
Notice of Independent Medical Review Determination

Dated: 12/9/2013

[REDACTED]

[REDACTED]

Employee:

[REDACTED]

[REDACTED]

Date of UR Decision:

7/29/2013

Date of Injury:

11/2/2008

IMR Application Received:

8/12/2013

MAXIMUS Case Number:

CM13-0009680

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Mirtazapine is medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Gabazolpidem-Zolpidem is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Sentra AM #60 is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Sentra PM #60 is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Theramine #120 is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Compound Cream & Capsaicin Cyclobenzaprine HCL is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/12/2013 disputing the Utilization Review Denial dated 7/29/2013. A Notice of Assignment and Request for Information was provided to the above parties on 10/11/2013. 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 **Mirtazapine is medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Gabazolpidem-Zolpidem is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Sentra AM #60 is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Sentra PM #60 is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Theramine #120 is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Compound Cream & Capsaicin Cyclobenzaprine HCL 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 Internal Medicine and is licensed to practice in New York. 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:

The claimant sustained a work related injury on 11/02/2008. She injured her back and her diagnoses to date include chronic pain syndrome secondary to herniated lumbar (L) disc at L4-5 with bilateral radiculopathy, anxiety, depression, and insomnia. Treatment has included medications, back brace, physical therapy, consideration for lumbar fusion surgery, and a psychological evaluation.

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 Mirtazapine :

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the California MTUS and National Library of Medicine, 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 Medscape Internal Medicine: Remeron 2013.

Rationale for the Decision:

Remeron is FDA approved for the treatment of depression and mood disorders. It is a noradrenergic and specific serotonergic antidepressant. It is used off label for the treatment of obsessive compulsive disorder, social anxiety disorder, insomnia, post-traumatic stress disorder, low appetite and nausea.

Antidepressants are used for the treatment of chronic neuropathic pain and usually tricyclic are considered first line therapy especially if the pain is accompanied by anxiety, anxiety, or depression. There is documentation provided indicating this employee completed a psychological assessment and has depression and insomnia. The requested treatment is not medically necessary. **The request for Mirtazapine is medically necessary and appropriate.**

2) Regarding the request for Gabazolpidem-Zolpidem :

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the California MTUS and National Library of Medicine, 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 Medscape Internal Medicine-Treatment of Insomnia 2012.

Rationale for the Decision:

Gabazolpidem-Zolpidem (Ambien) is a short-acting nonbenzodiazepine hypnotic indicated for the short-term treatment (two to six weeks) for managing insomnia. Long-term use is not recommended as there are associated risks of impaired function and memory with use more than opioids, as well as Ambien may be habit forming. The employee is maintained on Mirtazapine which is also used for

insomnia. There is no indication for the use of two medications prescribed for the treatment of insomnia. The requested treatment is not medically necessary. **The request for Gabazolpidem-Zolpidem is not medically necessary and appropriate.**

3) Regarding the request for Sentra AM #60 :

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the Official Disability Guidelines, Pain Chapter, Medical Foods, 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 Sentra AM product information.

Rationale for the Decision:

There is no documentation provided necessitating the use of Sentra AM. The product is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, neurotoxicity-induced fatigue syndrome and cognitive impairment involving arousal, alertness, and memory. It is a medical food that must be used under the supervision of a physician. There is no documentation provided indicating the employee has any of the above conditions and that any food supplement is required to provide a balance of this product's specific components to meet any increased requirements of muscle dysfunction sleep disturbances, cognitive impairment, and chronic stress. **The request for Sentra AM #60 is not medically necessary and appropriate.**

4) Regarding the request for Sentra PM #60 :

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the Official Disability Guidelines, Pain Chapter, and Section Medical Foods.

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 Sentra AM product Information.

Rationale for the Decision:

There is no documentation provided necessitating the use of Sentra AM. The product is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, neurotoxicity-induced fatigue syndrome and cognitive impairment involving arousal, alertness, and memory. It is a medical food that must be used under the supervision of a physician. There is no documentation provided indicating the employee has any

of the above conditions and that any food supplement is required to provide a balance of this product's specific components to meet any increased requirements of muscle dysfunction sleep disturbances, cognitive impairment, and chronic stress. **The request for Sentra PM #60 is not medically necessary and appropriate.**

5) Regarding the request for Theramine #120 :

The Medical Treatment Guidelines 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, pages 111-113, Topical Analgesics.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines (2009), pages 111-113, Topical Analgesics, which is part of the MTUS.

Rationale for the Decision:

There is no documentation provided necessitating use of the requested topical medication. Per California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case the requested compound Theramine is a formulation which includes neurotransmitter precursors (L- arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan), neurotransmitters (Gamma-aminobutyric acid), and anti-inflammatory and immunomodulatory peptides. Per MTUS Guidelines GABA, Choline, and L-Arginine are not supported. **The request for Theramine #120 is not medically necessary and appropriate.**

6) Regarding the request for Compound:

The Medical Treatment Guidelines Relied Upon by the Expert Reviewer to Make His/Her Decision

The Claims Administrator based its decision on the Chronic Pain Medical Treatment Guidelines, pages 111-113, Topical Analgesics, which is part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines (2009), pages 111-113, Topical Analgesics, which is part of the MTUS.

Rationale for the Decision:

There is no documentation provided necessitating use of the requested topical medication. Per California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, alpha-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor) Any compounded product that contains at least one drug (or drug class) that is not recommended (Cyclobenzaprine HCL in this case) is not recommended. **The request for Compound Cream & Capsaicin Cyclobenzaprine HCL 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

/cmol

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.