

Case Number:	CM14-0169535		
Date Assigned:	10/17/2014	Date of Injury:	12/27/1997
Decision Date:	01/14/2015	UR Denial Date:	09/26/2014
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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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:

The patient is a 44-year-old woman who sustained a work-related injury on December 27, 1997. Subsequently, she developed chronic low back pain. According to the clinical report dated August 22, 2014, the patient complained of lower backache radiating to bilateral legs, no associated weakness or sensation changes. The patient has past medical history significant for HTN, DM, migraine HA, L5/1 laminectomy in 1998, and L4-1 fusion in 2000, depression/anxiety. The patient has an IT pump with Hydrocodone, Baclofen, and Bupi. She is currently taking Flexeril, Prilosec, Norco, Promolaxin, GBP, Tramadol, and Medrox. Physical examination revealed full strength in bilateral lower extremities. Lower extremities reflexes were 2+ bilaterally. The patient's sensory was intact to light touch. There was tenderness to palpation of bilateral lumbar and thoracic paraspinals, limited range of motion. The patient was diagnosed with lumbosacral spondylosis without myelopathy, post-laminectomy syndrome of lumbar region, and lumbar or lumbosacral disc degeneration. The provider requested authorization for one Retrospective standard comprehensive pharmacy review for 11 medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Naproxen Sodium 550mg bid: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th Ed.

www.RxList.com. and the Official Disability Guidelines (ODG) Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Selective NSAIDS Page(s): 72.

Decision rationale: Naproxen (Naprosyn): delayed release (EC-Naprosyn), as Sodium (salt) (Anaprox, Anaprox DS, Aleve [OTC]) Generic available; extended-release (Naprelan): 375 mg. Different dose strengths and formulations of the drug are not necessarily bioequivalent. Dosing Information: Osteoarthritis or ankylosing spondylitis: Dividing the daily dose into 3 doses versus 2 doses for immediate-release and delayed-release formulations generally does not affect response. Morning and evening doses do not have to be equal in size. The dose may be increased to 1500 mg/day of Naproxyn for limited periods when a higher level of analgesic/anti-inflammatory activity is required (for up to 6 months). Naprosyn or Naproxyn: 250-500 mg PO twice daily. Anaprox: 275-550 mg PO twice daily. (Total dose may be increased to 1650 mg a day for limited periods). EC-Naprosyn: 375 mg or 500 mg twice daily. The tablet should not be broken, crushed or chewed to maintain integrity of the enteric coating. Naprelan: Two 375 mg tablets (750 mg) PO once daily or two 500 mg tablets (1000 mg) once daily. If required (and a lower dose was tolerated) Naprelan can be increased to 1500 mg once daily for limited periods (when higher analgesia is required). Pain: Naprosyn or Naproxyn: 250-500 mg PO twice daily. The maximum dose on day one should not exceed 1250 mg and 1000 mg on subsequent days. Anaprox: 275-550 mg PO twice daily. The maximum dose on day one should not exceed 1375 mg and 1100 mg on subsequent days. Extended-release Naprelan: Not recommended due to delay in absorption. (Naprelan Package Insert) There is no documentation of the rationale behind using Anaprox. NSAID should be used for the shortest duration and the lowest dose. There is no documentation from the patient file that the provider titrated Anaprox to the lowest effective dose and used it for the shortest period possible. Furthermore, there is no documentation that the provider followed the patient for NSAID adverse reactions that are not limited to GI side effect, but also may affect the renal function. There is no documentation that the patient developed arthritis pain that justify continuous use of Naproxen. There is no documentation of pain and functional improvement of previous use of Naproxen. Therefore, the request for Naproxen is not medically necessary.

Retrospective MSContin CR 30mg q 12 hours: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com., and on the Official disability Guidelines (ODG) Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov .

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids Page(s): 76-79.

Decision rationale: According to MTUS guidelines, ongoing use of opioids should follow specific rules:(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. 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 non-adherent) 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. There is no clear documentation of patient improvement in level of function, quality of life, adequate follow up for absence of side effects and aberrant behavior with a previous use of narcotics. The patient continues to have chronic pain despite the continuous use of narcotics. Therefore, the request for MSContin CR 30mg q 12 hours is not medically necessary.

Retrospective Norco 10/325mg q hs prn: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov .

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for Use of Opioids Page(s): 76-79.

Decision rationale: According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules:(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. 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 non-adherent) 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. According to the patient file, there is no objective documentation of pain and functional improvement to justify continuous use of Norco. Norco was used for longtime without documentation of

functional improvement or evidence of return to work or improvement of activity of daily living. There is no justification for the use for several narcotics. Therefore, the prescription of Norco 10/325mg q hs prn is not medically necessary.

Retrospective Zanaflex 4mg bid prn: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to MTUS guidelines, non-sedating muscle relaxants are recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic lumbosacral pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The patient in this case developed continuous pain does not have clear exacerbation of back pain and spasm and the prolonged use of Zanaflex is not justified. Furthermore, there is no clear evidence of chronic myofascial pain and spasm. Therefore, the request for Zanaflex 4mg is not medically necessary.

Retrospective Docusate Sodium 100mg bid prn: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.ca.gov .

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid Induced Constipation Treatment. (<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Opioidinducedconstipationtreatment>).

Decision rationale: According to ODG guidelines, Docusate/Sennosides is recommended as a second line treatment for opioid induced constipation. The first line measures are increasing physical activity, maintaining appropriate hydration, advising the patient to follow a diet rich in fiber, using some laxatives to stimulate gastric motility, and use of some other over the counter medications. It is not clear from the patient file that the patient developed constipation or that

first line measurements were used. Therefore the use of Docusate Sodium 100mg bid prn is not medically necessary.

Retrospective Gabapentin 600mg tid: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 49.

Decision rationale: According to MTUS guidelines, 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. There was no documentation that the patient is suffering from neuropathic pain including diabetic neuropathic pain or post-herpetic neuralgia condition. There is no documentation of efficacy and safety from previous use of Gabapentin. Therefore, the prescription of Gabapentin 600mg tid is not medically necessary.

Retrospective Cyclobenzaprine 7.5mg qd prn: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to MTUS guidelines, Cyclobenzaprine a non-sedating muscle relaxants is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic spasm and pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The guidelines do not recommend to be used form more than 2-3 weeks. The patient in this case does not have clear significant functional improvement with prior use of muscle relaxants. There is no indication of recent evidence of spasm. Cyclobenzaprine was previously used without clear documentation of efficacy. Therefore, the request for Cyclobenzaprine 7.5mg qd prn is not medically necessary.

Retrospective Prilosec DR 20mg qd: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68.

Decision rationale: According to MTUS guidelines, Omeprazole is indicated when NSAID are used in patients with intermediate or high risk for gastrointestinal events. The risk for gastrointestinal events are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. There is no documentation that the patient has GI issue that requires the use of Prilosec. There is no documentation in the patient's chart supporting that she is at intermediate or high risk for developing gastrointestinal events. Therefore, Prilosec DR 20mg prescription is not medically necessary.

Retrospective Tramadol ER 150mg qd: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

Decision rationale: According to MTUS guidelines, Ultram (Tramadol) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: (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 non-adherent) 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. There is no clear documentation of pain and functional improvement with previous use of Ultram. There is no clear documentation of continuous documentation of patient compliance to his medications. There no documentation for the need of several opioids for this patient. There is no documentation of the medical necessity of Ultram. Therefore, the prescription of Tramadol ER 150mg qd is not medically necessary.

Retrospective Medrox Ointment 0.0375-20.5%: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com, Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: Medrox ointment is formed by the combination of methyl salicylate, capsaicin, and menthol. According to MTUS, in Chronic Pain Medical Treatment guidelines section Topical Analgesics (page 111), topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Medrox patch contains Capsaicin a topical analgesic not recommended by MTUS. Furthermore, there is no documentation of failure or intolerance of first line oral medications for the treatment of pain. Based on the above Medrox Ointment 0.0375-20.5% is not medically necessary.

Retrospective Promolaxin 100mg qd: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Goodman and Gilman's The Pharmacological Basis of Therapeutics, 12th Ed. McGraw Hill, 2010. Physician's Desk Reference, 68th ed. www.RxList.com. ODG Workers Compensation Drug Formulary, www.odg-twc.com/odgtwc/formulary.htm, drugs.com, Epocrates Online, www.online.epocrates.com,

Monthly Prescribing Reference, www.empr.com, Opioid Dose Calculator-AMDD Agency Medical Directors' Group Dose Calculator, www.agencymeddirectors.wa.gov.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioid Induced Constipation Treatment. (<http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Opioidinducedconstipationtreatment>).

Decision rationale: According to ODG guidelines, Promolaxin is recommended as a second line treatment for opioid induced constipation. The first line measures are: increasing physical activity, maintaining appropriate hydration, advising the patient to follow a diet rich in fiber, using some laxatives to stimulate gastric motility, and use of some other over the counter medications. It is not clear from the patient file that the patient tried the first line measurements. Furthermore, there is no documentation of efficacy of previous use of Promolaxin with other constipation medications. Therefore the use of Promolaxin is not medically necessary.