

Case Number:	CM14-0172876		
Date Assigned:	10/23/2014	Date of Injury:	09/10/2002
Decision Date:	11/25/2014	UR Denial Date:	10/07/2014
Priority:	Standard	Application Received:	10/20/2014

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 Family Medicine, and is licensed to practice in North Carolina. 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:

The patient is a 58-year-old with a reported date of injury of 09/10/2002. The patient has the diagnoses of lumbar stenosis and multilevel discogenic pain, status post bilateral total knee arthroplasties, left leg laceration, left arm contusion, right elbow strain, chronic pain and insomnia. . Per the most recent progress notes provided for review from the primary treating physician dated 09/16/2014, the patient had complaints of achy upper back pain, achy low back pain, achy right arm pain and bilateral knee pain. The physical exam noted tenderness in the thoracic and lumbar paraspinal muscles with spasm, decreased sensation in the L5 and L4 dermatomes bilaterally and decreased range of motion. The knee exam noted left knee joint line tenderness. The treatment plan recommendations included Toradol injection and medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

One prescription of Cartivisc 500/200/150mg #90 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate). Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back-Lumbar & Thoracic (acute & chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines glucosamine Page(s): 50.

Decision rationale: The California chronic pain medical treatment guidelines section on glucosamine states: Glucosamine (and Chondroitin Sulfate) Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, double-blind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the [REDACTED] concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. Differences in results originate from the differences in products, study design and study populations. Symptomatic efficacy described in multiple studies performed with glucosamine sulphate (GS) support continued consideration in the OA therapeutic armamentarium. Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets. (Reginster, 2007) [Note: DONA Glucosamine Sulfate is the original crystalline glucosamine sulfate (GS), which was first developed and marketed for human use by [REDACTED], funding some of the initial trials. Glucosamine hydrochloride (GH) is not proprietary, so it tends to be less expensive but there has also been less funding for quality studies.] Recent research: This RCT assessed radiographic outcomes in OA of the knee in patients being treated with glucosamine hydrochloride (note: GH not GS), chondroitin sulfate (CS), glucosamine plus CS, celecoxib, or placebo. Over 2 years, no treatment achieved the predefined clinically important difference from placebo in terms of joint space width (JSW) loss. The effect of the combination of glucosamine plus CS may be less active than the effect of each treatment singly. Kellgren/Lawrence (K/L) grade 2 knees may represent a more potentially responsive population. Treatment effects on K/L grade 2 knees (less severe OA), but not on K/L grade 3 knees (more severe), showed a trend toward improvement relative to the placebo group. (Sawitzke, 2008) The requested medication is a nutritional supplement containing glucosamine, chondroitin and MSM. While the use of glucosamine sulfate and chondroitin are recommended

per the California MTUS, there is no such recommendation for the use of methylsulfonylmethane. There is no indication why the patient would need this component and not take simple glucosamine/chondroitin. Therefore the request is not certified.

One prescription of Hydrocodone/APAP 10/325mg #60 with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids (a) If the patient has returned to work (b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function while on the medication. There is no evidence of failure of other conservative treatment modalities and other first line choices for chronic pain.

There is no documentation of significant improvement in VAS scores while on the medication. For these reasons criteria for ongoing and continued use of the medication have not been met. Therefore the request is not certified.

One prescription of Ambien 10mg #30 with 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ambien

Decision rationale: The California MTUS and the ACOEM do not specifically address the requested medication. PER the ODG:Zolpidem is a prescription short-acting non-benzodiazepine hypnotic approved for the short-term treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain. While sleeping pills, so-called minor tranquilizers and anti-anxiety medications are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. There is also concern that they may increase pain and depression over the long-term. The medication is not intended for use greater than 6 weeks. There is no notation or rationale given for longer use in the provided progress reports. For these reasons the request is not certified.

One intramuscular injection of Toradol: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ketorolac (Toradol, generic available). Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ketorolac

Decision rationale: The California chronic pain medical treatment guidelines section on Ketorolac states:Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: This medication is not indicated for minor or chronic painful conditions.Per the ODG:Only recommended for short-term in management of moderately severe acute pain that requires analgesia at the opioid level.In this case, the documentation does not indicate acute pain treatment but rather than the treatment of a chronic pain condition. In the absence of acute pain treatment, the medication is not indicated per the California MTUS and the ODG. Therefore the request is not certified.