

Case Number:	CM13-0011309		
Date Assigned:	09/24/2013	Date of Injury:	10/02/2001
Decision Date:	05/05/2014	UR Denial Date:	07/21/2013
Priority:	Standard	Application Received:	08/15/2013

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 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 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 65-year-old male with a 10/2/01 date of injury. At the time (6/13/13) of request for authorization for prescription of Sentra PM, #60, retrospective request for prescription of Gaviscon #1 bottle DOS: 6/13/13, retrospective request for prescription of Colace 250 mg, #30 DOS: 6/13/13, and retrospective request for accucheck glucose test DOS: 6/13/13, there is documentation of subjective (worsening constipation and acid reflux, no change in diabetes and sleep quality, average fasting blood glucose in the 120s, and average systolic blood pressure between 130-145 mmHg) and objective (blood pressure of 131/72 mmHG, blood glucose of 163 mg/dL non-fasting with metformin, and edema of the left knee with limited range of motion secondary to pain) findings, current diagnoses (constipation secondary to medication, insulin dependent diabetes mellitus, obstructive sleep apnea, gastroesophageal reflux disease secondary to NSAIDs, and paresthesia of the bilateral lower extremity extremities), and treatment to date (Colace, Metformin, Sentra PM, and Insulin since at least 4/18/13). In addition, 6/13/13 medical report identifies initial use of Gaviscon. Regarding the requested prescription of Sentra PM, #60, there is no documentation of altered metabolic processes of sleep disorders associated with depression; that the product is a food for oral or tube feeding; is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; is 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 or medical services as a result of use with Sentra PM. Regarding the requested retrospective request for prescription of Colace 250 mg, #30 DOS: 6/13/13, 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 or medical services as a result of use with Colace. Regarding

the requested retrospective request for accucheck glucose test DOS: 6/13/13, there is no documentation of a rationale for continuous glucose monitoring for routine use.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETROSPECTIVE REQUEST FOR PRESCRIPTION OF SENTRA PM, #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, PAIN (ACUTE AND CHRONIC), SENTRA PM.

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 OTHER MEDICAL TREATMENT GUIDELINE OR MEDICAL EVIDENCE: TITLE 8, CALIFORNIA CODE OF REGULATIONS, SECTION 9792.20; AND [HTTP://WWW.PTLCENTRAL.COM/MEDICAL-FOODS-PRODUCTS.PHP](http://www.ptlcentral.com/medical-foods-products.php).

Decision rationale: The Expert Reviewer's 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 constipation secondary to medication, insulin dependent diabetes mellitus, obstructive sleep apnea, gastroesophageal reflux disease secondary to NSAIDs, and paresthesia of the bilateral lower extremity extremities. However, despite documentation of disturbed sleep quality, there is no documentation of altered metabolic processes of sleep disorders associated with depression. In addition, there is no documentation that the product is a food for oral or tube feeding; is labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and is used under medical supervision. Furthermore, given documentaiton of ongoing treatment with Sentra PM since at least 4/18/13, 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 or medical services as a result of use with Sentra PM. Therefore, based on guidelines and a review of the evidence, the request for retrospective request for prescription of Sentra PM, #60 is not medically necessary

RETROSPECTIVE REQUEST FOR PRESCRIPTION OF GAVISCON #1 BOTTLE DOS: 6/13/13: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NATIONAL GUIDELING CLEARINGHOUSE - UNIVERSITY OF MICHIGAN HEALTH SYSTEM. GASTROESOPHAGEAL REFLUX DISEASE (GERD). ANN ARBOR (MI): UNIVERSITY OF MICHIGAN HEALTH SYSTEM; 2012 MAY. 12P.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation [HTTP://WWW.WEBMD.COM/DRUGS/MONO-2123-CALCIUM+CARBONATE+ANTACID+-+ORAL.ASPX?DRUGID=18801&DRUGNAME=GAVISCON+ORAL](http://www.webmd.com/drugs/mono-2123-calcium+carbonate+antacid+-+oral.aspx?drugid=18801&drugname=gaviscon+oral)).

Decision rationale: The Expert Reviewer's decision rationale: MTUS and ODG do not address this issue. Medical Treatment Guideline identifies that Gaviscon (aluminum/magnesium trisilicate) is an antacid that works by neutralizing acid in the stomach. In addition, Medical Treatment Guideline identifies documentation of a condition/diagnosis (with supportive clinical findings) for which Gaviscon is indicated (such as heartburn, indigestion, and upset stomach), as criteria necessary to support the medical necessity of Gaviscon. Within the medical information available for review, there is documentation of a diagnosis of gastroesophageal reflux disease secondary to NSAIDs. In addition, given documentation of subjective findings (worsening acid reflux), there is documentation of a condition/diagnosis (with supportive clinical findings) for which Gaviscon is indicated (heartburn, indigestion, and upset stomach). Therefore, based on guidelines and a review of the evidence, the request for retrospective request for prescription of Gaviscon #1 bottle DOS: 6/13/13 is medically necessary

**RETROSPECTIVE REQUEST FOR PRESCRIPTION OF COLACE 250 MG, #30
DOS:6/13/13: Upheld**

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS-INDUCED CONSTIPATION TREATMENT.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS; INITIATING THERAPY Page(s): 77.

Decision rationale: The Expert Reviewer's decision rationale: MTUS Chronic Pain Medical Treatment Guidelines identifies that when initiating opioid therapy, prophylactic treatment of constipation should be initiated. 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 opioid-induced constipation is a common adverse effect of long-term opioid use. Medical Treatment Guideline identifies documentation of a diagnosis/condition for which Colace is indicated (such as short-term treatment of constipation and/or chronic opioid use), as criteria necessary to support the medical necessity of Colace. Within the medical information available for review, there is documentation of a diagnosis of constipation secondary to medication. However, given documentation of subjective findings (worsening constipation) and ongoing treatment with Colace since at least 4/18/13, 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 or medical services as a result of use with Colace. Therefore, based on guidelines and a review of the evidence, the request for retrospective request for prescription of Colace 250 mg, #30 DOS: 6/13/13 is not medically necessary.

RETROSPECTIVE REQUEST FOR ACCUCHECK GLUCOSE TEST DOS:6/13/13:

Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES, DIABETES (ACUTE AND CHRONIC), GLUCOSE MONITORING

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG) DIABETES CHAPTER, GLUCOSE MONITORING

Decision rationale: The Expert Reviewer's decision rationale: MTUS does not address this issue. ODG identifies documentation of type 1 diabetes or type 2 diabetes on insulin therapy, plus long-term assessment (using A1C), but not continuous glucose monitoring for routine use, as criteria necessary to support the medical necessity of glucose monitoring. Within the medical information available for review, there is documentation of a diagnosis of insulin dependent diabetes mellitus and that the patient is on Insulin. However, given documentation of subjective findings (average fasting blood glucose in the 120s), there is no documentation of a rationale for continuous glucose monitoring for routine use. Therefore, based on guidelines and a review of the evidence, the request for retrospective request for accucheck glucose test DOS: 6/13/13 is not medically necessary.