

Case Number:	CM15-0202155		
Date Assigned:	10/21/2015	Date of Injury:	01/02/2007
Decision Date:	12/30/2015	UR Denial Date:	09/30/2015
Priority:	Standard	Application Received:	10/14/2015

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, Texas, Florida

Certification(s)/Specialty: Anesthesiology, Pain Management, Hospice & Palliative 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:

This injured worker is a 64 year old male, who sustained an industrial injury on 01-02-2007. The injured worker was diagnosed as having accidental poisoning by other metals and their compounds and fumes, and degenerative joint disease-left hip replacement revision. On medical records dated 08-26-2015, 09-18-2015 and 09-01-2015, the subjective complaints were noted as left hip, left shoulder and pain in his right knee. The injured worker was noted to have a second opinion for hip replacement, and several lab test and specialist in regards to Cobalt poisoning. Per documentation the implanted hip in 08-2007 was recalled and apparently leaked Cobalt. Objective findings were noted as lumbar area back tenderness to paraspinal muscles lumbar area, stiff on range of motion and left hip with prosthesis. Treatments to date included left hip prosthesis 05-04-2015 and medication. Per documentation the laboratory studies were performed on 02-14-2013 revealed Cobalt blood 6.2 mcg- urine 52.1 mcg-L and 09-16-2013 Cobalt blood 4.8 mcg-L-urine 79.2 mcg-L Chromium 1.6- L and 09-2-2014 Cobalt blood 6.1 mcg-L- urine 90.7: Chromium 3.1 mcg-L. Per documentation the injured worker was noted to require dental prophylaxis to prevent left hip infection. Current medication was not listed on 08-26-2015. The Utilization Review (UR) was dated 09-30-2015. A Request for Authorization was submitted. The UR submitted for this medical review indicated that the request for Amoxicillin 500mg#20, acupuncture to the left hip , Quantity 8 , lab testing :serum chromium and lab testing: serum Cobalt was non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amoxicillin 500mg #20: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.uptodate.com; www.ada.org.

Decision rationale: Regarding the request for Amoxicillin 500mg #20, MTUS and ODG do not address the issue. Uptodate states: "Patients with prosthetic joints do not require antibiotic therapy prior to dental procedures. Although antibiotics were commonly given in the past in such circumstances, the American Academy of Oral Medicine, the American Dental Association, the American Academy of Orthopedic Surgery, and the British Society for Antimicrobial Chemotherapy all advise against the routine use of antibiotics prior to teeth cleaning, teeth scaling, or routine procedures such as filling of a dental cavity. However, active dental infections in patients with prosthetic joints should be treated promptly, and good oral hygiene should be maintained." And the American Dental Association article on "The use of prophylactic antibiotics prior to dental procedures in patients with prosthetic joints" states "The 2014 Panel made the following clinical recommendation: In general, for patients with prosthetic joint implants, prophylactic antibiotics are not recommended prior to dental procedures to prevent prosthetic joint infection. The practitioner and patient should consider possible clinical circumstances that may suggest the presence of a significant medical risk in providing dental care without antibiotic prophylaxis, as well as the known risks of frequent or widespread antibiotic use. As part of the evidence-based approach to care, this clinical recommendation should be integrated with the practitioner's professional judgment and the patient's needs and preferences.]" Within the documentation available for review, the request is for 2 pills of 500mg amoxicillin to be taken 2 hours before a dental procedure because the patient has a prosthetic joint. However the request is for #20 pills, this would exceed then number needed for one dental procedure and there is no mention of when the other nine dental procedures would take place, so that they would take place before the medicine expired and unfortunately, there is no provision to modify the current request. Furthermore, as mentioned above, the use of antibiotics before dental procedures for patients with prosthetic joints is no longer recommended in the literature. In light of these issues, the currently requested Amoxicillin 500mg #20 is not medically necessary.

Acupuncture to the left hip, quantity 8: Upheld

Claims Administrator guideline: Decision based on MTUS Acupuncture Treatment 2007.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment 2007.

Decision rationale: Regarding the request for Acupuncture to the left hip, quantity 8, California MTUS does support the use of acupuncture for chronic pain. Acupuncture is recommended to be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Additional use is supported when there is functional improvement documented, which

is defined as "either a clinically significant improvement in activities of daily living or a reduction in work restrictions" and a reduction in the dependency on continued medical treatment." A trial of up to 6 sessions is recommended, with up to 24 total sessions supported when there is ongoing evidence of functional improvement. Within the documentation available for review, it is unclear what current concurrent rehabilitative exercises will be used alongside the requested acupuncture. Additionally, the current request for a visit exceeds the 6 visit trial recommended by guidelines. Unfortunately, there is no provision to modify the current request. Finally, it appears the patient might have undergone acupuncture previously. It is unclear how many sessions have previously been provided. Also, there is no documentation of objective functional improvement from the therapy, if already provided. As such, the currently requested Acupuncture to the left hip, quantity 8 is not medically necessary.

Lab testing: Serum Chromium: Upheld

Claims Administrator guideline: Decision based on MTUS General Approaches 2004, Section(s): Cornerstones of Disability Prevention and Management.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.mayomedicallaboratories.com; Aviation, Space and Environmental Medicine. 2013: 84:242-245.; www.atsdr.cdc.gov;

Decision rationale: Regarding the request for Lab testing: Serum Chromium, California MTUS does not address the issue. ODG also does not address the issue. The CDC states "the mean levels of chromium in serum and urine are 0.10-0.16 and 0.22 g/L, respectively." Mayo medical laboratories state "elevated chromium and cobalt concentrations may indicate implant wear, but they are not indications of toxicity. Chromium+3 compounds are not considered a health hazard, while the toxicity and carcinogenic properties of chromium+6 are well known." A key point to note is that chromium+3 is not toxic, and that only chromium+3 is released from orthopedic implants. A number of Internet blogs and Web sites rely on the experience with chromium+6 exposure from the electroplating industry to make comments on the toxicity of chromium from hip implant deterioration; it is inappropriate, however, to make that comparison because chromium+6 is not released during implant wear." Sotos states "Although chromium can affect mood, and rises in tandem with cobalt in patients with metal-on-metal hips, the neurological presentation in the arthroprosthetic cases has generally been attributed to cobalt because of similar presentations in classic cobaltism cases where chromium exposure was not present" The inherent limitations of case reports are well known. As a recently-described illness of unknown prevalence, evidence-based guidelines cannot yet be formulated for arthroprosthetic cobaltism. To address these uncertainties, the US Food and Drug Administration recently ordered all manufacturers of metal-on-metal hip prostheses to conduct formal post-marketing studies of these joints, to determine the frequency and magnitude of systemic and periprosthetic complications related to metal-on-metal hips." Arthroprosthetic cobaltism is easily and inexpensively ruled out by simple measurement of serum cobalt levels. The clinical experience to date has been that normal serum cobalt levels rule out cobaltism. Unfortunately, an abnormally high cobalt level raises questions that cannot be answered in a rigorous, evidence-based way." Within the documentation available for review, the patient has had chromium levels checked multiple times in the past and they have all been elevated. However, current research does not point to chromium being a cause of problems from joint replacements. In light of the above issues, the currently requested Lab testing: Serum Chromium is not medically necessary.

Lab testing: Serum Cobalt: Upheld

Claims Administrator guideline: Decision based on MTUS General Approaches 2004, Section(s): Cornerstones of Disability Prevention and Management.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.mayomedicallaboratories.com; Aviation, Space and Environmental Medicine. 2013; 84:242-245.; www.schmidtlaw.com www.osha.gov; www.cdc.gov.

Decision rationale: Regarding the request for Lab testing: Serum Cobalt, California MTUS does not address the issue. ODG also does not address the issue. OSHA states "Cobalt does not accumulate in the body and is mainly excreted in urine. Measures of cobalt in blood and urine are indicative of recent exposures (Lauwerys and Lison 1994)." The CDC states Cobalt levels in the united states are 0.37 (0.35-0.40) mcg/L in the urine. Legal sites state "If the cobalt levels reach 1.9 micrograms per deciliter of blood, a doctor will likely recommend that the metal hip replacement should be removed. Patients who have the source of cobalt poisoning removed from their body often have normal cobalt levels within 6 months. However, if the cobalt poisoning was ongoing or severe, the patient may have permanent disability, bone loss, tissue death, or other severe side effects." Mayo medical laboratories state "Several case reports of patients with MoM implants suggest a relationship between high serum cobalt and nonspecific neurologic manifestations (fatigue, ataxia, cognitive function decline). However, no case control studies confirm such relationships. There is no definitive proof that high serum cobalt associated with MoM wear either causes toxicity or is benign. Large population studies are underway; more definitive information will evolve over the next few years." Sotos states "The inherent limitations of case reports are well known. As a recently-described illness of unknown prevalence, evidence-based guidelines cannot yet be formulated for arthroprosthetic cobaltism. To address these uncertainties, the US Food and Drug Administration recently ordered all manufacturers of metal-on-metal hip prostheses to conduct formal post-marketing studies of these joints, to determine the frequency and magnitude of systemic and periprosthetic complications related to metal-on-metal hips." Arthroprosthetic cobaltism is easily and inexpensively ruled out by simple measurement of serum cobalt levels. The clinical experience to date has been that normal serum cobalt levels rule out cobaltism. Unfortunately, an abnormally high cobalt level raises questions that cannot be answered in a rigorous, evidence-based way." Within the documentation available for review, the patient has had cobalt levels checked multiple times in the past and they have all been elevated. However, patient had the left hip replaced on 5/14/15. No cobalt lab values were available for review after surgery and it has been more than 6 months from surgery. Yet the patient does not complain of any symptoms of cobaltism after surgery and multiple documentation states that the patient is doing very well and is on no medication. It is unclear what decision making will be done based off any cobalt level given the patient's current symptoms and the medical literature. In light of the above issues, the currently requested Lab testing: Serum Cobalt is not medically necessary.