

MAXIMUS FEDERAL SERVICES, INC.

Independent Medical Review

P.O. Box 138009

Sacramento, CA 95813-8009

(855) 865-8873 Fax: (916) 605-4270



Notice of Independent Medical Review Determination

Dated: 11/7/2013

[REDACTED]

[REDACTED]

Employee:	[REDACTED]
Claim Number:	[REDACTED]
Date of UR Decision:	7/10/2013
Date of Injury:	11/26/2008
IMR Application Received:	8/1/2013
MAXIMUS Case Number:	CM13-0005529

- 1) MAXIMUS Federal Services, Inc. has determined the request for **outpatient MRI of the lumbar spine is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **outpatient urine toxicology screen is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **pharmacy purchase of topical creams is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **pharmacy purchase of Theramine #120 is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/1/2013 disputing the Utilization Review Denial dated 7/10/2013. A Notice of Assignment and Request for Information was provided to the above parties on 8/16/2013. A decision has been made for each of the treatment and/or services that were in dispute:

- 1) MAXIMUS Federal Services, Inc. has determined the request for **outpatient MRI of the lumbar spine is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **outpatient urine toxicology screen is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **pharmacy purchase of topical creams is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **pharmacy purchase of Theramine #120 is not medically necessary and appropriate.**

Medical Qualifications of the Expert Reviewer:

The independent Medical Doctor who made the decision has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice and is licensed to practice in California. 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 treatments and/or services at issue.

Expert Reviewer Case Summary:

This claimant is a 61-year-old male. On 12/19/2012, he was seen in clinic by [REDACTED], MD. He stated he was required to do standing, walking, or walking on uneven ground with sitting, bending, and lifting up to 100 pounds, as well as carrying, squatting, climbing, and kneeling and other activities. He stated he was no longer employed with that company. He states on 11/28/2008 during the course of his employment he sustained an injury to his back and right hand. He stated he drove to a store to deliver a box of meat and got off the truck and parked in an alley and entered the truck to grab the box of meat that weighed approximately 72 pounds. He had to climb over some empty pallets inside the truck and his right foot got stuck and he lost his balance and fell approximately 4 feet landing on his right hand and back. He stated he was unable to move due to the severe back pain and right hip inflammation and he crawled to the outside of the truck and entered the store and asked for help. He later was examined and x-rays were obtained and he was given medications for his pain and sent back to work with restrictions. He was later treated by another provider and x-rays were obtained of his back and right hand and MRI studies were also obtained and he started on a course of physical therapy. He then was referred to another provider for back surgery which was apparently performed in 2011. He stated the back surgery helped temporarily. He also reports being referred to a psychologist for treatment and just had

a sleep test performed. He complained of continuous low back pain with radiation to his legs, buttocks, knees, and feet at that time with pain increasing with prolonged standing, twisting, walking or other similar activities. Upon examination, he was a 60-year-old male at that time standing 5 feet 5 inches tall weighing 175 pounds. There was a posterior surgical scar that was well-healed about his lumbar spine with no signs of infection. Palpation elicited tenderness at the L3-4 spinous process, as well as the bilateral paravertebral musculature with 2+ spasms being noted. Deep tendon reflexes were 2+ in both patellae and 1+ in both Achilles tendons. Strength was assessed at 5/5 with the exception of knee extension bilaterally which was assessed at 5-/5 and sensation examination revealed hypoesthesia in the right L4 dermatomal distribution to light touch and pinprick. A previous MRI dated 12/17/2012 was reviewed demonstrating a facet cyst at the left L4 facet and a central herniation at L3-4 with severe stenosis. There was also L4-5 protrusion on the right causing neural foraminal narrowing. There was also notation of a prior L4-5 and L5-S1 discectomy and laminectomy with posterior pedicle fusion and intervertebral spacer placement. There was loss of intervertebral disc height and disc desiccation changes at L3-4 and to a lesser degree at L2-3. At L3-4, there was a right greater than left paracentral disc protrusion seen causing mild to moderate right greater than left spinal and neural foraminal stenosis and the left facet joint at L3-4 was also noted to have a small synovial cyst. On 03/11/2013, this claimant was taken to surgery by [REDACTED], MD for preoperative diagnosis of lumbar 3rd and 4th stenosis with facet cyst, radiculopathy, disc adjacent segment level breakdown, and prior fusion at L4-5 and L5-S1. The procedures performed at that time were a left direct lateral micro minimally invasive endoscopic discectomy at L3-4; partial vertebral corpectomy, anterior L3 and L4; anterior interbody fusion with a 14 mm expandable PEEK cage with bone morphogenetic protein; posterior removal of segmental pedicle screw instrumentation at both L4-5 and S1; laminectomy at L3-4 and L4-5 with reexploration and decompression of the spinal cord and nerve roots; placement of pedicle screws at L3, L4, and L5 and sacral 1 bilaterally; motor pedicle screw stimulation, posterolateral arthrodesis, and local bone autograft; microdissection of operating microscope; somatosensory evoked potential and motor evoked potential monitoring; interpretation of fluoroscopic images during surgery. On 06/14/2013, a urine toxicology review report was submitted indicating there are no opiates and no drugs tested reporting positive on that exam. On 06/03/2013, this claimant was seen in clinic by [REDACTED], MD with continued complaints of pain to his low back rated 7/10. He stated he was also seen in neurosurgery. He utilized a cane for ambulation. Flexion was moderately restricted and extension was considered normal. Assessment was lumbar disc disease with sciatica, low back syndrome, and status post lumbar spine surgery. On 07/10/2013, the claimant was seen in clinic by [REDACTED], MD for psychosocial pain medication progress. It was noted then that he had subjective complaints of being depressed with sleeplessness, fatigue, and palpitations. He complained that when he took trazodone and zolpidem he began to vomit and his nervousness increased. His opiate medications were reviewed and he was counselled as to the benefits and potential side effects of those medications at that time. On 07/15/2013, MRI of the lumbar spine was obtained revealing lumbar lordotic curvature was satisfactory. There was anterior spondylotic spurring noted at L1-2 and L3-4. Lumbar vertebral bodies were otherwise normal height configuration and marrow signal characteristics. There were no vertebral body compression fractures identified and no bony masses or destructive lesions were demonstrated. Disc spaces from L3-4 to L5-S1 were desiccated and reduced in height. There was a grade I spondylolisthesis at L5 upon S1 likely due to a facetectomy. Residuals of discectomy, laminectomy, and posterior spinal fusion were noted at L3-4 to L5-S1 and pedicle screws and artifact were

noted causing screws to be obscured. At L5-S1, a disc protrusion was identified and the spinal canal was normal in diameter and both neural foramina were patent. The facet joints and ligamentum flavum were normal in appearance.

Documents Reviewed for Determination:

The following relevant documents received from the interested parties and the documents provided with the application were reviewed and considered. These documents included:

- Application of Independent Medical Review
- Utilization Review Determination
- Medical Records from Claims Administrator
- Medical Treatment Utilization Schedule (MTUS)

1) Regarding the request for outpatient MRI of the lumbar spine:

Section of the Medical Treatment Utilization Schedule Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on 2009 ACOEM Guidelines which are not part of MTUS.

The Expert Reviewer based her decision on the American College of Occupational and Environmental Medicine Guidelines (ACOEM), 2nd Edition, (2004), Low Back Chapter, pgs 303-305 which is part of the MTUS and the Official Disability Guidelines (ODG), Low Back Chapter, which is not part of the MTUS.

Rationale for the Decision:

MTUS/ACOEM guidelines state relying solely on imaging studies to evaluate the source of low back and related symptoms carries a significant risk of diagnostic confusion. Guidelines further state that imaging studies should be reserved for cases in which surgery is considered or red flag diagnoses are being evaluated. The Official Disability Guidelines, Low Back Chapter indicates repeat MRI is not routinely recommended and should be reserved for significant change in symptoms and/or findings suggestive of significant pathology. In this case, the clinical note of 06/03/2013 fails to demonstrate significant radicular findings on clinical exam. The additional records provided for this review indicate that on 07/03/2013, this employee was seen. At that time, the employee rated back pain at 7/10. Examination revealed tenderness to the lumbar spine with some restriction in flexion, but extension was normal. There was no indication at that time that there were neurological deficits to warrant an MRI of the lumbar spine. It is important to note that the 12/19/2012 progress note described an MRI of the lumbar spine that was dated 12/17/2012. Thus, this request would be for a repeat MRI of the lumbar spine. **The request for outpatient MRI of the Lumbar Spine is not medically necessary and appropriate.**

2) Regarding the request for outpatient urine toxicology screen:

Section of the Medical Treatment Utilization Schedule Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on CA MTUS 2009 Chronic Pain Treatment Guidelines.

The Expert Reviewer based her decision on the Chronic Pain Medical Treatment Guidelines, pg 43, 78, Drug Testing, which is part of MTUS.

Rationale for the Decision:

MTUS Chronic Pain Medical Treatment Guidelines, indicates that drug testing is recommended as an option; using a urine drug screen to assess for the use or the presence of illegal drugs. Guidelines further indicate that “4 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 nonadherent) drug related behaviors. These domains have been summarized as the ‘4 A’s’ (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The records provided for review document no indication of aberrant drug-taking behaviors in this employee, as the last drug screen on 06/14/2013 failed to reveal illicit drugs. The clinical notes fail to reveal a concern for this employee taking illicit drugs. **The request for outpatient urine toxicology screen is not medically necessary and appropriate.**

3) Regarding the request for pharmacy purchase of topical creams:

Section of the Medical Treatment Utilization Schedule Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the CA MTUS 2009 Chronic Pain Treatment Guidelines.

The Expert Reviewer based her decision on the Chronic Pain Medical Treatment Guidelines pg 111-113, Topical Analgesics which is part of MTUS.

Rationale for the Decision:

Chronic Pain Medical Treatment Guidelines do not recommend topical analgesic creams as they are considered highly experimental without proven efficacy and are only recommended for the treatment of neuropathic pain after a failure of first-line treatment of antidepressants and anticonvulsants, which were not documented. There was no documentation as to the employee’s intolerance to these or similar medications to be taken on an oral basis based on the current records. In the absence of specific medication type, dosage and quantity, the medical necessity for a topical agent had not been established. In this case, the request does not specify which topical creams are to be purchased. **The request for pharmacy purchase of topical creams is not medically necessary and appropriate.**

4) Regarding the request for pharmacy purchase of Theramine #120:

Section of the Medical Treatment Utilization Schedule Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator did not cite any evidence based criteria for its decision.

The Expert Reviewer found that no section of the MTUS was applicable. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Expert Reviewer based his/her decision on the Official Disability Guidelines (ODG), Medication Chapter.

Rationale for the Decision:

The Official Disability Guidelines indicate that GABA is indicated for epilepsy, spasticity and tardive dyskinesia. The Official Disability Guidelines indicate that there is no high quality peer-reviewed literature that suggests that GABA is indicated for the treatment of insomnia. The product information for Theramine indicates that this is a proprietary formulation of neurotransmitter precursors such as L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan; neurotransmitters such as gamma-aminobutyric acid or GABA; and a neuromodulator such as L-serine. There are also polyphenolic antioxidants such as grape seed extract, cinnamon bark or cocoa and anti-inflammatory and immunomodulatory peptides such as whey protein hydrolysate. The Official Disability Guidelines indicate that L-serine was reviewed, and there is no indication in Micromedex, clinical pharmacology or AltMedDex for the use of that supplement. The Official Disability Guidelines indicate that L-arginine is not indicated in current references for pain or for inflammation and is indicated to detoxify the urine. As there is a lack of support for this medical food by the literature, and as there is a lack of support for this medical food by the ODG given its specific components and a lack of the specific relation as it is stated that this was a proprietary formulation, and as there is a lack of documentation of efficacy from when this employee was taking this medical food; **the request for pharmacy purchase of theramine #120 is not medically necessary and appropriate.**

Effect of the Decision:

The determination of MAXIMUS Federal Services and its physician reviewer is deemed to be the final determination of the Administrative Director, Division of Workers' Compensation. With respect to the medical necessity of the treatment in dispute, this determination is binding on all parties.

In accordance with California Labor Code Section 4610.6(h), a determination of the administrative director may be reviewed only if a verified appeal is filed with the appeals board for hearing and served on all interested parties within 30 days of the date of mailing of the determination to the employee or the employer. The determination of the administrative director shall be presumed to be correct and shall be set aside only upon proof by clear and convincing evidence of one or more of the grounds for appeal listed in Labor Code Section 4610.6(h)(1) through (5).

Sincerely,

Paul Manchester, MD, MPH
Medical Director

cc: Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th Floor
Oakland, CA 94612

/pas

Disclaimer: MAXIMUS is providing an independent review service under contract with the California Department of Industrial Relations. MAXIMUS is not engaged in the practice of law or medicine. Decisions about the use or nonuse of health care services and treatments are the sole responsibility of the patient and the patient's physician. MAXIMUS is not liable for any consequences arising from these decisions.