

Case Number:	CM13-0010155		
Date Assigned:	11/08/2013	Date of Injury:	08/19/2003
Decision Date:	08/01/2014	UR Denial Date:	07/11/2013
Priority:	Standard	Application Received:	08/12/2013

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 Emergency Medicine, and is licensed to practice in Florida. 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 patient is a 50-year-old with a date of injury of August 19, 2003. A progress report associated with the request for services, dated June 3, 2013, identified subjective complaints of right knee pain. Objective findings only included knee extension of 0 degrees and flexion of 90 degrees. Diagnoses included internal derangement of the right knee. Treatment has included NSAIDs (non-steroidal anti-inflammatory drugs), which were described as helpful and oral and topical analgesics. A Utilization Review determination was rendered on July 11, 2013 recommending non-certification of 1 prescription of naproxen #180 on June 3, 2013; 1 prescription of Dendracin 2 bottles on June 3, 2013; 1 prescription of Dendracin 2 bottles between June 3, 2013 and September 8, 2013; 1 prescription of Prilosec #180 on June 3, 2013; 1 prescription of Prilosec #180 between June 3, 2013 and September 8, 2013; and 1 prescription of naproxen #180 between June 3, 2013 and September 8, 2013.

IMR ISSUES, DECISIONS AND RATIONALES

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

One prescription of Naproxen, 180 count on June 3, 2013 and September 18, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

Decision rationale: Naproxen is a non-steroidal anti-inflammatory agent (NSAID). NSAIDs have been recommended for use in osteoarthritis. It is noted that they are: Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. They further state that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. Again, no one NSAID was superior to another. There is inconsistent evidence for the long-term treatment of neuropathic pain with NSAIDs. Precautions should be taken due to side effects. The record indicates that the therapy is long-term rather than for a short period. Since NSAIDs are recommended for the shortest period possible, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to naproxen during the time period requested and therefore no medical necessity. The request for one prescription of Naproxen, 180 count on June 3, 2013, is not medically necessary or appropriate.

One prescription of dendracin, two bottles on June 3, 2013 and September 8, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylate Topicals; Topical Analgesics Page(s): 28-29; 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back; Pain: Biofreeze Cryotherapy Gel; Topical Analgesics; Salicylate Topicals.

Decision rationale: Dendracin lotion has multiple ingredients that include methyl salicylate 30%, capsaicin 0.025%, and menthol USP 10%. The Chronic Pain Medical Treatment Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Specifically, the Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state that capsaicin topical is Recommended only as an option in patients who have not responded or are intolerant to other treatments. It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. The Medical Treatment

Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for one prescription of dendracin, two bottles on June 3, 2013, is not medically necessary or appropriate.

One prescription of dendracin, two bottles on June 3, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical; Salicylate Topicals; Topical Analgesics Page(s): 28-29; 105; 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back; and Pain Chapters, Biofreeze Cryotherapy Gel, Topical Analgesics, and Salicylate Topicals Subsections.

Decision rationale: Dendracin lotion has multiple ingredients that include methyl salicylate 30%, capsaicin 0.025%, and menthol USP 10%. The Chronic Pain Medical Treatment Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Specifically, the Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state that capsaicin topical is Recommended only as an option in patients who have not responded or are intolerant to other treatments. It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of

menthol for chronic pain. The Guidelines further state: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation, Dendracin. The request for prescription of Dendracin, two bottles between June 3, 2013 and September 8, 2013, is not medically necessary or appropriate.

One prescription of Prilosec, 180 count on June 3, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 68-69.

Decision rationale: Prilosec (omeprazole), a proton pump inhibitor, is a gastric antacid. The indication for the medication was not documented in the record. It is sometimes used for prophylaxis against the GI (gastrointestinal) side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes that these risk factors include (1) age is greater than 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA (acetylsalicylic acid), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered okay in patients with no risk factors and no cardiovascular disease. In this case, there is no documentation of any of the above risk factors. Therefore, the request for one prescription of Prilosec, 180 count on June 3, 2013, is not medically necessary or appropriate.

One prescription of Prilosec, 180 count between June 3, 2013 and September 8, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68-69.

Decision rationale: Prilosec (omeprazole), a proton pump inhibitor, is a gastric antacid. The indication for the medication was not documented in the record. It is sometimes used for prophylaxis against the GI side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes that these risk factors include (1) age greater than 65 years; (2) history of peptic ulcer, GI (gastrointestinal) bleeding or perforation; (3) concurrent use of ASA (acetylsalicylic acid), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered okay in patients with no risk factors and no cardiovascular disease. In this case, there is no documentation of any of the above risk factors. Therefore, the medical record does not document

the medical necessity for Prilosec. The request for one prescription of Prilosec, 180 count between June 3, 2013 and September 8, 2013, is not medically necessary or appropriate.

One prescription of Naproxen, 180 count between June 3, 2013: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

Decision rationale: Naproxen is a non-steroidal anti-inflammatory agent (NSAID). NSAIDs have been recommended for use in osteoarthritis. It is noted that they are: Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. They further state that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. Again, no one NSAID was superior to another. There is inconsistent evidence for the long-term treatment of neuropathic pain with NSAIDs. Precautions should be taken due to side effects. The record indicates that the therapy is long-term rather than for a short period. Since NSAIDs are recommended for the shortest period possible, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to naproxen during the time period requested and therefore no medical necessity. The request for one prescription of Naproxen, 180 count between June 3, 2013 and September 8, 2013, is not medically necessary or appropriate.