

Case Number:	CM14-0060086		
Date Assigned:	07/09/2014	Date of Injury:	01/22/2001
Decision Date:	07/02/2015	UR Denial Date:	04/01/2014
Priority:	Standard	Application Received:	04/30/2014

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. 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: Texas, Illinois

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 50 year old male who sustained an industrial injury on 01/22/01. Initial complaints and diagnoses are not available. Treatments to date include a spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain. Current diagnoses include post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. In a progress note dated 03/24/14 the treating provider reports the plan of care as continued medications including Fentanyl patch, Methadone, Neurontin, Amitiza, Fioricet, an EKG, a urine drug screen, and a reprogramming of his stimulator. Also requested were new medications Sprix, Theramine, Sentra AM and Sentra PM. The requested treatments are an EKG, Sprix, Theramine, Sentra AM and Sentra PM.

IMR ISSUES, DECISIONS AND RATIONALES

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

EKG: Overturned

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

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) Methadone.

Decision rationale: The injured worker sustained a work related injury on 01/22/01. The medical records provided indicate the diagnosis of post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. Treatments have included spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain. The medical records provided for review do indicate a medical necessity for an EKG. The medical records indicate the injured worker has been approved for the use of Methadone at 10 mg six times a day; the injured worker has been on prior treatment with this medication. The previous EKG done in 2012 was reported as bradycardia and LVH (though may be a normal variant); however, a repeat EKG was found to be normal. The MTUS is silent on EKG, but the Official Disability Guidelines recommends for EKG monitoring of people on methadone, and particularly if there is a history of arrhythmia, syncope, or structural heart disease, or if seizures of syncope develop after initiation of treatment.

Sprix #5: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Sprix (ketorolac tromethamine nasal Spray).

Decision rationale: The injured worker sustained a work related injury on 01/22/01. The medical records provided indicate the diagnosis of post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. Treatments have included spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain the medical records provided for review do indicate a medical necessity for Sprix #5. The MTUS is silent on this medication. The Official Disability Guidelines states that (Sprix Nasal Spray) is an NSAID containing (ketorolac tromethamine is recommended for the short-term management of moderate to moderately severe pain requiring analgesia at the opioid level. The total duration of use of this intranasal formulation, as with other ketorolac formulations, should be for the shortest duration possible and not exceed 5 days. The records indicate the injured worker has severe intractable pain requiring the use of very potent narcotics. The requested dose is 5 days, which is within the limits recommended by the Official Disability Guidelines.

Theramine #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain (Chronic).

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 Theramine®).

Decision rationale: The injured worker sustained a work related injury on 01/22/01. The medical records provided indicate the diagnosis of post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. Treatments have included spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain. The medical records provided for review do not indicate a medical necessity for Theramine #90. Theramine is a medical food. The MTUS is silent on medical foods, but the Official Disability Guidelines states that is a medical food containing 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). This guidelines recommends against the use of medical foods, because Medical they have not been shown to produce meaningful benefits or improvements in functional outcomes. Also, the FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

Sentra PM #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Section 5(b) of the Orphan Drug act (21 u.s.c.360ee (b) (3)).

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) Sentra PM.

Decision rationale: The injured worker sustained a work related injury on 01/22/01. The medical records provided indicate the diagnosis of post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. Treatments have included spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain. The medical records provided for review do not indicate a medical necessity for Sentra PM #60. The MTUS is silent on medical foods, but the Official Disability Guidelines states that it is a medical food containing Choline, Glutamic Acid, & 5-hydroxytryptophan.. This guideline recommends against the use of medical foods, because they have not been shown to produce meaningful benefits or improvements in functional

outcomes. Also, the FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

Sentra AM #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Section 5(b) of the Orphan Drug act (21 u.s.c.360ee(b)(3)).

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) Medical food; Nutrient Pharmacology http://nutrientpharmacology.com/sentra_AM.html.

Decision rationale: The injured worker sustained a work related injury on 01/22/01. The medical records provided indicate the diagnosis of post laminectomy syndrome, cervicobrachial neuritis or radiculitis, cervical sprain/strain, thoraco-lumbar neuritis or radiculitis, and neurogenic bowel. Treatments have included spinal cord stimulator placement, back surgeries, and medications. Diagnostic studies include MRIs of the cervical and lumbar spine. Current complaints include low back and neck pain. The medical records provided for review do not indicate a medical necessity for Sentra AM #60. The MTUS is silent on medical foods, but Nutrient Pharmacology states that it is a medical food containing choline and acetylcarnitine as precursors to acetylcholine production. The Official Disability guidelines recommends against the use of medical foods, because they have not been shown to produce meaningful benefits or improvements in functional outcomes. Also, the FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."