

Case Number:	CM15-0005808		
Date Assigned:	01/20/2015	Date of Injury:	07/17/2013
Decision Date:	04/01/2015	UR Denial Date:	12/30/2014
Priority:	Standard	Application Received:	01/12/2015

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: Maryland, Virginia, North Carolina
 Certification(s)/Specialty: Plastic Surgery

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 49-year-old female, who sustained an industrial injury on 1/17/2013. She has reported multiple complaints after a motor vehicle accident (MVA) including headaches, neck and back pain that radiate to shoulders and arms, and pain in the right chest near the area of the seat belt. The diagnoses have included cervical strain/sprain, bilateral shoulder strain/bursitis/tendinitis, back stain at approximately T8, lumbar strain/strain, left knee contusion, claimed displaced right breast implant secondary to MVA, and possible bilateral radial tunnel syndrome. Treatment to date has included Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), therapy, acupuncture, and therapeutic injection. Currently, the IW was with multiple complaints including right breast pain and changes in the right breast not previously present. Per the PR-2 dated 12/3/14, Magnetic Resonance Imaging (MRI) revealed bilateral capsular contractures of the breast, baker stage three (III): due probably to the surgery breast augmentation, possible worsening after the accident. On 12/30/2014 the Utilization Review non-certified pre-operative medical clearance (including laboratory Complete Blood Count (CBC), Urinary Analysis, electrocardiogram (EKG), PT/PTT), Keflex, Vicodin, and bilateral capsulectomy of the breast and bilateral removal and replacement of implants, noting the Magnetic Resonance Imaging (MRI) results from 9/16/14, were insufficient to support medical necessity. The MTUS, ACOEM Guidelines, and ODG did not address the surgical request. Alternate guidelines referenced included published abstracts, however, MTUS guidelines were cited for the medications requested. On 1/12/2015, the injured worker submitted an application for IMR for review of pre-operative medical clearance (including laboratory Complete Blood Count (CBC),

Urinary Analysis, electrocardiogram (EKG), PT/PTT), Keflex, Vicodin, and bilateral capsulectomy of the breast and bilateral removal and replacement of implants. The patient is noted to have a history of anemia.

IMR ISSUES, DECISIONS AND RATIONALES

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

Bilateral capsulectomy of the breast: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information, Guidelines and Indications for Breast Implant Capsulectomy.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation William P. Adams MD Capsular Contracture: What is It?, What Causes It?, How Can It Be Prevented and Managed?, Clinics in Plastic Surgery, Volume 36, Issue 1, Pages 119-126, Copyright © 2008.

Decision rationale: The patient is a 49-year-old female who had undergone augmentation mammoplasty in 2006 who was involved in a motor vehicle accident 7/17/13 who complained of pain in the right breast as well as displacement of the breast following the accident. Her pain was noted to affect her daily function. An MRI was performed on 9/16/14 that did not show an abnormality. The patient was noted to have Grade III capsular contracture associated with the original surgery, possibly worsening after the accident. Examination noted that the breasts are hard and tender, with the right side more ptotic. Recommendation was made for bilateral capsulectomy and implant exchange. From the reference, treatment of an established capsular contracture typically involves the gold standard of a total capsulectomy removing the entire affected capsule and implant. The majority of capsular contractures occur in the first year postimplantation. The timing of treatment for an early capsular contracture should allow enough time for the process to reach a homeostasis where there is not an ongoing progression in the contracture. Generally 6 to 9 months from the time of diagnosis is adequate for an early capsular contracture. Due to known issues with biofilms, which are extremely hard to eradicate from the silicone elastomer of the implant, it is advisable to use a new implant in the affected breast when treating the capsular contracture. The patient has a well-documented significant capsular contracture associated with pain and right breast displacement/ptosis/asymmetry. There is no way to determine the exact effect of her trauma on this occurrence, without an evaluation just prior to the accident. However, trauma to the chest can cause implant displacement and possibly implant rupture. It can also cause a hematoma that is associated with a greater risk of capsular contracture. Although the MRI did not show evidence of a hematoma, this study was performed over a year following her initial injury. Thus, there is no way to know for sure the exact effects of the trauma. However, the patient has a known painful significant capsular contracture and standard of care dictates open capsulectomy and implant exchange as outlined from the reference. Thus bilateral capsulectomy of the breast should be considered medically necessary.

Bilateral removal and replacement of breast implants: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Center for Biotechnology Information, The reoperation cascade after breast augmentation with implants: what the patient needs to know.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation William P. Adams MD Capsular Contracture: What is It? What Causes It? How Can It Be Prevented and Managed?, Clinics in Plastic Surgery, Volume 36, Issue 1, Pages 119-126, Copyright © 2008.

Decision rationale: The patient is a 49-year-old female who had undergone augmentation mammoplasty in 2006 who was involved in a motor vehicle accident 7/17/13 who complained of pain in the right breast as well as displacement of the breast following the accident. Her pain was noted to affect her daily function. An MRI was performed that did not show an abnormality. The patient was noted to have Grade III capsular contracture associated with the original surgery, possibly worsening after the accident. Examination noted that the breasts are hard and tender, with the right side more ptotic. Recommendation was made for bilateral capsulectomy and implant exchange. From the reference, treatment of an established capsular contracture typically involves the gold standard of a total capsulectomy removing the entire affected capsule and implant. The majority of capsular contractures occur in the first year post implantation. The timing of treatment for an early capsular contracture should allow enough time for the process to reach a homeostasis where there is not an ongoing progression in the contracture. Generally 6 to 9 months from the time of diagnosis is adequate for an early capsular contracture. Due to known issues with biofilms, which are extremely hard to eradicate from the silicone elastomer of the implant, it is advisable to use a new implant in the affected breast when treating the capsular contracture. The patient has a well-documented significant capsular contracture associated with pain and right breast displacement/ptosis/asymmetry. There is no way to determine the exact effect of her trauma on this occurrence, without an evaluation just prior to the accident. However, trauma to the chest can cause implant displacement and possibly implant rupture. It can also cause a hematoma that is associated with a greater risk of capsular contracture. Although the MRI did not show evidence of a hematoma, this study was performed over a year following her initial injury. Thus, there is no way to know for sure the exact effects of the trauma. However, the patient has a known painful significant capsular contracture and standard of care dictates open capsulectomy and implant exchange as outlined from the reference. Thus, bilateral removal and replacement of the implants should be considered medically necessary.

Pre op lab/ CBC: Overturned

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 Low back pain, Preoperative testing.

Decision rationale: The patient is a 49 year old who is determined to have medically necessary breast surgery. She has been documented to have a history of anemia and thus, a laboratory

study to assess this is reasonable. A CBC should be considered medically necessary. From ODG, Preoperative additional tests are excessively ordered, even for young patients with low surgical risk, with little or no interference in perioperative management. Laboratory tests, besides generating high and unnecessary costs, are not good standardized screening instruments for diseases. The decision to order preoperative tests should be guided by the patient's clinical history, comorbidities, and physical examination findings. Preoperative routine tests are appropriate if patients with abnormal tests will have a preoperative modified approach (i.e., new tests ordered, referral to a specialist or surgery postponement). Testing should generally be done to confirm a clinical impression, and tests should affect the course of treatment. (Feely, 2013) (Sousa, 2013) Criteria for Preoperative lab testing: A complete blood count is indicated for patients with diseases that increase the risk of anemia or patients in whom significant perioperative blood loss is anticipated. The patient is noted to have a history of anemia and thus a CBC can further evaluate this consistent with ODG guidelines and should be considered medically necessary.

Pre op urinalysis: Overturned

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 ODG, Low back pain, Preoperative testing.

Decision rationale: The patient is a 49 year old who is determined to have medically necessary breast surgery. The patient will have breast implants placed. Thus, a urinalysis should be considered medically necessary based on ODG guidelines as the patient will have foreign material (implant) placed. From ODG, Preoperative additional tests are excessively ordered, even for young patients with low surgical risk, with little or no interference in perioperative management. Laboratory tests, besides generating high and unnecessary costs, are not good standardized screening instruments for diseases. The decision to order preoperative tests should be guided by the patient's clinical history, comorbidities, and physical examination findings. Preoperative routine tests are appropriate if patients with abnormal tests will have a preoperative modified approach (i.e., new tests ordered, referral to a specialist or surgery postponement). Testing should generally be done to confirm a clinical impression, and tests should affect the course of treatment. (Feely, 2013) (Sousa, 2013) Criteria for Preoperative lab testing: Preoperative urinalysis is recommended for patients undergoing invasive urologic procedures and those undergoing implantation of foreign material.

Pre op EKG: 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 ODG, Preoperative electrocardiogram (ECG).

Decision rationale: The patient is a 49-year-old female who was noted to have medically necessary breast procedures. From the above guidelines, With respect to an EKG, from ODG, Preoperative electrocardiogram (ECG): Recommended for patients undergoing high-risk surgery and those undergoing intermediate-risk surgery who have additional risk factors. Patients undergoing low-risk surgery do not require electrocardiography. Patients with signs or symptoms of active cardiovascular disease should be evaluated with appropriate testing, regardless of their preoperative status. Preoperative ECGs in patients without known risk factors for coronary disease, regardless of age, may not be necessary. Preoperative and postoperative resting 12-lead ECGs are not indicated in asymptomatic persons undergoing low-risk surgical procedures. Low risk procedures (with reported cardiac risk generally less than 1%) include endoscopic procedures; superficial procedures; cataract surgery; breast surgery; & ambulatory surgery. An ECG within 30 days of surgery is adequate for those with stable disease in whom a preoperative ECG is indicated. (Fleisher, 2008) (Feely, 2013) (Sousa, 2013) There has been insufficient document to suggest the patient has signs or symptoms of active cardiovascular disease. The planned procedure is breast surgery and thus based on the guidelines EKG should not be considered medically necessary.

Pre op PT/PTT: 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 ODG, Low back pain, Preoperative testing.

Decision rationale: From ODG, low back pain, preoperative lab testing: Coagulation studies are reserved for patients with a history of bleeding or medical conditions that predispose them to bleeding, and for those taking anticoagulants. There is insufficient documentation that there is a history of bleeding or medical condition that predisposes the patient to bleeding. Thus, coagulation studies should not be considered medically necessary.

Keflex, unspecified dosage and qty: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation The Role of Postoperative Antibiotics in Reducing Biofilm-Related Capsular Contracture in Augmentation Mammoplasty Mirzabeigi, Michael N.; Sbitany, Hani; Jandali, Shareef; Serletti, Joseph M. Plastic & Reconstructive Surgery. 128(1):34e-35e, July 2011.

Decision rationale: The patient is a 49-year-old female who was noted to have medically necessary breast procedures that included placement of an implant. Antibiotics following this procedure is reasonable, (even though the reference suggests there may not be a need, this is not settled in the literature.) However, the exact dosing and amounts were not provided. Therefore,

the request should not be considered medically necessary. From the reference, In summary, our retrospective clinical information yielded no signs that administration of postoperative antibiotics for 3 days was effective in reducing capsular contracture (i.e., biofilms). However, we are recommending further study of postoperative prophylaxis and biofilms.

Vicodin, unspecified dosage and qty: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78-80, 91 & 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, initiating therapy Page(s): 77.

Decision rationale: Bilateral breast surgery was considered medically necessary and thus, acute surgical pain is reasonable to expect and treat. Although from the chronic treatment guidelines, initiating opioid therapy in an acute setting can be considered similarly. From page 77, Initiating Therapy (a) Intermittent pain: Start with a short-acting opioid trying one medication at a time. Although Vicodin would be consistent with this, there were no dosing or amounts documented and thus Vicodin as written should not be considered medically necessary.