

<b>Case Number:</b>	CM15-0121831		
<b>Date Assigned:</b>	06/25/2015	<b>Date of Injury:</b>	03/24/1999
<b>Decision Date:</b>	09/23/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/24/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: California  
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 injured worker is a 57 year old female, who sustained an industrial injury on March 24, 1999. Treatment to date has included lumbar laminectomy, radiofrequency ablation, narcotic pump trial and failure, and medications. Currently, the injured worker complains of constant pain in the back with ongoing spasms. She reports pain that radiates into her bilateral lower extremities and notes a burning sensation in the leg with associated numbness and tingling. She indicates that she cannot function without her pain medication and has been using Tramadol for breakthrough pain. She reports a 50% reduction in pain and 50% functional improvement with her activities of daily living when taking her medications. She rates her pain a 4 on a 10-point scale with medications and a 10 on a 10-point scale without her medications. On physical examination, the injured worker reveals palpable spasm of the lumbar trunk. She exhibits a limited range of motion on flexion and extension of the lumbar spine and bilateral straight leg raise tests were positive. She has sensory loss to light touch and pinprick in the right lateral calf and the bottom of her foot. She ambulates with a limp. The diagnosis associated with the request is lumbar degenerative joint disease. The treatment plan includes Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senokot, Zanaflex and Ambien.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Duragesic 75mcg, #10:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl transdermal (Duragesic) Page(s): 44.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Duragesic 75 Mcg, #10. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. MTUS guidelines page 44 recommends Fentanyl transdermal (Duragesic) for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p 80, 81 also states regarding chronic low back pain: "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Long-term use of opiates may be indicated for nociceptive pain per MTUS, stating, "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)." However, this patient does not present with pain that is presumed to be maintained by continual injury. Treater has not discussed this request. The patient has been prescribed Duragesic Patch since at least 01/07/13. MTUS requires appropriate discussion of the 4A's, however, in addressing the 4A's, treater does not discuss how Duragesic Patch significantly improves patient's activities of daily living with specific examples of ADL's. Analgesia is discussed, specifically showing significant pain reduction with use of Duragesic Patch. Per 05/20/15 progress report, UDS and CURES are current and consistent with patient's medications. MTUS does not support the use of opiates for chronic low back pain, only supporting it for a short-term relief. This request does not meet guideline recommendations and therefore, it is not medically necessary.

**Tramadol 50mg, #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Criteria For Use Of Opioids Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Tramadol 50 MG, # 120. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. MTUS Guidelines pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS p 77 states, "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." Pages 80, 81 of MTUS also states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." MTUS Chronic Pain Medical Treatment Guidelines for Tramadol, page 113 for Tramadol (Ultram) states: Tramadol (Ultram) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. For more information and references, see Opioids. See also Opioids for neuropathic pain. In 05/20/15 progress report, treater states, "She has weaned off Norco; she has been using Tramadol for breakthrough pain now." It is not clear how long the patient has been taking this medication as there are no prior records except in 05/20/15 progress report. With prior use of opiates (Norco, from 01/07/13 through 04/20/15), the 4A's are not specifically addressed. While UDS and CURES are current and consistent with patient's medications, there are no discussions regarding adverse reactions, aberrant behavior, specific ADL's, etc. Furthermore, the treater has not documented baseline pain and functional assessment, including daily activities. Given the lack of documentation as required by MTUS, the request is not medically necessary.

**Amitiza 24mcg, #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation McKay SL, Fravel M, Scanlon C. Management of Constipation. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter, under lubiprostone-Amitiza®.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Amitiza 24 Mcg, #60. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. The ODG Guidelines, under the pain chapter, has the following regarding lubiprostone-Amitiza - "recommended only as a possible second-line treatment for opiate-induced constipation. See opioid-induced constipation treatment." The MTUS Guidelines, Chronic Pain Medical Treatment Guidelines, page 77 discusses prophylactic medication for constipation while opiates are used. In this case, the patient is also taking Colace, a stool softener which relieves constipation and Senokot, a laxative. The reason for the requested Amitiza is not provided and there is no medical rationale provided that supports the use of Amitiza instead of a first-line treatment for constipation. Amitiza is recommended as a second-line treatment and there is no indication that the patient has failed first-line medication. Furthermore, the patient has been taking Senokot since at least 01/07/13 though there is no discussion of efficacy in the subsequent reports. Additionally, the associated Duragesic patches and Tramadol are not indicated owing to a lack of 4A's documentation. Therefore, the request is not medically necessary.

**Colace 250mg, #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Initiating Therapy. Decision based on Non-MTUS Citation McKay SL, Fravel M, Scanlon C. Management of Constipation. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines constipation Page(s): 77.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Colace 250 Mg, #60. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. Regarding constipation, MTUS Chronic Pain Medical Treatment Guidelines, page 77, states that prophylactic treatment of constipation should be initiated with therapeutic trial of opioids. It also states "Opioid induced constipation is a common adverse side effect of long-term opioid use." Colace has been included in patient's medications from 01/07/13 through 05/20/15, for

constipation. MTUS recognizes constipation as a common side effect of chronic opiate use. The patient has been prescribed opiates since 01/07/13 for chronic pain, though the treater has not documented its efficacy in the subsequent reports. Furthermore, the associated Duragesic patches and Tramadol are not indicated owing to a lack of 4A's documentation. Therefore, the request is not medically necessary.

**Senokot #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Initiating Therapy. Decision based on Non-MTUS Citation McKay SL, Fravel M, Scanlon C. Management of Constipation. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter, Under Opioid Induced Constipation.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Senokot #120. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. ODG Guidelines, Pain (chronic) Chapter, Under Opioid Induced Constipation Treatment states, "Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. MTUS Chronic Pain Medical Treatment Guidelines, page 77, states that prophylactic treatment of constipation should be initiated with therapeutic trial of opioids. It also states "Opioid induced constipation is a common adverse side effect of long-term opioid use." In this case, the patient is prescribed Senokot for opiate-induced constipation. This patient has been taking Senokot since at least 01/07/13 though there is no discussion of efficacy in the subsequent reports. Constipation prophylaxis is generally considered an appropriate measure in patients taking opioid medications. However, the associated Duragesic patches and Tramadol are not indicated owing to a lack of 4A's documentation. Therefore, the request is not medically necessary.

**Zanaflex 6mg, #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 66.

**Decision rationale:** The patient presents with pain in the low back radiating to the groin and bilateral legs. The request is for Zanaflex 6 Mg, #60. Patient is status post lumbar laminectomy surgery, date unspecified. Physical examination to the lumbar spine on 05/20/15 revealed palpable spasm in the lumbar trunk. Range of motion was decreased in all planes. Straight leg raising test was at 80 degrees bilaterally with right sided pain radiating to the right buttock and posterior thigh. Patient's gait was antalgic, with a limp with the right lower extremity. Per 05/29/15 Request For Authorization form, patient's diagnosis includes lumbar DJS. Patient's medications, per 04/20/15 progress report include Duragesic, Tramadol, Lyrica, Cymbalta, Amitiza, Colace, Senekot, Zanaflex, and Ambien. Patient's work status was not specified. MTUS Chronic Pain Medical Treatment Guidelines for Muscle Relaxants for pain, pg 66: "Anti-spasticity/Antispasmodic Drugs: Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain." The treater has not discussed this request. Patient has received prescriptions from 02/13/13 and 05/20/15; however, there is no discussion of its efficacy in terms of pain reduction and functional improvement. MTUS page 60 require that medication efficacy in terms of pain reduction and functional gains must be discussed when using for chronic pain. Therefore, this request is not medically necessary.