patients who are excluded from randomized trials of opioids, which limit the generalizability of current studies. They are also more likely to be receiving concomitant benzodiazepines. Studies show these patients are more likely to have higher rates of medical diagnoses and higher Charlson comorbidity scores. (Sullivan, 2005) (Braden, 2009) (Edlund 2010) (Morasco, 2010) (Kidner, 2010) (Sullivan, 2012) Risk factors for progressing to long-term opioid use: It is currently suggested that of the patients that proceed to long-term opioid use (90 days or more), two-thirds continue opioids for years later, creating life-long therapy. Current research involves evaluating what subsets of patients are likely to proceed to long-term use, particularly as (1) the vast majority of patients in randomized-controlled studies abandon opioids after short-term use due to adverse effects and/or lack of efficacy and (2) a small proportion of patients receive the majority of opioids dispensed. Subclasses of individuals who continue with long-term use have been identified as patients who use high daily doses (>120 mg morphine equivalent/day) and/or have a history of opioid misuse. The likelihood of receiving long-term opioids increases with number of pain sites, increased baseline pain, decreased baseline function, number of medical diagnoses, nicotine dependence, psychiatric diagnoses, lower self-reported mental health, fear avoidance beliefs, and lower certainty of return to work in the next six months. The most likely mental health diagnoses are anxiety disorder and post-traumatic stress disorder. It is suggested that long-term opioids are often unknowingly being used to treat the sequelae of both physical and psychological trauma. This is based on theories of endogenous opioid system disruption. (Sullivan, 2005) (Webster, 2007) (Dersh, 2007) (Dersh, 2008) (Weisner, 2009) (Braden, 2009) (Franklin, 2009) (Edlund 2010) (Morasco, 2010) (Martin, 2011) (Sullivan, 2012) Adverse effects: These include serious fractures, sleep apnea, hyperalgesia,

	immunosuppression, chronic constipation, bowel obstruction, myocardial infarction, and tooth decay due to xerostomia. Neuroendocrine problems include hypogonadism, erectile dysfunction, infertility, decreased libido, osteoporosis, and depression. Men taking opioids, especially high doses and over several months, are about 50% more likely to fill a prescription for erectile dysfunction (ED), according to a study of over 11,000 men. (Deyo, 2013) Risk of overdose: Since 2003, more overdose deaths have involved prescription opioid analgesics than heroin or cocaine combined. The CDC estimates that in 2008 there were almost 100 drug overdose deaths a day (in numbers nearing that of deaths from motor vehicle accidents). Opioid pain relievers accounted for 73.8% of deaths, with prescription drugs accounting for the largest increase in deaths. (MMWR, 2011) The risk of overdose increases when opioids are used with other drugs (such as benzodiazepines, cocaine, and/or heroin) or alcohol. Other risk factors include a history of substance abuse and/or of mental health disorder. The CDC states that the two main populations at risk for overdose are the approximate 9 million individuals who report long-term use of opioids, and the 5 million individuals who report non-medical use of this class of drugs. The CDC also reports increased risk for individuals on high doses of daily opioids (defined as > 100 mg of oral morphine equivalents a day) who seek care from multiple providers. Individuals with these characteristics were found to represent 40% of overdose deaths. Another concern is that this is a group of individuals who are likely to divert drugs. Statewide data has found that 25% to 66% of those who die of pharmaceutical overdose were taking drugs prescribed to someone else. (Mirakbari, 2003) (CDC, 2012) (CDC, 2011) (Webster, 2011). (Gomes, 2011) (Dunn, 2010) (Bohnert, 2011) (Bohnert 2012) See Opioid, dosing. Concomitant use with other medications: Benzodiazepines and other sedative drugs: Benzodiazepines are commonly implicated in opioid overdose deaths and they lower the lethal opioid dose. Consideration of tapering the use of sedative hypnotics and benzodiazepines before starting opioid use if possible is strongly recommended. (Mirakbari, 2003) (Kahan, 2011) (Gomes, 2011) (Toblin 2010) Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: 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. (Nicholas, 2006) (Ballantyne, 2006) Tolerance and addiction: Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. (Ballantyne, 2006) (Ballantyne, 2003) See Substance abuse (tolerance, dependence, addiction). Behavior reinforcement: A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as psychosocial or behavioral therapy, may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional restoration. (Ontario, 2000) It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient. (Fordyce, 1991) Overall treatment suggestions: Current guidelines suggest the following: - A trial of opioids for chronic pain as a first step in treatment for appropriate conditions that have not responded to other interventions after careful screening and patient informed consent. The steps involved are outlined in the Criteria for Use of Opioids. The trial includes an initiation phase that involves selection of the opioid and initial dose. - There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should

	be discontinued. - The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) (VA/DOD, 2010) See Substance abuse (tolerance, dependence, addiction). See also Implantable pumps for narcotics. See also Opioids in the Low Back Chapter. See Criteria for Use of Opioids.

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)**