

Case Number:	CM15-0181704		
Date Assigned:	09/23/2015	Date of Injury:	12/19/2002
Decision Date:	11/16/2015	UR Denial Date:	08/29/2015
Priority:	Standard	Application Received:	09/15/2015

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: Emergency Medicine

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 58 year old male, who sustained an industrial injury on 12-19-02. The injured worker was diagnosed as having osteoarthritis unspecified lower extremity; chronic pain; degenerative joint disease right knee; pain in joint lower leg. Treatment to date has included physical therapy; medications. Currently, the PR-2 notes dated 7-23-15 indicated the injured worker complains of right knee - continued and unchanged. The provider documents the pain level as "7-8 out of 10" with a description of symptoms as "moderate" and frequency as "constant". The provider also notes the injured worker reports "Left knee flare-up - The patient reports that the series of left knee Synvisc injections about a year ago helped but the pain has now returned." He notes the pain level as "8-9 out of 10; constant." The provider also notes the injured worker complains of "Bilateral wrists" pain level as "8-9 out of 10; frequent, constant." The injured worker is a status post right knee arthroscopic surgeries with partial meniscectomy twice (2005 and 2007) and is scheduled for right knee surgery in October 2015. The provider also documents x-ray evidence of moderate medial compartment degenerative joint disease (right knee). The notes indicate the injured worker is not working. The provider's treatment plan includes instruction to continue home care assistance 4 hours a day for three days a week for six weeks, medication refill, a replacement TENS unit, series of three left knee Synvisc and bilateral wrist ultrasound cortisone injections. PR-2 note dated 7-30-15 indicates the injured worker complains of "no improvement in right knee pain level 8 out of 10". Objective findings are noted by the provider as "right knee pain with decreased range of motion". PR-2 notes dated 7-2-15 indicates the injured worker complained "no improvement in right knee pain level 8 out of 10".

Objective findings are documented by the provider indicating "right knee pain with extension and flexion". The provider also notes "scheduled for right knee replacement 7-9-15". A Request for Authorization is dated 9-15-15. A Utilization Review letter is dated 8-30-15 and non-certification was for Dulcolax 5mg #60; Amitiza 25mcg #60; TENS unit; 1 series of 3 left knee Synvisc injections 48ml-6ml and 1 cortisone injection to the bilateral carpal tunnels under ultrasound guidance. Utilization Review denied the requested treatment for not meeting the CA MTUS, ACOEM and ODG Guidelines. Utilization Review certified the requested Hydroxyzine 50mg #60. The provider is requesting authorization of Dulcolax 5mg #60; Amitiza 25mcg #60; TENS unit; 1 series of 3 left knee Synvisc injections 48ml-6ml and 1 cortisone injection to the bilateral carpal tunnels under ultrasound guidance.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dulcolax 5mg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation McKay SL, Fravel M, Scanlon C. Management of Constipation. Iowa City (IA); University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p. [44 references].

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)/Opioid-induced constipation treatment.

Decision rationale: The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications do not work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is

different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for noncancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic noncancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug Lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 ml for the treatment of opioid-induced constipation in patients taking opioids for noncancer pain. (FDA, 2014)As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The patient is not known currently to be on a medication in the opioid class. There is also inadequate documentation of an etiology of the patients symptoms or discussion of initial measures undertaken including increasing water and fiber intake. As such, the request is not medically necessary.

Amitiza 25mcg #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation McKay SL, Fravel M, Scanlon C. Management of Constipation. Iowa City (IA); University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2009 Oct. 51 p. [44 references].

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)/Opioid-induced constipation treatment.

Decision rationale: The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in

fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for noncancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic noncancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug Lubiprostone (Amitiza) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 ml for the treatment of opioid-induced constipation in patients taking opioids for noncancer pain. (FDA, 2014)As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The patient is not known currently to be on a medication in the opioid class. There is also inadequate documentation of an etiology of the patient's symptoms or discussion of initial measures undertaken including increasing water and fiber intake. As such, the request is not medically necessary.

TENS unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg (acute & chronic)/TENS.

Decision rationale: The request is for the use of a TENS unit for pain relief. The official disability guidelines state the following regarding this topic: Recommended as an option for patients in a therapeutic exercise program for osteoarthritis as a treatment for pain. The addition of TENS plus exercise appears to produce improved function (greater cumulative knee extensor torque, stride length, gait velocity and range of motion) over those treated with exercise only, although the difference has not been found to be significant. (Philadelphia, 2001) (Hulme-Cochrane, 2002) (Ng, 2003) (Cheing, 2004) (BlueCross BlueShield, 2005) (Osiri, 2000) (Mont, 2006) (Garland, 2007) Transcutaneous electrical nerve stimulation offers clinically relevant short-term pain relief for osteoarthritis of the knee, according to a report in the June 22nd issue

of BMC Musculoskeletal Disorders. (Bjordal, 2007) Transcutaneous electrical nerve stimulation can help with short-term pain control among patients with hip or knee OA. (Zhang, 2008) A 6-week program of progressive strength training targeting the quadriceps femoris muscle group substantially improves strength and function following total knee arthroplasty for treatment of osteoarthritis, compared to patients who received standard of care therapy; however, addition of neuromuscular electrical stimulation (NMES) to the strength training exercise did not improve outcomes. (Pettersen, 2009) There is no conclusive evidence that TENS reduces knee pain or physical disability from osteoarthritis, even with years of clinical use and a plethora of clinical trials, based on a recent Cochrane Review, because the studies had poor methodological quality, inadequate reporting, and small sample size. Treatment responses - however minimal - occurred in 29 of 100 people treated with electrostimulation and in 26 of 100 people who had sham treatments or usual care. (Rutjes, 2009) See also BioniCare knee device. In this case, request for a TENS unit is not medically necessary. This is secondary to the patient already being issued the device. There is inadequate documentation as to why another unit is needed. Pending this discussion, there is no indication for providing another unit.

1 series of 3 left knee Synvisc injections 48ml/6ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Knee and Leg (Acute & Chronic): Synvisc Injections (2015).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & leg (acute & chronic)/hyaluronic acid injections.

Decision rationale: The request is for a hyaluronic acid injection to aid in pain relief. The official disability guidelines state the following regarding this topic: Criteria for Hyaluronic acid injections: Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative nonpharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 3 months. Documented symptomatic severe osteoarthritis of the knee, which may include the following: Bony enlargement; Bony tenderness; Crepitus (noisy, grating sound) on active motion; Less than 30 minutes of morning stiffness; No palpable warmth of synovium; Over 50 years of age. Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease; Failure to adequately respond to aspiration and injection of intra-articular steroids; Generally performed without fluoroscopic or ultrasound guidance; Are not currently candidates for total knee replacement or who have failed previous knee surgery for their arthritis, unless younger patients wanting to delay total knee replacement. (Wen, 2000) Repeat series of injections: If documented significant improvement in symptoms for 6 months or more, and symptoms recur, may be reasonable to do another series. No maximum established by high quality scientific evidence; see Repeat series of injections above. Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, or patellofemoral arthritis, patellofemoral syndrome (patellar knee pain), plantar nerve entrapment syndrome, or for use in joints other than the knee

(e.g., ankle, carpo-metacarpal joint, elbow, hip, metatarso-phalangeal joint, shoulder, and temporomandibular joint) because the effectiveness of hyaluronic acid injections for these indications has not been established. In this case, this treatment is not medically necessary. This is secondary to inadequate pain relief with previous injections. Also, the patient is a candidate for a total knee replacement. For these reasons, the patient does not qualify for a hyaluronic acid injection based on the guidelines.

1 cortisone injection to the bilateral carpal tunnels under ultrasound guidance: Upheld

Claims Administrator guideline: Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Forearm, wrist, hand (acute & chronic)/Injection.

Decision rationale: The request is for a corticosteroid injection to aid in relief of carpal tunnel syndrome. The official disability guidelines state the following regarding this topic: Recommend a single injection as an option in conservative treatment. Corticosteroid injections will likely produce significant short-term benefit, but many patients will experience a recurrence of symptoms within several months after injection. In mild cases wait four to six weeks before consider injection, but sooner in severe cases, given the success of surgery, and the success/predictive value of injections. Therapy decisions should branch based on mild versus severe. Carpal tunnel syndrome may be treated initially with a night splint and medications before injection is considered, except in the case of severe CTS (thenar muscle atrophy and constant paresthesias in the median innervated digits). Outcomes from carpal tunnel surgery justify prompt referral for surgery in moderate to severe cases. Nevertheless, surgery should not be performed until the diagnosis of CTS is confirmed by history, physical examination and possible electrodiagnostic studies. Symptomatic relief from a cortisone/anesthetic injection will facilitate the diagnosis, however the benefit from these injections although good is short-lived. (Various references listed under "Injections") (Marshall-Cochrane, 2002) (AHRQ, 2003) (Armstrong, 2004) (Goodyear-Smith, 2004) (Gerritsen, 2002) (Sevim, 2004) (Aygul, 2005) (Gokoglu, 2005) (Agarwal, 2005) (Dammers, 2005) (Ucan, 2006) Steroid injections and wrist splinting may be effective for relief of CTS symptoms but have a long-term effect in only some patients. Symptom duration of less than 3 months and absence of sensory impairment at presentation are predictive of an improved response to conservative treatment. Selected patients (i.e., with no thenar wasting or obvious underlying cause) presenting with mild to moderate carpal tunnel syndrome may receive either a steroid injection or wear a night wrist splint for 3 weeks. This will allow identification of the patients who respond well to conservative therapy and may not need surgery. (Graham, 2004) A recent clinical trial found that, at 3 months of follow-up, 94.0% of the wrists in the steroid injection group showed improvement; at 6 months 85.5% showed improvement, and at 12 months 69.9% showed improvement. Over the short term, local steroid injection was better than surgical decompression for the symptomatic relief of CTS, but at 1 year, local steroid injection was slightly less effective compared to surgical decompression (but about "as effective"). (Ly-Pen, 2005) Compared with steroid injection, open carpal tunnel release resulted in better symptomatic and neurophysiologic outcome but not grip strength in patients with idiopathic carpal tunnel syndrome over a 20-week period. (Hui, 2005)

Local corticosteroid injections provide good symptom relief for CTS for one-month vs. placebo (number needed to treat, 2). (Stephens, 2008) This systematic review found that the usefulness of steroid injections as initial treatment for improving CTS symptoms is still supported by the recent literature, but these effects are temporary. (Bernardino, 2011) In this case, this treatment is not indicated. This is secondary to inadequate documentation of conservative therapy including a night splint and medication with failure seen. As such, the request is not medically necessary.