

Case Number:	CM14-0185573		
Date Assigned:	11/13/2014	Date of Injury:	01/31/2012
Decision Date:	12/19/2014	UR Denial Date:	10/28/2014
Priority:	Standard	Application Received:	11/07/2014

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:

70 year old male with date of injury 1/31/2012 continues care with treating physician. Patient has chronic low back pain with radiation of pain to left leg. Past treatments have included physical therapy, acupuncture (only mentioned in UR evaluation), narcotics, pool therapy, transcutaneous electrical nerve stimulation (TENS) unit and decompression with discectomy 10/16/2012. Per the records supplied for review, patient has been maintained on Norco and Lidopro with Tramadol and Ultracet also prescribed. Physical findings include positive straight leg raise test on the left. Per the records of the treating physician, patient reports 50% improvement in pain with regimen as of 6/3/2014, including medications, pool therapy and TENS units. The physical therapy notes indicate patient "perceives" a 5% improvement at the time of physical therapy discharge, 7/30/2014. Per the notes after those dates, pain stable at "50% improved." The treating physician requests refill on Norco, new prescription for Terocin, and refill on patches for TENS unit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 5/325 mg, thirty count,: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89, 91.

Decision rationale: 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 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. (Passik, 2000) 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. (Chelminski, 2005) 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?" Per the records supplied for review, the patient of concern has less pain, though not consistently, with his regimen which includes Norco. However, the records do not indicate any objective, verifiable assessment of function / functional improvement. As pain levels continue to fluctuate, and there is no documentation of functional assessment that shows improvement, the request to continue Norco is not medically indicated.

Terocin 120 ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 111-113.

Decision rationale: Terocin lotion is comprised of Methyl salicylate 25%, capsaicin 0.025%, menthol 10% and lidocaine hydrochloride 2.50%. Per the MTUS Guidelines, topical analgesics may be indicated for specific conditions when other therapies have failed. However, the guidelines make it clear that if a drug or drug class in a given topical compound is "not recommended," then the entire compounded topical is not recommended. Per the guidelines, capsaicin topical can only be recommended for those who have failed to respond to or are intolerant of other options for pain relief. Some good randomized studies suggest that capsaicin is useful for osteoarthritis, fibromyalgia and chronic non-specific back pain (consistent with patient of concern). However, higher doses of capsaicin (anything over 0.025% based on available studies) are considered experimental and have no studies to support use in the above conditions. It is noted that capsaicin has moderate to poor efficacy, but can work, alone or in compound, for patients whose pain has not been controlled with conventional therapies. Capsaicin produces "highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds." (Maroon, 2006) The above statements, it should be noted, support only the use of 0.025% dose capsaicin. Per the guidelines, Lidocaine, in the formulation of a dermal patch (Lidoderm), is recommended for "localized peripheral pain" (neuropathy) after failure of or contraindication to first line therapy (Tricyclic Antidepressants, serotonin-norepinephrine reuptake inhibitors (SNRI) Antidepressants or Anti-epilepsy drugs), and has FDA orphan status for that indication. No other topical formulations of Lidocaine (creams, lotions, gels) are indicated for neuropathic pain. (Other formulations of Lidocaine can be used as local superficial anesthetics) Lidocaine, in any formulation, is not recommended for non-neuropathic pain due to lack of evidence for its efficacy and safety. Per the records, patient has not had a trial of first line therapies for neuropathic pain (Tricyclic Antidepressants, SNRI Antidepressants or Anti-epilepsy drugs), and the requested formulation includes Lidocaine in a lotion formulation which is not approved for use in neuropathic pain, or non-neuropathic pain. The MTUS Guidelines do not address methyl salicylate or menthol topical preparations, which in this case are not relevant as the Lidocaine component is considered not recommended, so the entire topical analgesic compound, Terocin, is not medically indicated.

Transcutaneous electrical nerve stimulation (TENS) patches, two pairs,: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 114-116.

Decision rationale: Per the Guidelines: "Electrotherapy represents the therapeutic use of electricity and is another modality that can be used in the treatment of pain, though not recommended a primary modality. The earliest, and still most commonly used electrotherapy devices to apply current to the skin, are known as TENS (transcutaneous electrical nerve stimulation) units. A TENS unit can be one of several devices. (H-wave stimulation device, Interferential Current Stimulation, Microcurrent electrical stimulation or MENS devices, RS-4i sequential stimulator, Electroceutical Therapy, Neuromuscular electrical stimulation or NMES devices, Sympathetic therapy, and Dynatron STS Though not recommended as first line treatment, a TENS unit may be considered for use as part of a functional restoration program for specific conditions. While use of TENS units continues to be standard of care in many communities, the evidence is lacking to establish effectiveness short term or long term. The Guidelines specify conditions in which TENS unit may be useful: Neuropathic pain: Some evidence (Chong, 2003), including diabetic neuropathy (Spruce, 2002) and post-herpetic neuralgia. (Niv, 2005) Phantom limb pain and CRPS II: Some evidence to support use. (Finsen, 1988)(Lundeberg, 1985) Spasticity: TENS may be a supplement to medical treatment in the management of spasticity in spinal cord injury. (Aydin, 2005) Multiple sclerosis (MS): While TENS does not appear to be effective in reducing spasticity in MS patients it may be useful in treating MS patients with pain and muscle spasm. (Miller, 2007) Recent evaluation of available studies on TENS unit use reveals that current studies lack quality methodology and evidence based conclusions, so TENS unit is not known to be effective in chronic musculoskeletal pain. The Guidelines establish criteria for TENS unit use: -Pain for at least 3 months - Documentation that other therapies, including medications, have been tried, and failed. -A one month trial of TENS unit use should be in the record, as part of a functional restoration program, with frequency of use noted, as well as pain relief and functional improvement achieved. -Other treatments ongoing during same time as the TENS units trial should be in the record. -Goals of treatment with the TENS unit should be documented. (including long and short term goals) -A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary -Form-fitting TENS device: For use in large area or because of skin condition or because TENS unit to be used under a cast. -Post-operative use of TENS unit: Recommended for first 30 days after surgery." Per the records for the patient of concern, patient has been using TENS units for an extended period of time, not in conjunction with a functional restoration program. The records do indicate that patient has failed to improve with multiple other therapies, and that TENS unit, with patient's other current treatments, does help pain. The records supplied for review did not include information on the TENS unit trial, specifically the frequency of use, and the objective evaluation of functional improvements. Also, there is no documentation of the goals of treatment for the TENS unit. The notes also do not address functional improvement with ongoing treatment. As the TENS unit is not being used with a functional restoration program, and as there is no documentation of objective functional improvement with the TENS unit, the continued use of the TENS unit is not considered medically necessary. Therefore, the request for TENS unit patches is not medical necessary.