
Notice of Independent Medical Review Determination

Dated: 12/16/2013

[REDACTED]

[REDACTED]

Employee: [REDACTED]
Claim Number: [REDACTED]
Date of UR Decision: 8/8/2013
Date of Injury: 3/8/1993
IMR Application Received: 8/22/2013
MAXIMUS Case Number: CM13-0014693

- 1) MAXIMUS Federal Services, Inc. has determined the request for **Sentra AM #60 is not medically necessary and appropriate.**
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Sentra PM #60 is not medically necessary and appropriate.**
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Teramine #90 is not medically necessary and appropriate.**
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Citrucel one to two (1-2) BID prn #120 x 2 is not medically necessary and appropriate.**
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Multivitamin one (1) QS #30 x 2 is not medically necessary and appropriate.**
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Zinc sultrate 220 mg QD #30 x 2 is not medically necessary and appropriate.**
- 7) MAXIMUS Federal Services, Inc. has determined the request for **Senna one (1) BID prn #60 x 2 is not medically necessary and appropriate.**
- 8) MAXIMUS Federal Services, Inc. has determined the request for **Gaviscon one (1) tsp BID #1 bottle x 2 is not medically necessary and appropriate.**
- 9) MAXIMUS Federal Services, Inc. has determined the request for **Probiotics one (1) BID #60 is not medically necessary and appropriate.**

INDEPENDENT MEDICAL REVIEW DECISION AND RATIONALE

An application for Independent Medical Review was filed on 8/22/2013 disputing the Utilization Review Denial dated 8/8/2013. A Notice of Assignment and Request for Information was provided to the above parties on 10/4/2013. 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 **Sentra AM #60** is not **medically necessary and appropriate**.
- 2) MAXIMUS Federal Services, Inc. has determined the request for **Sentra PM #60** is not **medically necessary and appropriate**.
- 3) MAXIMUS Federal Services, Inc. has determined the request for **Teramine #90** is not **medically necessary and appropriate**.
- 4) MAXIMUS Federal Services, Inc. has determined the request for **Citrucel one to two (1-2) BID prn #120 x 2** is not **medically necessary and appropriate**.
- 5) MAXIMUS Federal Services, Inc. has determined the request for **Multivitamin one (1) QS #30 x 2** is not **medically necessary and appropriate**.
- 6) MAXIMUS Federal Services, Inc. has determined the request for **Zinc sultrate 220 mg QD #30 x 2** is not **medically necessary and appropriate**.
- 7) MAXIMUS Federal Services, Inc. has determined the request for **Senna one (1) BID prn #60 x 2** is not **medically necessary and appropriate**.
- 8) MAXIMUS Federal Services, Inc. has determined the request for **Gaviscon one (1) tsp BID #1 bottle x 2** is not **medically necessary and appropriate**.
- 9) MAXIMUS Federal Services, Inc. has determined the request for **Probiotics one (1) BID #60** 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 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 patient is a 71-year-old female with a reported date of injury of 03/08/1993. The mechanism of injury was described as an automobile accident while responding to a child emergency situation. An Agreed Medical Evaluation was performed on 03/02/2000 at which time she had complaints of cervical spine pain, pain radiating down her entire right arm to the little finger, and complaints of pain about the right shoulder. She also had complaints of pain about the left thumb. She had complaints about the

lumbosacral spine stating that she had complaints of pain to the midline going into the right buttock occurring off and on. She has undergone surgery for her left thumb and has seen in chiropractic as well. She returned on 06/18/2013 with complaints of frequent headaches, and neck pain rated at 4/10 that radiates down the upper extremities right greater than left and associated with numbness and tingling. She also complained of frequent right shoulder pain rated at 6/10 with increased pain upon range of motion. She was taking Tylenol and Imitrex at that time for her complaints of pain. Objectively, she had tenderness to palpation to the cervical paraspinal musculature, biceps, and trapezius. She returned on 07/09/2013 noting that she had improving gastroesophageal reflux disease, but no changes were seen to her irritable bowel syndrome or constipation, sleep quality, appetite, or fatigue. She denied diarrhea at that time. Lungs were clear to auscultation without rales or wheezing being appreciated. She had normal S1 and S2 heart sounds. She had normal active bowel sounds and there was no clubbing, cyanosis, or edema to the extremities. There was tenderness to the extremities and range of motion was deferred. Medications were ordered at that time. The treatment plan was to provide Sentra, Teramine, Citrucel, multivitamin, zinc sulfate, Senna, Gaviscon, and probiotics for this patient.

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:



1) 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 (ODG), Pain Chapter, Medical Food, 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 Official Disability Guidelines (ODG) Pain chapter, Medical Food, which is not part of the MTUS.

Rationale for the Decision:

The ODG, in discussing medical foods, indicates that this is 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 the distinctive nutritional requirements, based on the recognized scientific principles, are established by medical evaluation. To be considered the product must, at a minimum, meet criteria including documentation that the product must be a food for oral or tube feeding, the

product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, and the product must be used under medical supervision. Sentra is a medical food that has a proprietary formulation of amino acids and polyphenol ingredients in specific proportions. The records do not indicate that this medication is to be used as a dietary management for a specific medical disorder, disease, or condition. The clinical note of 07/09/13 provided for review does not describe which condition this medication is to be used for and this employee has several conditions and co-morbidities. **The request for Sentra AM #60 is not medically necessary and appropriate.**

2) 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 (ODG) Pain Chapter, 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 Official Disability Guidelines (ODG) Pain Chapter, Medical Food section, which is not part of the MTUS.

Rationale for the Decision:

The ODG, in discussing medical foods, indicates that this is 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 the distinctive nutritional requirements, based on the recognized scientific principles, are established by medical evaluation. To be considered the product must, at a minimum, meet criteria including documentation that the product must be a food for oral or tube feeding, the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, and the product must be used under medical supervision. Sentra is a medical food that has a proprietary formulation of amino acids and polyphenol ingredients in specific proportions. The medical records submitted for review do not indicate that this medication is to be used as a dietary management for a specific medical disorder, disease, or condition. Further the clinical note of 07/09/13 does not describe which condition this medication is to be used for and this employee has several conditions and co-morbidities. **The request for Sentra AM #60 is not medically necessary and appropriate.**

3) Regarding the request for Teramine #90 :

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 (ODG) Pain chapter, Teramine, 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 Official Disability Guidelines (ODG) Pain chapter, Medical Food, which is not part of the MTUS.

Rationale for the Decision:

ODG, in discussing medical foods, indicates that there should be documentation that the product must be a food for oral or tube feeding, the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements, and the product must be used under medical supervision. The clinical note of 07/09/13 provided for review does not describe a specific condition or disease for which this medical food was prescribed for the employee. **The request for Teramine #90**

4) Regarding the request for Citrucel one to two (1-2) BID prn #120 x 2 :

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

The Claims Administrator based its decision on the <http://www.drugs/pro/citrucil.html>, which is not a part of MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Opioids Chapter, pg. 77, which is a part of MTUS.

Rationale for the Decision:

The medical records submitted for review documents that the employee has indicated on 07/09/13 that there was no change in the irritable bowel syndrome, sleep quality, appetite, or fatigue, but denied diarrhea at that time. Citrucel is a fiber product designed to enhance conditions such as constipation and/or diarrhea. This employee denies diarrhea on the most recent clinical exam of 07/09/13. However, the records do not describe any clinical exams after that date to objectively document complaints regarding diarrhea or constipation. MTUS Chronic Pain Guidelines, in describing patients on opiates, indicates that prophylactic treatment of constipation should be initiated. However, the last clinical note dated 07/09/13 fails to indicate this employee was on any opiates for which the side effects might be the cause of the constipation and/or diarrhea. As stated previously, there are no recent notes after 07/09/2013 to objectively document that diarrhea or constipation at this time. **The request for Citrucel one to two (1-2) BID prn #120 x 2 is not medically necessary and appropriate.**

5) Regarding the request for Multivitamin one (1) QS #30 x 2 :

The Medical Treatment Guidelines 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 Official Disability Guidelines (ODG) Pain Chapter, Vitamins section, which is not part of the MTUS.

Rationale for the Decision:

ODG, in discussing vitamins, indicates that vitamin is not recommended. Vitamin D is recommended for chronic pain patients and supplementation if necessary and is currently under study as an isolated pain treatment. Furthermore, vitamin D deficiency, according to the Official Disability Guidelines Pain Chapter, is not considered a workers' compensation condition. Laboratory analysis should be provided to document that there is deficiency in vitamins prior to initiating a multivitamin at this point in time. The medical records submitted for review do not document deficiency in vitamins. **The request for Multivitamin one (1) QS #30 x 2 is not medically necessary and appropriate.**

6) Regarding the request for Zinc sultrate 220 mg QD #30 x 2 :

The Medical Treatment Guidelines 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 Other Medical Treatment Guideline or Medical Evidence: Physicians Desk Reference (PDR), zinc sulfate, which is not part of the MTUS.

Rationale for the Decision:

The PDR online indicates that this medication is designed to treat zinc deficiency and may also be used for other conditions as determined by a doctor as it is a mineral and it works by replacing zinc in the body. The medical records submitted for review do not document laboratory results to include amylases levels evidencing that this employee is deficient in zinc sulfate. **The request for Zinc sultrate 220 mg QD #30 x 2 is not medically necessary and appropriate.**

7) Regarding the request for Senna one (1) BID prn #60 x 2 :

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

The Claims Administrator based its decision on the <http://www.drugs.com/ppa/senna.html>, which is not part of the MTUS.

The Expert Reviewer based his/her decision on the Chronic Pain Medical Treatment Guidelines, Opioids Chapter, pg. 77, which is part of the MTUS.

Rationale for the Decision:

MTUS Guidelines indicate that for patients on opiates, prophylactic treatment of constipation should be initiated. However, the medical records submitted for review do not indicate this employee is on opiate medications at this time. The employee does describe there is no change in the irritable bowel syndrome, but

states she does not have diarrhea as of the last clinical note of 07/09/13. No other clinical notes were provided for this review to objectively document that the employee is in need of this medication at this time as there have been no clinical notes submitted after 07/09/13. **The request for Senna one (1) BID prn #60 x 2 is not medically necessary and appropriate.**

8) Regarding the request for Gaviscon one (1) tsp BID #1 bottle x 2 :

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

The Claims Administrator based its decision on the <http://www.drugs.com/mtm/gaviscon-extra-strength.html>, 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 Other Medical Treatment Guideline or Medical Evidence: Physicians Desk Reference (PDR), Gaviscon, which is not part of the MTUS.

Rationale for the Decision:

The Physician Desk reference (PDR) indicates that Gaviscon is used to create a barrier to coat the stomach. These minerals occur naturally and are used as antacids. The medical records provided for this review do not indicate this employee has need for an antacid medication at this time. The most recent clinical note dated 07/09/2013 indicates the employee has continued improving gastroesophageal reflux disease (GERD) but there are no changes in the irritable bowel syndrome and has had no diarrhea. Abdomen was soft and normoactive bowel sounds were noted. Therefore, rationale for this medication at this time has not been demonstrated by the records and is not supported. **The request for Gaviscon one (1) tsp BID #1 bottle x 2 is not medically necessary and appropriate.**

9) Regarding the request for Probiotics one (1) BID #60 :

The Medical Treatment Guidelines 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 Other Medical Treatment Guideline or Medical Evidence: Physicians Desk Reference (PDR), Probiotics, which is not part of the MTUS.

Rationale for the Decision:

The Physician's Desk Reference (PDR) online indicates that Probiotics are a drug classified by the chemical type of the active ingredient used to treat a particular condition. They are live microorganisms designed or a healthy gut. The medical records provided for this review do not indicate for which condition

this medication was prescribed, and also do not indicate that the employee has significant problems at this time as documented in the most recent clinical note dated 07/13. **The request for Probiotics one (1) BID #60 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

/sce

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.