

Case Number:	CM15-0107201		
Date Assigned:	06/11/2015	Date of Injury:	09/10/2010
Decision Date:	07/13/2015	UR Denial Date:	05/12/2015
Priority:	Standard	Application Received:	06/03/2015

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, Pain Management

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 51-year-old male who sustained an industrial injury on 9/10/10 from a motor vehicle rollover accident resulting in musculoskeletal injuries to the left shoulder and lower back in the form of fractured left clavicle and compression fracture of L1. During his medical evaluation, the above injuries were confirmed with computed tomography scans. He currently complains of mid-back pain; left hip and shoulder pain. His pain level is 5-7/10. He uses a cane for ambulation. He performs activities of daily living with assistance due to pain. Medications are MS-Contin, Morphine sulfate, Fentora, prazosin, Linzess, Lorzone. Diagnoses include adhesive capsulitis; healed left clavicle fracture; thorocolumbar strain/ sprain; compression fracture of L1; chronic pain syndrome; iatrogenic narcotic addiction; dental injuries; lumbar spondylosis; myofascial pain/ spasm; posttraumatic stress disorder, anxiety/ depression; poor sleep hygiene; left hip pain. Treatments to date include medications; transcutaneous electrical nerve stimulator unit which helpful; psychiatric treatments; physical therapy. Diagnostics include MRI of the thoracic spine (3/15/11) showing a chronic compression fracture; MRI of the lumbar spine (3/15/11) showing chronic compression fracture of L1, disc bulging; MRI of the shoulder (3/15/11) showing possible prior rotator cuff tear; electromyography/ nerve conduction studies of upper extremities was normal. In the progress note dated 5/4/15, the treating provider's plan of care included requests for Linzess; Fentora; H-wave unit. A progress report dated April 21, 2014 states that the patient uses Linzess for constipation and Fentora for pain control. A progress report dated May 4, 2015 states that the patient purchased a tens unit which is helping.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fentora 400mg, #56: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentora (fentanyl buccal tablet) Page(s): 47.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines x 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 76-79, 44 and 47 of 127. Decision based on Non-MTUS Citation X Official Disability Guidelines (ODG) Pain Chapter, Fentora and Other Medical Treatment Guidelines
http://fentora.com/hcp/?utm_source=google&utm_medium=cpc&utm_term=fentanyl&utm_content=Fentanyl%25Prescribing%25Information%25/%25Generic&utm_campaign=Brand&gclid=CjwKEAjwt_isBRDuisOm1dTQqGISJAAfRrEAMvPngBojSsJJjy_T3bzeWso2qyCSYboi6D3Tz5c6nRoCW6Hw_wcB&gclsrc=aw.ds.

Decision rationale: Regarding the request for Fentora (fentanyl), California MTUS cites that, due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use when opiates are utilized. They do not specifically address this formulation of fentanyl, but they do specifically recommend against the use of other short-acting formulations of fentanyl for musculoskeletal pain. ODG states that Fentora is not recommended for musculoskeletal pain and is approved for the treatment of breakthrough pain in certain cancer patients. Within the documentation available for review, there is no clear rationale presented for the use of this medication for musculoskeletal pain in addition to both long-acting and short-acting opioids, despite guideline recommendations. It should be noted that opiates should not be abruptly stopped; however, unfortunately, there is no provision for modification of the current request. In light of the above issues, the currently requested Fentora is not medically necessary.

Linzess 290mg, #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 77.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain Chapter, Opioid Induced Constipation Treatment and Other Medical Treatment Guidelines
<http://www.linzess.com/?CtID=01PbSsOTHbrd15030231&DtID=1SO8FSmX>.

Decision rationale: Regarding the request for Linzess, California MTUS does not contain criteria regarding constipation treatment. ODG states that opioid induced constipation is recommended to be treated by physical activity, maintaining appropriate hydration, and following a diet rich in fiber. Over-the-counter medication such as stool softeners may be used as well. Second line treatments include prescription medications. Within the documentation

available for review, there are no recent subjective complaints of constipation. There is no statement indicating whether the patient has tried adequate hydration, well-balanced diet, and activity to reduce the complaints of constipation should they exist. Additionally, there is no documentation indicating how the patient has responded to treatment with Linzess. Additionally, Linzess is not indicated for the treatment of opiate induced constipation. As such, the currently requested Linzess is not medically necessary.

Durable medical equipment (DME) H-wave unit (purchase): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines H-wave stimulation (HWT).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines x 8 C.C.R. 9792.20 - 9792.26 MTUS (Effective July 18, 2009) Page(s): 114, 117-118 of 127.

Decision rationale: Regarding the request for H-wave unit, Chronic Pain Medical Treatment Guidelines state that electrotherapy represents the therapeutic use of electricity and is another modality that can be used in the treatment of pain. Guidelines go on to state that H-wave stimulation is not recommended as an isolated intervention, but a one-month home-based trial of H-wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain, or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy and medications plus transcutaneous electrical nerve stimulation. Within the documentation there is no indication that the patient has failed a tens unit trial as recommended by guidelines. In fact, the patient has reported good pain relief with TENS unit use. As such, the currently requested H wave device is not medically necessary.