

Case Number:	CM14-0156040		
Date Assigned:	09/25/2014	Date of Injury:	03/25/2012
Decision Date:	10/27/2014	UR Denial Date:	08/19/2014
Priority:	Standard	Application Received:	09/19/2014

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 Family 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:

This is a 60-year-old male patient who reported an industrial injury on 3/25/2012, 2 years ago, to the back attributed to the performance of his usual, and customary job tasks. The patient reported increased lower back pain from sitting and standing. The pain was characterized as radiating from the buttocks down to the bilateral legs and lower thigh. The patient was noted to have had degenerative disc disease at L4-L5 with a 50% decrease and disc height. The objective findings on examination included normal lower extremity reflexes; heel-toe gait on walking good but guarded; use of a cane for ambulation; tenderness to the right SI joint; tenderness to palpation to the paralumbar area. The patient was prescribed Vicodin; Tenormin; diclofenac; and Naprosyn. The patient was also prescribed the medical foods Theracodophen; Theraproxen; Gabitidine; Sentra AM and topical Diclofenac gel. The patient was placed on modified work with no lifting above 10 pounds.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac 5% gel 300mg #1 tube: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: The topical NSAID, Diclofenac 5% gel, is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical Diclofenac gel for chronic back pain. The patient has received topical NSAID gels for a prolonged period of time exceeding the time period recommended by evidence-based guidelines. There is no demonstrated medical necessity for both an oral NSAID and a topical NSAID. There is no provided subjective or objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the CA MTUS, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no documented functional improvement by the provider attributed to the topical NSAID. The use of topical NSAIDs is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. The patient was prescribed an oral opioids and topical NSAID concurrently. The use of the topical creams/gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prolonged use of topical Diclofenac cream 5% gel one tube is not supported by the applicable evidence-based guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be medically necessary. The prescribed topical Diclofenac 5% topical gel is not demonstrated be medically necessary.

Theracodophen 325mg (includes Theramine 2 tablets every 6 hours #90, Norco 2 tablets every 4-6 hours as needed for pain #60): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: There is no objective evidence provided by the treating physician to support the medical necessity of the prescribed medical foods for the patient as opposed to conventional medications. The diagnosis of chronic back pain does not support the medical necessity of the prescribed medical foods. The patient was prescribed both medical foods and conventional oral medications. There is no objective evidence provided by the treating physician to override the

recommendations of the California MTUS for the prescription of medical foods as opposed to conventional oral pharmaceuticals. The patient has not been demonstrated to have failed treatment on conventional medications and the dispensed medical foods are not demonstrated to be medically necessary for the treatment of the effects of the industrial injury. The Theramine was prescribed to reduce pain and inflammation. Medical foods are not FDA approved. The patient was also prescribed or Gabapentin; Hydrocodone-APAP; and Ranitidine and no medical necessity was provided for supplemental medical foods. The medical necessity of the prescribed medical food Theracodophen for pain relief was not supported with any evidence-based guidelines. The rationale for the prescription of medical foods over prescribed oral medications is not explained fully or supported with objective evidence. The prescription of the medial foods has not been supported with the criteria recommended by the Official Disability Guidelines. There is no demonstrated medical necessity for the prescribed Theramine medical foods. The use of the prescribed medical foods is based on anecdotal evidence and there is no evidence-based medicine or current literature to establish the effectiveness medical foods or to establish functional capacity improvement with the use of the medical foods. There is no medical necessity for the prescription of this medical food for chronic back pain. There is no subjective/objective evidence provided to support the use of Theracodophen over a generic oral prescription for the same component medications. There is no documented objective evidence that the patient requires both the oral medications and the compounded medication for the treatment of the stated diagnoses. The objective findings in the clinical documentation provided does not support the prescription of Theracodophen as the compounded medications were not subjectively or objectively documented to have improved function or decreased pain. The prescription of medical foods is not recommended by the CA MTUS or the Official Disability Guidelines. The combination of Theramine with Naprosyn, Tramadol, Hydrocodone, Gabapentin, and Cyclobenzaprine is not medically necessary and is not supported with objective medically based evidence. The use of the prescribed medical foods is based on anecdotal evidence and there is no evidence-based medicine or current literature to establish the effectiveness medical foods or to establish functional capacity improvement with the use of the medical foods. There is no subjective/objective evidence provided to support the use of Gabitidine; Theraproxen over a generic oral prescription for Naproxen; and Theratramadol over a generic oral prescription for Tramadol. Theramine is a Medical Food product advertized to aid in the nutritional management of pain syndromes. Theramine is purported to stimulate the production of serotonin, GABA, norepinephrine, nitric oxide and acetylcholine, the neurotransmitters that are reported to be involved or deficient in pain disorders. If the timing and secretion of these neurotransmitters are effectively modulated, it is alleged that acute and chronic pain disorders are more effectively managed. Theramine is advertized to provide L-Arginine at low dose along with choline and L-glutamine to inhibit the NMDA and opioid receptors. Theramine is reported to be prescribed to manage the nutritional deficiencies associated with pain syndromes. The prescription of the amino acid Theramine as a medical food is not recommended by the MTUS, ACOEM Guidelines, or the Official Disability Guidelines. There is no objective evidence that compounding the amino acid with Naproxen or Hydrocodone is any more effective than the generic medications without Theramine. There is no demonstrated medical necessity for the prescription of Theraproxen.

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain. Decision based on Non-MTUS Citation Official

Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: There is no objective evidence provided by the requesting provider to support the medical necessity of the prescribed medical foods for the patient as opposed to conventional medications. There is no objective evidence provided by the treating physician to override the recommendations of the California MTUS for the prescription of medical foods as opposed to conventional oral pharmaceuticals. The medical necessity of the prescribed medical food Theraproxen for pain relief and anti-inflammation for the lower back was not supported with any evidence-based guidelines. The rationale for the prescription of medical foods over prescribed oral medications is not explained fully or supported with objective evidence. The prescription of the medical foods has not been supported with the criteria recommended by the Official Disability Guidelines. The use of the prescribed medical foods is based on anecdotal evidence and there is no evidence-based medicine or current literature to establish the effectiveness of medical foods or to establish functional capacity improvement with the use of the medical foods. There is no medical necessity for the prescription of this medical food for an ankle strain. There is no subjective/objective evidence provided to support the use of Theraproxen over a generic oral prescription for the same component medications. There is no documented objective evidence that the patient requires both the oral medications and the compounded medication for the treatment of the stated diagnoses. The objective findings in the clinical documentation provided do not support the prescription of Theraproxen as the compounded medications were not subjectively or objectively documented to have improved function or decreased pain. The prescription of medical foods is not recommended by the CA MTUS or the Official Disability Guidelines. The combination of Theramine with Naprosyn, Tramadol, Hydrocodone, and Cyclobenzaprine is not medically necessary and is not supported with objective medically based evidence. The prescription for the compounded medical foods is recommended to be noncertified. The medical necessity of the medical foods is not demonstrated and is not recommended by the Official Disability Guidelines. There is no provided objective medically based evidence to support the prescription of the medical foods as checked off in the Medication section of the submitted PR-2. The use of the prescribed medical foods is based on anecdotal evidence and there is no evidence-based medicine or current literature to establish the effectiveness of medical foods or to establish functional capacity improvement with the use of the medical foods. There is no subjective/objective evidence provided to support the use of Gabapentin; Theraproxen over a generic oral prescription for Naproxen; and Theratramadol over a generic oral prescription for Tramadol. Theramine is a Medical Food product advertised to aid in the nutritional management of pain syndromes. Theramine is a Medical Food product advertised to aid in the nutritional management of pain syndromes. Theramine is purported to stimulate the production of serotonin, GABA, norepinephrine, nitric oxide and acetylcholine, the neurotransmitters that are reported to be involved or deficient in pain disorders. If the timing and secretion of these neurotransmitters are effectively modulated, it is alleged that acute and chronic pain disorders are more effectively managed. Theramine is advertised to provide L-Arginine at low dose along with choline and L-glutamine to inhibit the NMDA and opioid receptors. Theramine is reported to be prescribed to manage the nutritional deficiencies associated with pain syndromes. The prescription of the amino acid Theramine as a medical food is not recommended by the MTUS, ACOEM Guidelines, or the Official Disability Guidelines. There is no objective evidence that compounding the amino acid with hydrocodone is any more effective than generic oral hydrocodone or conventional oral medications for the treatment of osteoarthritis pain. There is no objective evidence that compounding the amino acid with gabapentin is any more effective than generic oral gabapentin or conventional oral medications for the treatment of osteoarthritis pain. There is no objective evidence to support the medical necessity of the medical food Theramine or the prescribed Theracodphen for the treatment of the provided diagnosis.

Sentra AM 1-2 tablets every 4-6 hours for chronic fatigue: 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), Pain Procedure Summary

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: There was no substantive objective evidence provided by to support the medical necessity of a medical food, such as, Sentra AM over the medications readily available over the counter for similar purposes. There is no demonstrated medical necessity for the requested Sentra AM for the treatment of the effects of the reported industrial injury. The prescription of the medical food Sentra AM (Strazepam) as a medical food is not recommended by the ACOEM Guidelines or the Official Disability Guidelines for the treatment of insomnia or a sleep disorder. The prescribed Sentra AM was not demonstrated to be medically necessary. It is not clear that the patient is diagnosed with a sleep disorder or experiences occasional insomnia. There is no medical necessity for the prescription of Sentra AM for the patient. There is no documented evidence that the patient has failed the use of the numerous available sleep aids over-the-counter. The request for the authorization of Sentra AM is not supported with objective medically based evidence. There is no medical necessity for the medical food Sentra AM for the effects of the industrial injury. There is no evidence that this prescribed medical food provides functional improvement or even helps with sleep. The prescription of medical foods is not recommended by the CA MTUS or the Official Disability Guidelines. The use of the medical food is not supported with clinical evidence or supported with objective peer-reviewed evidence. The medical foods prescribed in addition to the oral medications prescribed are not demonstrated to be medically necessary. Sentra AM was prescribed for sleep. The medical food is prescribed routinely for sleep and not on a prn basis. The medical food is not FDA approved. There is no documented failure of the many sleep remedies available OTC. There is no demonstrated medical necessity for the continuation of a sleep aid eight (8) years after the DOI. There is no medical necessity for a medical food for increased energy with AM or PM formulations.