

Case Number:	CM13-0023961		
Date Assigned:	12/11/2013	Date of Injury:	06/25/2009
Decision Date:	02/03/2014	UR Denial Date:	08/19/2013
Priority:	Standard	Application Received:	09/13/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice, 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 physician 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:

Per the documentation, the patient was doing well on the current medication regimen. The patient is a 52-year-old female who reported injury on 06/25/2009. The mechanism of injury was not provided. The patient was noted to have 2 cortisone injections into the right shoulder. The patient was noted to have positive impingement signs and AC joint tenderness along with crepitus and pain on motion. The patient was noted to have increased pain with abduction. The diagnosis was not provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flubiprofen, 15%/10%, quantity 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen; Topical Analgesics Page(s): 72,111.

Decision rationale: The Physician Reviewer's decision rationale: Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The CA MTUS indicates topical analgesics are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants

have failed....Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period." This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended." Per the submitted documentation from the pharmacy, the medication being requested was Flubiprofen15%/10%. However, per California MTUS Guidelines, the addition of these medications is not recommended as neither one of them are recommended for topical use. Given the above, the request for Flurbiprofen 15%/10%, quantity 180gm, is not medically necessary

Cyclobenzaprine, 15%/10%, quantity 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics Page(s): 41, 111.

Decision rationale: The Physician Reviewer's decision rationale: Cyclobenzaprine is classified as a non-steroidal anti-inflammatory agent. The CA MTUS indicates topical analgesics are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period." This agent is not currently FDA approved for a topical application. FDA approved routes of administration for cyclobenzaprine include oral tablets and ophthalmologic solution. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended." Per the submitted documentation from the pharmacy, the medication being requested was Cyclobenzaprine, 15%/10%, quantity 180gm. However, per California MTUS Guidelines, the addition of these medications is not recommended as neither one of them are recommended for topical use. Given the above, the request for Cyclobenzaprine, 15%/10%, quantity 180gm, is not medically necessary.

Ultraderm, 15%/10%, quantity 180gm: Upheld

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

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

Decision rationale: The Physician Reviewer's decision rationale: Per California MTUS, Topical Analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Clinical documentation submitted for review failed to indicate what products were in Ultraderm 15%/10%. Given the above lack of documentation, the request for Ultraderm 15%/10%, quantity 180 gm is not medically necessary.

Tramadol 8%/10%/2%/2%0.5%, quantity 180gm is not: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105, 111, 1.

Decision rationale: The Physician Reviewer's decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. Tramadol is not recommended as a first line therapy. Gabapentin: Not recommended. There is no peer-reviewed literature to support us. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Clinical documentation submitted for review by way of the pharmacy bill revealed the ingredients for this product were tramadol, gabapentin, menthol, camphor, and capsaicin. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. As such, the request for capsaicin 8%/10%/2%/2%/0.5%, quantity 180 gm is not medically necessary.

Gabapentin powder, 8%/10%/2%/2%0.5%, quantity 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105,.

Decision rationale: The Physician Reviewer's decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended....Topical Salicylates are recommended... Tramadol is not recommended as a first line therapy...Gabapentin: Not recommended. There is no peer-reviewed literature to support use... Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments....There have been no

studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Clinical documentation submitted for review by way of the pharmacy bill revealed the ingredients for this product were tramadol, gabapentin, menthol, camphor, and capsaicin. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. As such, the request for capsaicin 8%/10%/2%/2%/0.5%, quantity 180 gm is not medically necessary.

Menthol, 8%/10%/2%/2%0.5%, quantity 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105,.

Decision rationale: The Physician Reviewer's decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended... Tramadol is not recommended as a first line therapy. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Clinical documentation submitted for review by way of the pharmacy bill revealed the ingredients for this product were tramadol, gabapentin, menthol, camphor, and capsaicin. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. As such, the request for capsaicin 8%/10%/2%/2%/0.5%, quantity 180 gm is not medically necessary.

Camphor, 8%/10%/2%/2%0.5%, quantity 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105, 111,.

Decision rationale: The Physician Reviewer's decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. Tramadol is not recommended as a first line therapy. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a

0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Clinical documentation submitted for review by way of the pharmacy bill revealed the ingredients for this product were tramadol, gabapentin, menthol, camphor, and capsaicin. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. As such, the request for capsaicin 8%/10%/2%/2%/0.5%, quantity 180 gm is not medically necessary.

Capsaicin, 8%/10%/2%/2%0.5%, quantity 180gmis not: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Topical Salicylates, Topical Analgesics, Gabapentin, Capsaicin Page(s): 82, 105, 1.

Decision rationale: The Physician Reviewer's decision rationale: The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Salicylates are recommended. Tramadol is not recommended as a first line therapy. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Clinical documentation submitted for review by way of the pharmacy bill revealed the ingredients for this product were tramadol, gabapentin, menthol, camphor, and capsaicin. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. As such, the request for capsaicin 8%/10%/2%/2%/0.5%, quantity 180 gm is not medically necessary.

Ultraderm, 8%/10%/2%/2%0.5%, quantity 180gm: Upheld

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

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

Decision rationale: The Physician Reviewer's decision rationale: Per California MTUS, Topical Analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Clinical documentation submitted for review failed to indicate was products were in Ultraderm 8%/10%/2%/2%0.5%, quantity 180

gm. Given the above lack of documentation, the request for Ultraderm 8%/10%/2%/2%0.5%, quantity 180 gm, quantity 180 gm is not medically necessary.