

Case Number:	CM14-0194105		
Date Assigned:	12/03/2014	Date of Injury:	07/08/2014
Decision Date:	01/21/2015	UR Denial Date:	11/17/2014
Priority:	Standard	Application Received:	11/19/2014

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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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 is a 49 year old patient with a date of injury of 07/08/2014. Medical records indicate the patient is undergoing treatment for cervical spine sprain/strain, cervical radiculopathy, right shoulder sprain/strain, right shoulder bursitis, AC arthrosis and rule out right shoulder rotator cuff tear. Subjective complaints include burning, radicular neck pain and muscle spasms, pain described as constant and moderate to severe cause numbness and tingling of the bilaterally upper extremities; sharp, burning right shoulder pain, rated at 8-9/10 described as constant and moderate to severe. Objective findings include tenderness to cervical paraspinal muscles, cervical range of motion - flexion 40 degrees, extension 40, left and right rotation 60, left and right lateral flexion 20. The patient has tenderness to palpation of right shoulder AC joint, subacromial space, levator scapula, supraspinatus, infraspinatus and trapezius muscles, right shoulder range of motion - flexion 25, extension 10, abduction 15, adduction 5, external rotation 0, internal rotation 3, supraspinatus on the right is positive; light touch slightly diminished over the C5, C6, C7, C8 and T1 dermatomes in the right upper extremity. MRI of the right shoulder from 09/06/2014 found minimal subacromial and suscapularis bursitis, osteoarthropathy of acromioclavicular joint, no other gross abnormality is noted. Treatment has consisted of physical therapy, shockwave therapy, Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, and Cyclobenzaprine topical and Ketoprofen cream. The utilization review determination was rendered on 11/17/2014 recommending non-certification Retrospective use of Synapryn (DOS 10/19/14), Retrospective use of Deprizine (DOS 10/19/14), Retrospective use of Fanatrex (DOS 10/19/14), Tabradol (DOS 10/19/14), Retrospective use of Ketoprofen Topical Cream 20% (DOS 10/19/14), Retrospective use of Cyclobenzaprine Topical Cream 5% (DOS 10/19/14), Prospective use of Synapryn, Prospective use of Deprizine, Prospective use of Fanatrex,

Prospective use of Tabradol, Prospective use of Ketoprofen Topical Cream 20% and Cyclobenzaprine Topical Cream 5%.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective use of Synapryn (DOS 10/19/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=594bad96-d0e0-4a12-8a38-762962f54a66>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94.

Decision rationale: Synapryn is the liquid version of Tramadol that contains Tramadol, Glucosamine, and "other proprietary ingredients." MTUS states regarding Tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." The treating physician did not provide sufficient documentation that the patient has failed her trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Synapryn prior to the initiation of this medication. While MTUS does state that Synapryn (Tramadol) may be used for neuropathic pain, it is not recommended as a first-line therapy. As such, the retrospective request for Synapryn (DOS 10/19/14) is not medically necessary.

Retrospective use of Deprizine (DOS 10/19/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: Deprizine contains Ranitidine and other proprietary ingredients. Ranitidine is an H2 blocker and like a PPI can be utilized to treat dyspepsia secondary to NSAID therapy. MTUS Chronic Pain Medical Treatment Guidelines states, "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." MTUS also states that, "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or Misoprostol or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient

has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, treatment of dyspepsia secondary to NSAID therapy or other GI risk factors as outlined in MTUS. As such, the retrospective request for Deprizine (DOS 10/19/14) is not medically necessary.

Retrospective use of Fanatrex (DOS 10/19/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fanatrex.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin)

Decision rationale: The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. Official Disability Guidelines states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, Official Disability Guidelines states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain." The treating physician does document neuropathic pain but the treating physician did not document improved functionality and decreased pain after starting Fanatrex. The medical documentation provided does not document functional improvement with the use of Fanatrex. As such, the retrospective request for Fanatrex (DOS 10/19/14) is not medically necessary.

Retrospective use of Tabradol (DOS 10/19/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) and <http://www.drugs.com/cons/fusepaq-tabradol.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Cyclobenzaprine (Flexeril) and Other Medical Treatment Guideline or Medical Evidence: UpToDate, Flexeril

Decision rationale: MTUS Chronic Pain Medical Treatment states for Tabradol (Cyclobenzaprine), "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with

the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" UpToDate, regarding Flexeril, also states "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of Tabradol. Official Disability Guidelines states regarding Cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of Cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with Tabradol, which Official Disability Guidelines recommends against. As such, the retrospective request for Tabradol (DOS 10/19/14) is not medically necessary.

Retrospective use of Ketoprofen Topical Cream 20% (DOS 10/19/14): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

Decision rationale: MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Per Official Disability Guidelines and MTUS, Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis and photosensitization reactions." As such, the retrospective request for Ketoprofen Topical Cream 20% (DOS 10/19/14) is not medically necessary.

Retrospective use of Cyclobenzaprine Topical Cream 5% (DOS 10/19/14): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

Decision rationale: MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical Cyclobenzaprine is not indicated for this usage, per MTUS. As such, the retrospective request for Cyclobenzaprine Topical Cream 5% (DOS 10/19/14) is not medically necessary.

Prospective use of Synapryn: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=594bad96-d0e0-4a12-8a38-762962f54a66>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94.

Decision rationale: Synapryn is the liquid version of Tramadol that contains Tramadol, Glucosamine, and "other proprietary ingredients." MTUS states regarding Tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." The treating physician did not provide sufficient documentation that the patient has failed her trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Synapryn prior to the initiation of this medication. While MTUS does state that Synapryn (Tramadol) may be used for neuropathic pain, it is not recommended as a first-line therapy. The treating physician has not provided documentation of a trial and failure of first line therapy. As such, the request for prospective use of Synapryn is not medically necessary.

Prospective use of Deprizine: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

Decision rationale: Deprizine contains Ranitidine and other proprietary ingredients. Ranitidine is an H2 blocker and like a PPI can be utilized to treat dyspepsia secondary to NSAID therapy. MTUS Chronic Pain Medical Treatment Guidelines states, "Determine if the patient is at risk for

gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." MTUS also states that, "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or Misoprostol or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, treatment of dyspepsia secondary to NSAID therapy or other GI risk factors as outlined in MTUS. As such, the request for prospective use of Deprizine is not medically necessary.

Prospective use of Fanatrex: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fanatrex.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin)

Decision rationale: The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. Official Disability Guidelines states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, Official Disability Guidelines states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain." The treating physician does document neuropathic pain but the treating physician did not document improved functionality and decreased pain after starting Fanatrex. The medical documentation provided does not document functional improvement with the use of Fanatrex. As such, the request for prospective use of Fanatrex is not medically necessary.

Prospective use of Tabradol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) and <http://www.drugs.com/cons/fusepaq-tabradol.html>

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain,

Cyclobenzaprine (Flexeril) and Other Medical Treatment Guideline or Medical Evidence:
UpToDate, Flexeril

Decision rationale: MTUS Chronic Pain Medical Treatment states for Tabradol (Cyclobenzaprine), "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" UpToDate, regarding Flexeril, also recommends "Do not use longer than 2-3 weeks." Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of Tabradol. Official Disability Guidelines states regarding Cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of Cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with Tabradol, which Official Disability Guidelines recommends against. As such, the request for prospective use of Tabradol is not medically necessary.

Prospective use of Ketoprofen Topical Cream 20%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

Decision rationale: MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Per Official Disability Guidelines and MTUS, Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis and photosensitization reactions." As such, the request for prospective use of Ketoprofen Topical Cream 20% is not medically necessary.

Prospective use of Cyclobenzaprine Topical Cream 5%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

Decision rationale: MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical Cyclobenzaprine is not indicated for this usage, per MTUS. As such, the request for Cyclobenzaprine Topical Cream 5% is not medically necessary.