

Case Number:	CM14-0211089		
Date Assigned:	12/23/2014	Date of Injury:	12/03/2010
Decision Date:	02/19/2015	UR Denial Date:	11/24/2014
Priority:	Standard	Application Received:	12/16/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabn

CLINICAL CASE SUMMARY

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

The patient is a 57 year old male with an injury date of 12/03/10. Based on the 08/19/14 progress report, the patient complains of left shoulder pain, neck pain, and low back pain with radiation into the lower extremities. He rates his pain as a 7-8/10 without medication and a 5-6/10 with medication. He has a decreased sensation in the left hand mainly in digits number four and five and partially in digits number three, restricted lumbar/cervical/left shoulder range of motion, positive Spurling's on the right, and tenderness to palpation/muscle spasm in the neck. On 09/23/14, the patient rated his pain as a 10/10 without medication and a 5-6/10 with medication. He has a positive Tinel's at the left elbow. The 10/09/14 report states that the patient has severe radiculopathy at L4, L5, and S1 with tingling and numbness to both legs. He has pain over the bilateral buttock radiating to posterior and lateral aspect of bilateral thigh with numbness and tingling increasing in severity. The patient has severe sacroiliac joint inflammation, walks with a cane, rates his pain as a 9/10, has a positive Gaenslen's test, has a positive Patrick Fabre test, and sacroiliac joint thrust demonstrated severely positive. The patient's diagnoses include the following: 1. Lumbar musculoligamentous injury 2. Lumbar paraspinal muscle spasms 3. Lumbar disc herniation 4. Lumbar radiculitis/radiculopathy of lower extremities 5. Sacroilitis of right sacroiliac joint The utilization review determination being challenged is dated 11/24/14. There are three treatment reports provided from 08/19/14, 09/23/14, and 10/09/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Lotion: 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.

Decision rationale: The patient presents with left shoulder pain, neck pain, and low back pain with radiation into the lower extremities. The request is for Terocin Lotion. The report with the request is not provided. Terocin cream is considered a topical analgesic and contains methyl salicylate, capsaicin, lidocaine, and menthol. MTUS Guidelines page 112 on topical lidocaine states, "recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy, tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially-approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain." The patient has a decreased sensation in the left hand mainly in digits number four and five and partially in digits number three, restricted lumbar/cervical/left shoulder range of motion, positive Spurling's on the right, tenderness to palpation/muscle spasm in the neck, positive Tinel's at the left elbow, severe sacroiliac joint inflammation, positive Gaenslen's test, positive Patrick Fabre test, and sacroiliac joint thrust demonstrated severely positive. MTUS Guidelines state, "any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended". MTUS Guidelines do not allow any other formulation of lidocaine other than in patch form. Terocin lotion consists of lidocaine, which is not is not medically necessary.

Compounded medication (Flurbipro/ Lidocaine/Amitripty/Pcca Lipo): 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.

Decision rationale: The patient presents with left shoulder pain, neck pain, and low back pain with radiation into the lower extremities. The request is for compounded medication (flurbiprofen, lidocaine, amitriptyline, pcca lipo). The report with the request is not provided. MTUS has the following regarding topical creams (page 111, chronic pain section): "Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. 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. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has

been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." Flurbiprofen, an NSAID, is indicated for peripheral joint arthritis/tendinitis. MTUS also states that many agents are compounded for pain control including antidepressants and that there is little to no research to support their use. "There is currently one Phase III study of baclofen-amitriptyline-ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer review literature to support the use of topical baclofen." The patient has a decreased sensation in the left hand mainly in digits number four and five and partially in digits number three, restricted lumbar/cervical/left shoulder range of motion, positive Spurling's on the right, tenderness to palpation/muscle spasm in the neck, positive Tinel's at the left elbow, severe sacroiliac joint inflammation, positive Gaenslen's test, positive Patrick Fabre test, and sacroiliac joint thrust demonstrated severely positive. MTUS Guidelines do not recommend a compounded product if one of the compounds are not indicated for use. Neither Amitriptyline nor Lidocaine (in a non-patch form) is indicated for use as a topical formulation. Therefore, the requested compounded medication is not medically necessary.

Compounded medication (Gabapent/ Cyclobenz/Tramadol/Penderm C): 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.

Decision rationale: The patient presents with left shoulder pain, neck pain, and low back pain with radiation into the lower extremities. The request is for compounded medication (gabapentin/cyclobenzaprine/ tramadol/ penderm c). The report with the request is not provided. MTUS guidelines have the following regarding topical creams (p111, chronic pain section): "Topical analgesics are largely experimental and used 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. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration... Gabapentin: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Cyclobenzaprine is a muscle relaxant and is not supported for any topical formulation. There is no support for tramadol as a topical compound either. There is lack of evidence that topical tramadol can help chronic pain. The patient has a decreased sensation in the left hand mainly in digits number four and five and partially in digits number three, restricted lumbar/cervical/left shoulder range of motion, positive Spurling's on the right, tenderness to palpation/muscle spasm in the neck, positive Tinel's at the left elbow, severe sacroiliac joint inflammation, positive Gaenslen's test, positive Patrick Fabre test, and sacroiliac joint thrust demonstrated severely positive. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. Neither Gabapentin, Cyclobenzaprine, nor Tramadol are indicated for use as a topical formulation. Therefore, the requested compounded medication is not medically necessary.

Somnicin # 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://skylarholdings.com/somnicin%E2/84%A2/>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesic Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter online in the section on Medical Foods; ODG guidelines, Pain Chapter online, under Vitamin B

Decision rationale: The patient presents with left shoulder pain, neck pain, and low back pain with radiation into the lower extremities. The request is for Somnicin #30. The report with the request is not provided. Somnicin is reported to be a compounded product containing Melatonin 2mg, 5HTP 50mg, L-tryptophan 100mg, pyridoxine 10mg (vitamin B6) and Magnesium 50mg. MTUS, ACOEM and ODG guidelines do not discuss Somnicin specifically. MTUS Guidelines page 111 states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." ODG guidelines under the Pain chapter online in the section on Medical Foods, offers some support for 5HTP, but overall states Medical foods are not recommended for chronic pain. ODG guidelines, Pain Chapter online, under Vitamin B states this is not recommended for the treatment of chronic pain. The patient has a decreased sensation in the left hand mainly in digits number four and five and partially in digits number three, restricted lumbar/cervical/left shoulder range of motion, positive Spurling's on the right, tenderness to palpation/muscle spasm in the neck, positive Tinel's at the left elbow, severe sacroiliac joint inflammation, positive Gaenslen's test, positive Patrick Fabre test, and sacroiliac joint thrust demonstrated severely positive. MTUS page 111 states that if one of the compounded topical products is not recommended, then the entire product is not. Since one component of the compound Somnicin is not recommended (Vitamin B), the whole compounded product cannot be completely recommended. The requested Somnicin #30 is not medically necessary.