

Case Number:	CM14-0169040		
Date Assigned:	10/17/2014	Date of Injury:	05/18/2010
Decision Date:	12/10/2014	UR Denial Date:	09/29/2014
Priority:	Standard	Application Received:	10/14/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in Colorado. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

57 year old female with date of injury 5/18/2010 continues care with the treating physician as well as Spine Surgeon and Psychologist / Psychiatrist. She has chronic low back pain, and continues with some leg pain as well. Her symptoms failed to improve with multiple medications, physical therapy, and chiropractic care. She achieved some relief with epidural steroid injections, but no lasting relief. She then underwent L2-L5 lumbar decompression which, as of most recent notes available, has decreased her overall pain, especially in the legs. She continues to struggle with depression as well as her pain, and continues on psychiatric medications in addition to pain medications. The treating physician's notes indicate that patient does not consistently take medications because of insurance denials of medications. The notes are not clear from visit to visit exactly when she is taking medications and when she is not. The treating physician's notes indicate that the opioids are helping decrease patient pain and improve patient function. The treating physician requests refill on Nucynta for continued opioid use.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Nucynta 50mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation ODG

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 74-75, 79-80, 85, 88-89. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: www.fda.gov

Decision rationale: Nucynta (Tapentadol) is a Pure opioid agonist approved for use by FDA in 2008. The MTUS Guidelines do not address Nucynta specifically as it was not available when the Guidelines were published, but the recommendations for its use are the same as the recommendations for use of any opioid. As a pure opioid agonist, the Nucynta does not have a "ceiling effect" for its analgesia, and it does not counteract other pure opioid agonists. The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated clinical tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. 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. Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids, 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function, 4) Patient has evidence of unacceptable side effects, 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence," Per the Guidelines, Chelminski defines "serious substance misuse" or non-adherence as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed, 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction, 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work? Has patient had improved function and decreased pain with the opioids? For the above patient, there are only a few notes supplied that address pain

management since patient surgery 5/19/2014. She has consistently been on Nucynta, except when not approved through insurance, and the records are not clear as to how those denials actually affect medication use. Per the records, pain level is addressed at each visit, and is improved when taking the Nucynta, in addition to other medications. The treating physician's notes also address function, but only in a general way, based on patient's statements about activities. The records indicate patient urine drug screens are "appropriate," but the only urine drug screen result available for review was negative for opiates at a time when patient was to be taking Nucynta. As appropriate, patient is in long term management for depression, and the treating Psychologist's notes indicate patient has struggled repeatedly with suicidal thoughts and has considered overdosing on her prescription medications in the past because of her pain and the sequelae of her accident. While patient's pain is documented as improved, there is no objective evaluation documented for functional improvement. Furthermore, patient is at high risk for misuse of opioids given her recurrent suicidal ideations and history of plan to overdose on her medications, and given the evidence of negative urine drug screen when patient was to be taking opioids. As the records do not establish that recommended monitoring / management of opioids is ongoing, the Nucynta is not considered medically indicated to continue. Therefore this request is not medically necessary.