

Case Number:	CM14-0092840		
Date Assigned:	08/08/2014	Date of Injury:	02/07/2013
Decision Date:	12/23/2014	UR Denial Date:	05/29/2014
Priority:	Standard	Application Received:	06/19/2014

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. The expert reviewer is Board Certified in Preventive 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 disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

According to the records made available for review, this is a 53-year-old male with a 2/7/13 date of injury. At the time (4/9/14) of request for authorization for Prilosec 20 mg, QTY: 30, Ketoprofen cream 20%, QTY: 2, Sentra AM, QTY: 60, Sentra PM, QTY: 60, Theramine, QTY: 90, Trepadone, QTY: 120, and Sprix 15.75 mg, QTY: 5, there is documentation of subjective (persistent shoulder and knee pain) and objective (positive pivot sign, positive McMURPHY'S sign in right knee, tenderness over the medial and lateral ligaments, and restricted shoulder range of motion) findings, current diagnoses (right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear), and treatment to date (including ongoing treatment with Prilosec, Ketoprofen cream, Sentra am/pm, Theramine, Anaprox, and Trepadone), previous TENS treatment, and physical therapy). Medical report identifies that the patient has gastritis due to chronic NSAID use. Regarding Sentra Am, Sentra PM, and Trepadone, there is no documentation that the product is a food for oral or tube feeding; labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and used under medical supervision; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra Am, Sentra PM, and Trepadone use to date. Regarding Sprix, there is no documentation of moderate to moderately severe pain requiring analgesia at the opioid level.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec 20 mg, QTY: 30: Overturned

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 Chapter, Proton Pump Inhibitors

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Proton pump inhibitors (PPIs)

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that risk for gastrointestinal event includes age greater than 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; and/or high dose/multiple NSAID. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies documentation of risk for gastrointestinal events and preventing gastric ulcers induced by NSAIDs, as criteria necessary to support the medical necessity of Omeprazole. Within the medical information available for review, there is documentation of diagnoses of right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear. In addition, there is documentation of ongoing treatment with Prilosec with NSAID use. Furthermore, given documentation that the patient has gastritis due to chronic NSAID use, there is documentation of risk for gastrointestinal events. Therefore, based on guidelines and a review of the evidence, the request for Prilosec 20 mg, QTY: 30 is medically necessary.

Ketoprofen cream 20%, QTY: 2: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that ketoprofen, lidocaine (in creams, lotion or gels), Capsaicin in a 0.0375% formulation, Baclofen and other muscle relaxants, and Gabapentin and other antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of diagnoses of lumbar strain and left knee strain/sprain. However, Ketoprofen cream 20% contains at least one component (Ketoprofen) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Ketoprofen cream 20%, QTY: 2 is not medically necessary.

Sentra AM, QTY: 60: 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): Web Edition, Pain, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food

Decision rationale: An online source identifies Sentra AM as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes associated with fatigue and cognitive disorders. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear. However, there is no documentation that the product is a food for oral or tube feeding; labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and used under medical supervision. In addition, given documentation of ongoing treatment with Sentra AM, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra AM use to date. Therefore, based on guidelines and a review of the evidence, the request for Sentra AM, QTY: 60 is not medically necessary.

Sentra PM, QTY: 60: 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) Web Edition, Pain, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food and on Other Medical Treatment Guideline or Medical Evidence:
<http://www.ptlcentral.com/medical-foods-products.php>

Decision rationale: An online source identifies Sentra PM as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes of sleep disorders associated with depression. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a

reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear. However, there is no documentation that the product is a food for oral or tube feeding; labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and used under medical supervision. In addition, given documentation of ongoing treatment with Sentra PM, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra PM use to date. Therefore, based on guidelines and a review of the evidence, the request for Sentra PM, QTY: 60 is not medically necessary.

Theramine, QTY: 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): Web Edition, Pain, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Theramine

Decision rationale: MTUS does not address the issue. ODG identifies that Theramine is a medical food and is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Theramine, QTY: 90 is not medically necessary.

Trepadone, QTY: 120: 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): Web Edition, Pain, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food and on Other Medical Treatment Guideline or Medical Evidence:
<http://www.ptlcentral.com/medical-foods-products.php>

Decision rationale: An online source identifies Trepadone as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the dietary management of the altered metabolic processes associated with pain and inflammation related to joint disorders. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance;

and/or a reduction in the use of medications or medical services. ODG identifies that the product must be a food for oral or tube feeding; must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and must be used under medical supervision; as criteria to support the medical necessity of medial food. Within the medical information available for review, there is documentation of diagnoses of right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear. However, there is no documentation that the product is a food for oral or tube feeding; labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and used under medical supervision. In addition, given documentation of ongoing treatment with Trepadone, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Trepadone use to date. Therefore, based on guidelines and a review of the evidence, the request for Trepadone, QTY: 120 is not medically necessary.

Sprix 15.75 mg, QTY: 5: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: MTUS does not address the issue. ODG identifies documentation of moderate to moderately severe pain requiring analgesia at the opioid level as criteria necessary to support the medical necessity of short duration (not to exceed 5 days) of Sprix nasal spray. In addition, ODG does not recommended Sprix as a first-line medication for chronic pain. Within the medical information available for review, there is documentation of diagnoses of right knee internal derangement, right knee medial meniscus tear, and right shoulder rotator cuff tear. However, there is no documentation of moderate to moderately severe pain requiring analgesia at the opioid level. Therefore, based on guidelines and a review of the evidence, the request for Sprix 15.75 mg, QTY: 5 is not medically necessary.