

Case Number:	CM14-0198414		
Date Assigned:	12/08/2014	Date of Injury:	07/16/2013
Decision Date:	01/26/2015	UR Denial Date:	10/30/2014
Priority:	Standard	Application Received:	11/25/2014

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 Internal 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 30-year-old server/busboy reported a low back injury with a date of 7/16/13. The mechanism of injury is not described in the available records. Treatment has included medications, chiropractic manipulation and physical therapy. Early status reports indicate that the patient received Norco and Flexeril from 8/9/13 to 1/31/14. A pain management specialist's noted on 1/31/14 states that the patient has lumbar muscle strain, spasm and L5 radiculopathy "recalcitrant chiropractic and physical therapy". An epidural steroid injection was requested, but not documented as performed. There are 3 progress notes in the records from the current primary treater, an orthopedist, dated 7/3/14, 8/21/14 and 9/30/14. All of them document that the patient has low back pain, which increases each visit (5-6/10 to 7-8/10 to 7-9/10). Documented physical findings are minimal and include tenderness and spasm and decreased range of motion of the back which is not recorded in degrees, so it is unclear if it changes with time. All notes list diagnoses of lumbosacral musculoligamentous strain/sprain with radiculitis, lumbosacral spine discogenic disease per the patient's history, and intermittent loss of bowel movement. The latter two notes add the diagnosis of right lumbar radiculopathy, per NCV. The plan on 8/21 includes prescription of physical therapy 2x/week for 6 weeks, Vicodin, and Fluriflex and TGHOT topical creams. On 9/30, the provider notes that "physical therapy helps decrease pain, tenderness and spasm", and that the patient indicates that his function has improved with physical therapy, and that his activities of daily living have improved by 20%. Physical exam findings include paraspinal muscle tenderness, which "has decreased to 2-3 from grade 3" and spasm which "has decreased to 2-4 from grade 3-4". Range of motion is not documented. Plan includes physical therapy for the lumbar spine, twice per week for six weeks. Vicodin 5/300 #60 every 12 hours, Cyclobenzaprine 7.5 mg #60 twice per day, Motrin 600 mg #60 2-3 times per day, Fluriflex 180 gms, and TGHOT 180 gms were also requested. There is a note that topical medications were

prescribed in order to minimize possible neurovascular complications; and to avoid complications associated with the use of narcotic medications, as well as upper GI bleeding from the use of NSAID medications, The patient's work status remains at temporarily totally disabled in all three notes. (The patient does not appear to have worked since his injury.) None of the notes document any specific functions which the patient is or is not capable of performing, nor do they document any functional goals. Urine drug screens are performed on 8/21 and 9/30. The records contain drug screen results from 5/22/14, 9/30/14 and 11/6/14, all of which are negative for hydrocodone, which is not commented on in any progress note. The Vicodin, cyclobenzaprine, ibuprofen, Fluriflex cream and TGHOT cream were all non-certified, and the physical therapy was partially certified in UR on 10/30/14. MTUS Chronic Pain Guidelines were cited for all of the requests. In addition, ODG Pain chapter was cited for cyclobenzaprine, and ODG Low Back chapter was cited for PT.

IMR ISSUES, DECISIONS AND RATIONALES

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

Vicodin 5/300mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for Use of Opioids, Steps to Take Before a Therapeutic Tr.

Decision rationale: Vicodin 5/300 is brand-name hydrocodone 5 mg with acetaminophen 300 mg. Hydrocodone is an opioid analgesic. Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. Opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine if the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. The clinical findings in this case do not demonstrate that any of the above criteria have been met. This patient has been prescribed Vicodin at least intermittently since 8/13. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. The documented diagnoses of radiculitis and radiculopathy would imply that the patient's pain is neuropathic. Neuropathic pain does not necessarily respond well to opioids. No assessment was made of whether or not opioid use was likely to be helpful in this patient, or of his potential for abuse. It is quite concerning that several urine drug screens have been negative for hydrocodone during the past year, which should have raised concerns about diversion. No specific functional goals were set or followed. Most importantly, Vicodin was not discontinued when it became clear that it has not produced any functional improvement. The

patient's status has remained at totally disabled, which implies that he has profound disabilities and inability to do even the lightest sedentary work. Based on the evidence-based guidelines cited above, and the clinical documentation provided for my review, Vicodin 5/300 #60 is not medically necessary.

Cyclobenzaprine 7.5mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Muscle relaxants Page(s): 60,63-66.

Decision rationale: Cyclobenzaprine 7.5 mg is a long-acting form of a sedating muscle relaxant. The most common brand name for its short-acting form is Flexeril, and the long-acting form is usually sold as Fexmid. Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. Per the second reference, non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In most low back pain patients, they show no benefit beyond that of NSAIDs. There is no additional benefit if they are used in combination with NSAIDs. Cyclobenzaprine is only recommended for a short course of therapy, as there is no evidence to support its long-term use. Its greatest effect appears to occur within the first four days of treatment. Side effects include drowsiness, urinary retention, dry mouth and headaches. Its use should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. The clinical documentation in this case does not support the use of cyclobenzaprine. Its prescription clearly extends beyond the four days that it is likely to be effective. It is prescribed with an NSAID, which means it is unlikely to provide additional benefit. Finally, Fexmid is long-acting and sedating, particularly when combined with an opioid such as Vicodin. It actually may make it more difficult for this patient to increase his level of activity and thus interfere with his recovery. Based on the MTUS citations above and on the clinical records provided for my review, cyclobenzaprine 7.5 mg #60 is not medically necessary in this case because there is no evidence to support its long-term use, because it is prescribed in conjunction with an NSAID, and because its side effects may in fact interfere with this patient's recovery.

Motrin 600mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, and NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 60,67-.

Decision rationale: Motrin is brand-name ibuprofen, which is an NSAID. Per the first reference cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. The NSAID references state that NSAIDs are recommended at the lowest dose for the shortest period possible for patients with moderate to severe pain due to osteoarthritis. There is no evidence to recommend one drug over another in terms of efficacy or pain relief. Cardiovascular risk occurs with all NSAIDs, and there is no evidence of long-term effectiveness for pain or function. NSAIDs are recommended as an option for short-term symptomatic relief of chronic low back pain. There is inconsistent evidence to support their use for neuropathic pain. All NSAIDs have the potential to raise blood pressure in susceptible patients. The clinical documentation in this case does not support the provision of Motrin to this patient. It appears to have been started at the same time as cyclobenzaprine, which would make it impossible to distinguish which drug caused any positive or negative effect that occurs. Although the provider has not specified a rationale for the use of Motrin, the most likely one appears to be that it is for chronic low back pain. If that is the case, a less than 30-day supply for short-term relief should have been prescribed. Based on the MTUS citations above and on the clinical documentation provided for my review, Motrin 600 mg #60 is not medically necessary.

FluriFlex Cream 180g #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Topical analgesics Page(s): 60,111-113.

Decision rationale: Fluriflex contains Flurbiprofen 15% and cyclobenzaprine 10%. Flurbiprofen is an NSAID, and cyclobenzaprine is a muscle relaxant. The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second guideline states that topical analgesics 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical Flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Baclofen is not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation in this case does not support the use of Fluriflex cream. The provider's rationale for its use, that it was prescribed "in order to minimize possible neurovascular complications; and to avoid complications associated with the use of narcotic medications, as well as upper GI bleeding from the use of NSAID medications", is ridiculous, since it is being prescribed in conjunction with a narcotic and an oral NSAID. In fact, the cyclobenzaprine in this medication is also being prescribed in oral form. Using this medication means that two medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional

improvement that might result. As discussed above, Flurbiprofen is not FDA-approved for topical use, and there is no evidence to support the use of topical cyclobenzaprine. Based on the MTUS references above and on the clinical documentation provided for my review, Fluriflex cream 180gm is not medically necessary.

TGHot Cream 180g #1: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment, Medications for Chronic Pain, Topical analgesics Page(s): 60,11.

Decision rationale: TGHot cream contains tramadol, gabapentin, menthol, camphor and Capsaicin. Tramadol is an opioid analgesic. Gabapentin is an anti-epileptic drug (AED). Capsaicin is an active component of chili peppers that is used as a topical irritant/analgesic. Menthol is an aromatic topical analgesic. Camphor is an aromatic compound used in anti-itch creams. The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second guideline states that topical analgesics 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support its use. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. There is no evidence supporting formulations which contain over 0.025% Capsaicin. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. The clinical documentation in this case does not support the use of TGHot cream. The provider's rationale for its use, that it was prescribed "in order to minimize possible neurovascular complications; and to avoid complications associated with the use of narcotic medications, as well as upper GI bleeding from the use of NSAID medications", is ridiculous, since it is being prescribed in conjunction with a narcotic and an oral NSAID. The use of this cream means that 5 medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. As discussed above, gabapentin is not recommended for topical use, since there is no evidence to support it. Since the concentration of Capsaicin in this cream is not given, it is not clear whether or not its use is evidence-supported. Based on the MTUS references above and on the clinical documentation provided for my review, TGHot cream 180gm is not medically necessary.

Physical Therapy 2 times a week for 6 weeks Lumbar Spine: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 98-99.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Improvement and Physical Medicine Page(s): 9,98-99.

Decision rationale: Per the first guideline cited above, all therapies should be focused on the goal of functional improvement rather than just pain elimination, and assessment of treatment efficacy is accomplished by reporting functional improvement. The second reference states that passive therapy is for the early phase of treatment. Active therapy is recommended over passive care, with transition to home therapy. A maximum of 9-10 visits over 8 weeks is recommended for myalgia or myositis, and a maximum of 8-10 visits over 4 weeks is recommended for neuralgia, neuritis and radiculitis. The clinical records in this case do not support continuing physical therapy. This patient has already had multiple sessions of physical therapy, and presumably has been instructed in home exercise. No goals for functional improvement are documented anywhere in the records, and there is no documentation of any goals that have been met. The records do not support the provider's statements that the patient has improved with PT. A decrease in tenderness from 3-4 to 2-4 is meaningless, as is a statement that the patient's ADLs have improved by 20% without citing any particular activity as an example. The patient's work status, however, has clearly not improved and remains at totally disabled. There is no documentation as to why this patient would be likely to receive further benefit from PT in addition to that which he has already had, or as to why any such benefits could not be accomplished with home exercise. Based on the MTUS citations above and the clinical documentation provided for my review, 8 additional physical therapy 2times a week for 6 weeks for the lumbar spine are not medically necessary.