

Case Number:	CM14-0217572		
Date Assigned:	02/13/2015	Date of Injury:	03/10/2014
Decision Date:	05/20/2015	UR Denial Date:	12/16/2014
Priority:	Standard	Application Received:	12/29/2014

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 & Rehabilitation

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 injured worker is a 50 year old male, who sustained an industrial injury on 03/10/2014. He has reported tripping over a pipe and falling straight on his back on metal and concrete sustaining an injury to the lower back. Diagnoses include lumbar herniated disc, lumbar pain, and lumbar sprain/strain. Treatment to date has included electromyogram, nerve conduction velocity, lumbar magnetic resonance imaging, laboratory studies, therapy, E-Stim, home exercise program, and medication regimen. In a progress note dated 10/04/2014 the treating provider reports residual central low back with tingling to the buttocks. The treating physician noted that the injured worker uses an E-Stim machine at home that is helpful, but the documentation does not indicate the specific reason for requesting the below listed treatments. The Request for Authorization dated 10/17/2014 indicate the services requested were: compounded medication of Fluri (Nap) Cream LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams; Gabacyclotram (Gabapentin 10%, Cyclobenzaprine 6%, Tramadol 10%) 180 grams; Terocin patches with a quantity of 30 (Lidocaine); Somnicin capsules quantity of 30; neurostimulator; interferential unit; multi-stim unit; Micro-Z Unit; aqua relief system; acupuncture; and home therapy.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compounded medication: Fluri (Nap) cream - LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%) 180 grams: Upheld

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

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

Decision rationale: The request for compounded medication: Fluri (Nap) cream - la (flurbiprofen 20%, lidocaine 5%, amitriptyline 5%) 180 grams is not medically necessary. Topical analgesics are largely experimental in use with few randomized controlled trials to determine the efficacy or safety of their use. They are generally recommended for neuropathic pain upon failure of antidepressants and anticonvulsants as first line treatment. It is also noted that any compounded product or medication that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The requested medication contains flurbiprofen, which is an NSAID, and per the referenced guidelines, it is stated that the only FDA approved topical NSAID is Voltaren gel 1%. It is also noted that the injured worker's injury was to the lumbar spine, and per the California MTUS Guidelines, the use of topical NSAIDs is recommended for the relief of osteoarthritis pain in joints that lend themselves to topical treatment, such as the ankle, elbow, foot, hand, knee, and wrist. There has not been evaluated treatment of topical NSAIDs for injuries to the spine, hip, or shoulder. It is also noted the requested medication contains lidocaine and the only FDA form of the medication lidocaine is the form of a Lidoderm patch. Given that this medication contains multiple medications that are not recommended, medical necessity for the request is not established and the requested medication would not be medically necessary.

Gabacyclotram (Gabapentin 10% Cyclobenzaprine 6% Tramadol 10%) 180 grams: Upheld

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

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

Decision rationale: The decision for gabacyclotram (gabapentin 100 mg 10%, cyclobenzaprine 6%, and tramadol 10%) 180 gm is not medically necessary. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety of their use. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The requested medication contains the medication gabapentin and cyclobenzaprine. Per the referenced guidelines, it is stated that muscle relaxants and gabapentin are not recommended in a topical form as there is no evidence of use of any muscle relaxant as a topical product and there is no peer reviewed literature to support the use of topical gabapentin. Given that the requested topical analgesic contains multiple medications that are not recommended per the referenced guidelines; the entire medication is not recommended.

As such, the requested gabacyclotram (gabapentin 100 mg 10%, cyclobenzaprine 6%, and tramadol 10%) 180 gm is not medically necessary.

Terocin patches #30 (Lidocaine): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Drugs.com.

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

Decision rationale: The use of Terocin patches is not medically necessary. The California MTUS/ACOEM do not specifically address the medication Terocin. The Official Disability Guidelines do not specifically address this medication, as well. However, Drugs.com states that this medication is lidocaine. The only FDA form of the medication lidocaine is in the form of a Lidoderm patch. There was no documentation of a failed attempt at first line treatment with an antidepressant or an anticonvulsant to treat the injured worker's condition prior to the use of the requested topical analgesic medication. Given this information, medical necessity for Terocin patches has not been established and the request for Terocin patch #30 (lidocaine) is not medically necessary.

Somnicin capsules #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.napharm.com and Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical food and Somnicin.

Decision rationale: Somnicin capsules are not medically necessary. The California MTUS/ACOEM do not specifically address this medication. However, the Official Disability Guidelines state that Somnicin is not recommended for chronic pain. Somnicin is a nutritional supplement that contains multiple medications to include melatonin, magnesium oxide, oxitriptan (which is the L form of 5 hydroxytryptophan), 5 hydroxytryptophan, tryptophan, and vitamin B6. Per the referenced guidelines, 5 hydroxytryptophan is an alternative medication that is used for insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches, and various pain disorders. However, current peer reviewed evidence is inconclusive to support these claims. As the use of medical foods is not recommended and peer reviewed literature does not provide any conclusive evidence to support the use of these medical foods or the medicine Somnicin for chronic pain, medical necessity for the request is not established. As such, the request for Somnicin capsules #30 is not medically necessary.

Neurostimulator: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 121. Decision based on Non-MTUS Citation National Library of Medicine.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Neuromuscular electrical stimulation (NMES devices) Page(s): 120.

Decision rationale: The use of a neurostimulator is not medically necessary. The use of a neuromuscular electrical stimulator, or neurostimulator, is not recommended. It is primarily recommended as part of a rehabilitation program following a stroke. There was no evidence to support its use in chronic pain. The use of a neuromuscular stimulator is recommended to stimulate the quadriceps muscle following major knee surgeries to maintain an enhanced strength during rehabilitation. The information submitted does not provide documentation indicating the injured worker has undergone a recent major knee surgery to warrant the use of the requested neurostimulator. Additionally, there was no documentation of the injured worker's participation in a recent rehabilitation program following a stroke that would support the use of the requested medical equipment. Given the information submitted for review, the medical necessity for the request is not established and the requested neurostimulator is not medically necessary.

Interferential unit: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Page(s): 114, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Interferential Current Stimulation (ICS) Page(s): 118-120.

Decision rationale: Use of an interferential unit is not medically necessary. Per the California MTUS Guidelines, the use of interferential units is not recommended as an isolated intervention. There has been no quality evidence of effectiveness except in conjunction with recommended treatments to include exercise, medicine, and return to work, and there has been limited evidence of improvement on those recommended treatments alone. As there was no documentation of the injured worker's participation in any type of exercise program and the use of an interferential unit is not recommended as an isolated intervention, medical necessity for the request is not established. As such, the request for an interferential unit is not medically necessary.

Multi-stim unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 118-121.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Interferential Current Stimulation (ICS) and TENS, chronic pain (transcutaneous electrical nerve stimulation) Page(s): 114-116 and 118-120.

Decision rationale: Use of a multi-stim unit is not medically necessary. A multiunit is a combination unit of interferential therapy and TENS therapy (transcutaneous electrical nerve stimulation). There is no peer reviewed literature to support the use of a combination unit. The California MTUS Guidelines state that the use of a TENS unit is not recommended as a standalone treatment, but a 1 month home based TENS trial can be considered as a noninvasive conservative option if it is used as an adjunct to a program of evidence based functional restoration. The clinical information submitted does not provide documentation of a failed attempt of the injured worker undergoing a 30 day (or 1 month) TENS home use with documented functional improvement with the use of a TENS unit. Given this information, the medical necessity for the request is not established and the requested multi-stim unit is not medically necessary.

Micro z-unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 120. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation) Page(s): 114-116.

Decision rationale: Use of a micro Z unit is not medically necessary. A micro Z unit is a TENS unit (or a transcutaneous electrical nerve stimulation unit). Per the California MTUS Guidelines, it is not recommended as a primary treatment modality; however, a 1 month home based TENS trial can be considered as a noninvasive conservative option if used as an adjunct to a program of evidence based functional restoration. The clinical information submitted does not provide documentation indicating the injured worker is participating in any type of program of evidence based functional restoration in conjunction with the requested TENS unit. Additionally, there was no documentation of the injured worker having undergone a 1 month home based TENS trial prior to the requested micro Z unit. Given the information submitted for review, medical necessity for the request is not established and the request is not medically necessary.

Aqua relief system: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Guideline Clearinghouse.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg Chapter, Continuous-flow cryotherapy.

Decision rationale: The decision for an aqua relief system is not medically necessary. The California MTUS/ACOEM does not address cold therapy units, or continuous flow cryotherapy units. Per the Official Disability Guidelines, the use of a continuous flow cryotherapy unit is recommended as an option after surgery, but not for nonsurgical treatment. Postoperative treatment is up to 7 days, including home use. It is also noted per the referenced guidelines that

mechanical circulating units or pumps have not been proven to be more effective than passive hot or cold therapy. There was no documentation indicating the injured worker has had a failure of attempts with local application of heat and cold prior to the requested aqua relief system. As there was no indication that the injured worker was in the postoperative setting to warrant a 7 day use of the requested equipment, and the unit is generally recommended for only up to 7 days including home use, medical necessity for the request is not established. As such, the request for an aqua relief system is not medically necessary.

Acupuncture: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: Acupuncture is not medically necessary. Per the California MTUS Acupuncture Guidelines, acupuncture is used as an option when pain medicine is reduced or not tolerated, and it is used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. There is a recommendation for 3 to 6 treatments. With documentation of functional improvement, additional treatments can be recommended. The request as submitted is not specific as to the number of acupuncture treatments being requested. Additionally, there was no indication from the information that the injured worker has had a reduction in his pain medication or that they have not been tolerated. There was also no indication that the injured worker is participating in any type of physical rehabilitation or surgical intervention in conjunction with the requested acupuncture treatment. Given that there was no documentation of the injured worker having a reduction in his pain medication or being intolerant to his medication regimen, and the request as submitted it not specific as to the number of sessions requested, medical necessity has not been established. As such, the request for acupuncture is not medically necessary.

Home therapy: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Page(s): 114, Chronic Pain Treatment Guidelines Page(s): 51. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Home health services, and Physical Medicine Page(s): 51 and 98-99.

Decision rationale: Home therapy is not medically necessary. The clinical information submitted does not provide documentation indicating that the injured worker is unable to participate in an outpatient therapy program. Per the California MTUS Guidelines, home health services are recommended if a patient is home bound on a part time or intermittent basis. It is also generally recommended for up to no more than 35 hours a week. The request as submitted is not specific as to the body part to receive the home therapy service, the number of hours to receive home therapy, and the length of time that therapy is requested. Additionally, there was

no documentation of the injured worker being unable to participate in an outpatient therapy program. Given this information, medical necessity for the request is not established and the request for home therapy is not medically necessary.