

Vanguard MedReview, Inc.

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Notice of Independent Review Decision

March 3, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Extension: Medication- Nucynta 75mg, Tablets

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

This physician is Board Certified in Family Medicine and has over 12 years of experience.

REVIEW OUTCOME:

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

Upheld (Agree)

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

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The Claimant is a male who was injured on xx/xx/xx, he was struck in the right shoulder. He immediately had pain and was seen the following day at Occupational Medicine for X-Rays and medications and was returned to work.

05/06/2013: Initial Consultation. **Assessment:** Neck and right shoulder pain secondary to work injury. The patient could not tolerate his work duties the day after his injury due to pain and was sent home. Since then, the patient has been working full time with restrictions. He initially had 15 pound lifting restrictions but this was decreased to 10 pounds. An MRI done in April 2013 showed three separate muscle tears with retraction of the rotator cuff muscles. The patient has been referred to me for medication management. **Plan:** Start Norco 10/325 one to

two p.o.q.4hrs prn pain, #100. Start Tramadol 50mg one p.o.q.i.d. prn pain, #240. Start Senokot-S two p.o.b.i.d. for constipation, #100. Start Compounded Pain Cream-Gabapentin 10%, Ketamine 10%, Ketoprofen 10%, Lidocaine 10%-use 1-2 grams three times daily as needed, #240 grams.

05/28/2013: Progress Notes. **Assessment:** Patient was scheduled tomorrow for surgery but issues with pre-op EKG. Patient was working full time with restrictions up until today but now will be off work for six weeks. Sleeping 5-6 hours okay, but has to wake up to take meds at times. He presented with an increase in pain since discontinuing the compounded pain cream. States current meds relieve a significant amount of the pain so he can function but pain is becoming overwhelming and interfering with all ADLs. **Plan:** UDS Sent to lab/PC-consistent med directions. Prescription written for Tramadol 50mg #240 ii po qid prn pain, Norco 10/325, #100 i-ii poq 4 hrs prn pain, Senokot-S #100 ii po bid for constipation.

06/24/2013: Progress Notes. **Assessment:** Patient has been cleared for surgery and waiting to be scheduled. Meds are working. Still not able to work due to decreased ROM and flaring up symptoms. **Plan:** Medications prescribed: Tramadol 50mg #120 i- ii po qid prn pain, Norco 10/325, #180 i-ii poq 4 hrs prn pain, Senokot-S #100 ii po bid prn for constipation.

07/24/2013: Progress Notes. **Assessment:** Patient had surgery 7/10/13 on R shoulder to repair tear-has had increased pain since surgery and was authorized to increase meds. Still having a lot of weakness on RUE but started PT twice weekly. **Plan:** Celebrex 200 mg #30 I po qd, Tramadol 50mg #150 i- ii po qid prn pain, Norco 10/325, #200 i-ii poq 4 hrs prn pain, Senokot-S #200 ii po bid for constipation.

08/15/2013: Progress Notes. **Assessment:** Sleeping 6-7 hours per night. Cannot tolerate any weight on R shoulder. Pt is on PT twice weekly. Meds allow a significant decrease in pain and the ability to perform some ADL's and active PT. **Plan:** Medications: Celebrex 200 mg #30 i po qd, Tramadol 50mg #150 i- ii po qid prn pain, Norco 10/325, #200 i-ii poq 4 hrs prn pain, Senokot-S #200 ii po bid for constipation.

09/13/2013: Progress Notes. **Assessment:** Patient continues PT twice weekly and has increased ROM. Sleeping 5-6 hours per night. **Plan:** Celebrex 200 mg #30 I po qd, Tramadol 50mg #200 i- ii po qid prn pain, Norco 10/325, #200 i-ii poq 4 hrs prn pain, Senokot-S #200 ii po bid for constipation.

10/25/2013: Progress Notes. **Assessment:** Doing well since last visit. Has started Nucynta. Sleeping well 6-7 hours per night. **Plan:** Continue current meds and start Medrol Dose Pack take as directed #T Pack, refill Tramadol, Nucynta 50mg po tid #90

10/30/2013: Evaluation. **Assessment:** presented in the office today, he is continuing to have complaints of pain in the shoulder. He had a very significant

exacerbation of his symptoms last week in doing his home exercises. He underwent active physical therapy in the office today. We started with light myofascial release about the shoulder blade. His ROM is limited to 70 degrees of flexion, 70 degrees of abduction, extension was 20 degrees. He noted a very significant increase in pain during the course of these movements. The patient has continued to have a difficult time with forward flexion as well as extension.

Plan: I'll have the patient work on stretching exercises at home and try to improve his ROM to decrease overall symptoms. He should continue to work on stabilization exercises at home and continue cryotherapy that if he has any additional flare up of his symptoms. I will follow up with him on a two time per week basis and I would also encourage him to follow as needed and to continue to follow up as he sees necessary.

11/05/2013: Evaluation. **Assessment:** Patient rates pain in the upper right extremity at 2-3/10 with increased symptoms to 4-5/10 with activity. He continues stretching exercises at home but in the last couple of weeks he has had a fairly significant increase in his pain. I discontinued the active therapy for a few days to try to alleviate his inflammation. He is back in active therapy today. He stated that he is continuing to have numbness and the pins and needles in the upper extremity complete. He underwent active therapy in the office for 45 minutes today. We worked on flexibility exercises including flexion, internal and external rotation. He was provided with myofascial release of the supraspinatus, the infraspinatus, subscapularis and the Teres minor muscle. We also worked on the anterior joint capsule and had the patient work on the posterior joint capsule and the pectoralis tendon. **Plan:** We will see him now on a one-time per week basis for treatment of these active symptoms and encourage him to continue to work on his stretching exercises at home.

11/20/2013: Evaluation. **Assessment:** The patient suffered an exacerbation of the shoulder pain with increased arm numbness and the sharp reduction in his active range of motion after doing some exercise with the five pound weight. We worked up to these exercises and he was in fact able to tolerate it but unfortunately had a significant flare up. We postponed a couple of visits of active therapy and developed passive modalities to reduce his radicular symptoms and to improve his functional ability. Since then, we have now returned to his active exercises, at this time with a three pound weight. He worked on internal and external rotation exercises with the light therapy band. He has been working on flexion and extension and we have moved into wall push-ups. The patient participated in circumduction exercises and we provided him with myofascial release of the supraspinatus, the infraspinatus, and scapular muscles. We worked on the tendons, the biceps and we also worked on the pectoral muscles. **Plan:** Follow up 1-2 times per week.

11/26/2013: Progress Notes. **Assessment:** The patient presented with an increase in pain due to doing exercises at home. Nucynta has been reducing a significant amount of pain but he had to increase back to 4 a day due to greater efficacy. **Prescribed:** Nucynta 50mg i po qd #120, Celebrex 200 mg #30 i po qd,

Tramadol 50mg #200 i- ii po qid prn pain, Senokot-S #100 ii po bid for constipation.

12/27/2013: Progress Notes. **Assessment:** The patient is doing okay since last visit, he had 2 severe pain flare ups over the past month due to over exerting during exercise. PT states he takes Norco if he starts running low on Nucynta and is still taking Tramadol 6-7 days a week due to continued pain even after taking Nucynta. **Plan:** Reviewed to not take both Tramadol and Nucynta at the same time routinely to see if one or the other is enough relief. **Prescribed:** Nucynta 75mg i po qid #120, Celebrex 200 mg #30 i po qd, Tramadol 50mg #240 i- ii po qid prn pain, Senokot-S #120 ii po bid for constipation.

12/31/2013: UR. Rational for Denial: I spoke on 12/30/13 and based on our discussion and the clinical information available for my review, the request does not meet preliminary guidelines and is not supported by medical necessity. The record is a bit confusing and the way I read it there are too many mgs of Nucynta in play in the one pt at the present time. And it appears the iw is still on Norco? We are advised that Nucynta was preferred as the original opioid caused severe constipation. That is fine but the dose and quantity of Nucynta seems off. IW had R shoulder RCR and DCE 7/10/13. The entry Nucynta ER 100mg to 250mg #180 tabs certed 9/25/13. Then one month later Nucynta 50mg #90 10/28/13. Now Nucynta 75mg #120. We are almost 6 months out from surgery. IW under normal circumstances should be being weaned at present not increased. I am unable to cert at present until explanation can be obtained.

01/22/2014: Prior Authorization Request. indicated that the patient is taking Nucynta 75 mg one p.o.q.i.d. for chronic shoulder pain and that he takes Norco 10/325 episodically for severe increased pain if he is not getting any relief from the Nucynta. He also had to take Norco regularly when his refill was delayed last month because of insurance authorization and was totally out of the Nucynta. The patient states the Nucynta is significantly helpful with decreasing his pain and allowing him to participate in physical therapy. He takes Tramadol 50 mg in between the doses of Nucynta for additional pain relief. The patient will be starting a work hardening program in the next few weeks and feels the medication is medically necessary to allow him to tolerate the increased activity. She also stated that the patient had lethargy and constipation when he took the Norco on a daily basis and his pain relief was not as significant.

01/29/2014: UR. Rational for Denial: I am unable to authorize this reconsideration based upon the clinical information available and/or our discussion. Based on review of the medical records provided, the proposed treatment consisting of Medication-Nucynta 75mg, Tablets is not medically necessary. Per the records provided the claimant has chronic right shoulder pain. The claimant is already 7 months s/p right shoulder surgery. He is already taking Norco prn and tramadol qid. Nucynta (tapentadol) is centrally acting opioid agonist similar to tramadol. Rationale for prescribing two medications from the same pharmacological group is not specified in the records provided. With this, it is deemed that based on the clinical information submitted for this review and using the evidence-based, peer-

reviewed guidelines the medical necessity for Nucynta 75mg tablets is not fully established for this claimant at this juncture.

02/20/2014: Progress Notes. **Assessment:** Patient recently completed a work hardening program for 10 days and states it was very helpful with improving activity tolerance. He states that Nucynta has allowed him to participate in work hardening program without a significant increase in pain. **Plan:** PT advised that Nucynta 75 mg is being denied and sent to an IRO for review. He would have to increase Norco until insurance approval. **Prescribed:** Celebrex 200 mg #30 i po qd, Tramadol 50mg #240 i- ii po qid prn pain, Norco 10/325 i-ii po qid aid prn pain, Senokot-S ii.

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

The previous adverse determinations are upheld. In review of the records provided to me, the IW is 8 months s/p R shoulder surgery. He is utilizing 3 short term opioids for pain control-Nucynta 75mg, Norco 10mg and Tramadol 50mg-all at high doses. At this point, weaning narcotics should be the goal. If he has chronic pain, he should be in a pain management program, utilizing all non-narcotic options and relying on long acting narcotics only if necessary. It does not appear any adjunctive medications for chronic pain, such as gabapentin, Lyrica, or Cymbalta have been tried. After reviewing all of the available records submitted and using evidence-based guidelines and accepted clinical practices, the requested Extension: Medication- Nucynta 75mg, Tablets does not appear to be an established medical necessity at this time.

Tapentadol (Nucynta™)	Recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) On November 21, 2008, the FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. Tapentadol, manufactured by Johnson & Johnson Pharmaceutical, is a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta™ (tapentadol) was made a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. Nucynta™ may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009) Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks
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	<p>that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) Gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. (Wild, 2010) This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine. (Prommer, 2010) But the manufacturer disagrees. (Nelson, 2011) In August 2011 FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. (FDA, 2011)</p>
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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)**