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## Notice of Independent Medical Review Determination

Dated: 11/4/2013

[REDACTED]

[REDACTED]

Employee:

Claim Number:

Date of UR Decision:

Date of Injury:

IMR Application Received:

MAXIMUS Case Number:

[REDACTED]

7/15/2013

5/27/2006

7/29/2013

CM13-0004524

- 1) MAXIMUS Federal Services, Inc. has determined the request for UA toxicological evaluation **is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for chiropractic manipulation, three times a week for six weeks **is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for physical therapy three times a week for six weeks **is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for compounded Ketoprofen 20% in PLO gel, 120gms, #1 **is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for compounded Cyclophene 5% in PLO gel, 120gms, #1 **is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for Synapryn 10mg/1ml oral suspension 500ml #1 **is not medically necessary and appropriate.**
- 7) MAXIMUS Federal Services, Inc. has determined the request for Tabradol 1mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**

- 8) MAXIMUS Federal Services, Inc. has determined the request for Deprizine 15mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**
- 9) MAXIMUS Federal Services, Inc. has determined the request for Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml **is not medically necessary and appropriate.**
- 10) MAXIMUS Federal Services, Inc. has determined the request for Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml # 1 **is not medically necessary and appropriate.**

## INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 7/29/2013 disputing the Utilization Review Denial dated 7/15/2013. A Notice of Assignment and Request for Information was provided to the above parties on 8/9/2013. 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 UA toxicological evaluation **is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for chiropractic manipulation, three times a week for six weeks **is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for physical therapy three times a week for six weeks **is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for compounded Ketoprofen 20% in PLO gel, 120gms, #1 **is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for compounded Cyclophene 5% in PLO gel, 120gms, #1 **is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for Synapryn 10mg/1ml oral suspension 500ml #1 **is not medically necessary and appropriate.**
- 7) MAXIMUS Federal Services, Inc. has determined the request for Tabradol 1mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**
- 8) MAXIMUS Federal Services, Inc. has determined the request for Deprizine 15mg/ml oral suspension 250ml #1 **is not medically necessary and appropriate.**
- 9) MAXIMUS Federal Services, Inc. has determined the request for Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml **is not medically necessary and appropriate.**
- 10) MAXIMUS Federal Services, Inc. has determined the request for Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml # 1 **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 Physical Medicine and Rehabilitation 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 57-year-old male with complaints of chronic pain following injury on 5/27/2006. On 7/19/2012, he was seen in clinic by [REDACTED], MD. He complained of burning radicular low back pain and muscle spasms with pain rated at 6/10 to 7/10. He had well-healed surgical incisions to his low back and abdomen. He was able to heel and toe walk, but had pain with toe walking. There was tenderness to palpation about the lumbosacral spine. Sensation was diminished over an L4, L5, and S1 dermatome in the bilateral lower extremities and motor strength was decreased in the lower extremities secondary to pain. Patellar and Achilles deep tendon reflexes were 2+ in the bilateral lower extremities. The patient was prescribed Synapryn which contains Tramadol and glucosamine, as well as Tabradol which contains Cyclobenzaprine, methylsulfonylmethane, and other proprietary ingredients. He was also given Cyclobenzaprine cream and ketoprofen cream for his pain. He was seen in clinic again on 10/30/2012 by [REDACTED], MD. At that time, he still expressed pain. He stated medications were offering temporary relief of his pain. Physical exam remained essentially unchanged. He was continued on medications including Deprizine, Dicopanol, Imitrex, Synapryn, and Tabradol. He returned to clinic with further evaluation on 6/11/2013 by [REDACTED], MD. At that time, his current pain was 7/10 to 8/10 with associated numbness and tingling in his bilateral lower extremities. On 6/14/2013, a note was submitted indicating that certain medications had been prescribed which contained proprietary ingredients including Dicopanol, Deprizine, Fanatrex, Synapryn, and Tabradol. On 6/25/2013, the medication summary list was submitted by Medi-Lab indicating there was an inconsistent result with an analyte detected without described medication.

**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 UA toxicological evaluation :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Drug Testing Section, page 43, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Drug Testing, Ongoing Opioid Management Sections, pages 43 and 78, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines state drug testing is recommended as an option using a drug screen to assess for the use or presence of illegal drugs. The records provided for review did not demonstrate aberrant drug taking behavior or misuse and there was no medical necessity for a urine drug test. The additional records provided for this review failed to indicate medical necessity for the drug testing. **The request for UA toxicological evaluation is not medically necessary and appropriate.**

**2) Regarding the request for chiropractic manipulation, three times a week for six weeks :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Manual Therapy and Manipulation Section, pages 58-59, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Low Back Complaints (ACOEM Practice Guidelines, 2<sup>nd</sup> Edition (2004), Chapter 12), pages 298-300, which is part of the MTUS, and the Chronic Pain Medical Treatment Guidelines, Manual Therapy and Manipulation Section, pages 58-59, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate chiropractic treatment may be recommended as an option with a trial of 6 visits over 2 weeks with evidence of objective functional improvement; a total of up to 18 visits over 6 to 8 weeks may be considered reasonable and necessary. The guidelines state that elective or maintenance care is not medically necessary. The records reviewed fail to indicate a specific rationale for the requested chiropractic treatment. The employee's injury was in 2006, yet he had persistent pain, but the extent of conservative completed care to date had not been made clear. There is no documentation of a new injury or inciting event. The records do indicate the employee's injury date is in the remote past and there is no evidence that he sustained any new or recent injuries. **The request for chiropractic manipulation, three times a week for six weeks is not medically necessary and appropriate.**

**3) Regarding the request for physical therapy three times a week for six weeks :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Physical Medicine Section, pages 98-99, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Low Back Complaints (ACOEM Practice Guidelines, 2<sup>nd</sup> Edition (2004), Chapter 12), pages 298-300, which is part of the MTUS, and the Chronic Pain Medical Treatment Guidelines, Physical Medicine Section, pages 98-99, which is part of the MTUS.

Rationale for the Decision:

The ACOEM indicates physical therapy may be recommended as an option with a trial of 6 visits over 2 weeks with evidence of objective functional improvement; a total of up to 18 visits over 6 to 8 weeks may be considered reasonable and necessary. The guidelines state that elective or maintenance care is not medically necessary. The records reviewed fail to document a specific rationale for the requested physician. As the employee does not have evidence of a new injury or inciting event, the requested physical therapy is not consistent with the guideline recommendations. **The request for physical therapy three times a week for six weeks is not medically necessary and appropriate.**

**4) Regarding the request for compounded Ketoprofen 20% in PLO gel, 120gms, #1 :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Topical Analgesics Section, pages 111-113, which is part of the MTUS.

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

Rationale for the Decision:

The Chronic Pain guidelines indicate topical medications such as this are “largely experimental in use with few randomized controlled trials to determine efficacy or safety.” The guidelines note that these medications are primarily recommended for neuropathic pain when trials of antidepressants or anticonvulsants have failed. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. For non-steroidal anti-inflammatories, guidelines indicate these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Guidelines indicate if this medication is to be used, indications would be for tendinitis, particularly that of the knee or elbow, or other

joints that are immutable to topical treatment. Further, this medication is recommended for short-term use and there is little evidence to indicate topical NSAIDs are efficacious for treatment of osteoarthritis of the spine, hip, or shoulder or for neuropathic pain. The records submitted and reviewed do not demonstrate the effectiveness of this medication for the employee with reports of pain ranging from 6/10 to 7/10 with medications. **The request for compounded Ketoprofen 20% in PLO gel, 120gms, #1 is not medically necessary and appropriate.**

**5) Regarding the request for compounded Cyclophene 5% in PLO gel, 120gms, #1 :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Topical Analgesics Section, pages 111-113, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Topical Analgesics Section, pages 63-66 and 111-113, which are part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate topical analgesics are largely experimental with few randomized controlled trials to determine efficacy or safety. Additionally, MTUS chronic pain guidelines recommend muscle relaxants for short term use as a second line option for acute exacerbations in patients with low back pain. The records submitted do not indicate this is intended for short term use nor do the records indicate a failure of a first line medication. **The request for compounded Cyclophene 5% in PLO gel, 120gms, #1 is not medically necessary and appropriate.**

**6) Regarding the request for Synapryn 10mg/1ml oral suspension 500ml #1 :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Tramadol Section, page 113, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Tramadol Section, pages 78, 100 and 113, which are part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines state "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 nonadherent) 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 for documentation of the clinical use of these controlled drugs." The records submitted do not demonstrate that this medication has resulted in adequate analgesia. **The request for Synapryn 10mg/1mg oral suspension 500mg #1 is not medically necessary and appropriate.**

**7) Regarding the request for Tabradol 1mg/ml oral suspension 250ml #1 :**

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 Chronic Pain Medical Treatment Guidelines, (2009), Muscle Relaxants for Chronic Pain Section, pages 63-64, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, (2009), Cyclobenzaprine Section, pages 41-42, which is part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines state "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 nonadherent) 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 for documentation of the clinical use of these controlled drugs." The records submitted do not demonstrate that this medication has resulted in adequate analgesia. **The request for Tabradol 1mg/ml oral suspension 250mg #1 is not medically necessary and appropriate.**

**8) Regarding the request for Deprizine 15mg/ml oral suspension 250ml #1 :**

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 Chronic Pain Medical Treatment Guidelines, (2009), NSAIDs, GI Symptoms and Cardiovascular Risk Section, page 68, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines (2009), pages 41-42 and 69, which are part of the MTUS.

Rationale for the Decision:

The PDR states this medication has not received FDA approval for safety and efficacy. The records provided for review do not document an indication for this medication. **The request for Deprizine 15mg/ml oral suspension 250mg #1 is not medically necessary and appropriate.**

**9) Regarding the request for Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml :**

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 Official Disability Guidelines (ODG), Treatment Index, 11<sup>th</sup> Edition (web), 2013, Pain Chapter, Insomnia Treatment, Over the Counter Medications, which is not part of the MTUS.

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 Physician's Desk Reference (PDR), which is not part of the MTUS.

Rationale for the Decision:

The PDR states this medication has not received FDA approval for safety and efficacy. The records provided for review do not document an indication for this medication. **The request for Dicopanol (diphenhydramine) 5mg/ml oral suspension 150 ml is not medically necessary and appropriate.**

**10)Regarding the request for Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml # 1:**

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 Chronic Pain Medical Treatment Guidelines, (2009), Gabapentin (Neurontin) Section, page 18, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, (2009), Gabapentin (Neurontin) Section, pages 16-19 and 49, which are part of the MTUS.

Rationale for the Decision:

The Chronic Pain guidelines indicate gabapentin may be used for a first-line treatment for neuropathic pain. The records reviewed did not include evidence of neuropathic pain. In addition, the records do not indicate the employee is unable to take a table form of this medication. **The request for Fanatrex (gabapentin) 25mg/ml oral suspension 420ml #1 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, 18<sup>th</sup> Floor  
Oakland, CA 94612

/sab

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.