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Notice of Independent Review Decision

IRO REVIEWER REPORT TEMPLATE –WC

April 19, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Removal of intact mammary implant; mammoplasty augmentation with implant, acellular dermal matrix implant, and open periprosthetic capsulotomy breast to the right breast

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Board Certified Plastic Surgeon**

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female who on xx/xx/xx, was lifting and moving boxes at work when she experienced a tear/pull in her right breast.

PRE-INJURY RECORDS: On March 23, 2005, plastic surgeon, noted that the patient had a history of bilateral micromastia. He performed bilateral retropectoral augmentation mammoplasty via the inframammary approach.

From 2006 through 2011, there are no records available.

POST-INJURY RECORDS

2012: On January 9, 2012, the patient was seen for the injury that she sustained on xx/xx/xx, to her right breast while moving boxes. She complained of hurting in her right breast with constant, sharp, stabbing and burning pain. Examination revealed tenderness in the outer lower quadrant of the right breast with crepitus on palpation. The patient was a known smoker and allergic to Keflex and sulfa. diagnosed chest wall strain, recommended ice application and referred the patient to a plastic surgeon for further evaluation and treatment.

On January 11, 2012, a plastic and reconstructive surgeon, noted complaints of tearing and pulling pain in the right lower breast and asymmetry of the right breast with right breast lower than left. also noted that the patient had breast augmentation with saline subpectoral inframammary fold incision. Comprehensive breast examination with chaperone included positive findings of right inframammary fold 1 cm lower than left. believed that the patient's right inframammary fold had broken through as a result of her work injury resulting in asymmetry and a weak right inframammary fold. Diagnosis was mechanical complication prosthesis. He discussed non-operative options of supporting the right inframammary fold with taping and with an underwire bra versus surgical options of repair of right inframammary fold. He recommended re-evaluation after a month to stabilize the inframammary fold.

On January 24, 2012, re-evaluated the patient for swelling of her breast which she reportedly had developed a day after the injury and some bruising which had gradually diminished. The patient had been given Soma with slight improvement

in pain, but she did have pain when she touched her breast. The patient denied any shortness of breath after the injury. On examination, noted bilateral breast asymmetry, grade II capsular contracture of her breast implant with the left being greater than the right and some implant displacement. There were no true palpable breast masses, nipple discharge or axillary adenopathy. assessed bilateral breast asymmetry status post augmentation-mammoplasty. He stated that the patient did have some residual capsular contracture and breast asymmetry, which she stated occurred after the injury. He discussed surgical options for correction of her breast asymmetry including repositioning of the implants, closure of the capsule, open capsulotomy and possible removal and replacement of implants with silicone gel filled implants. He also gave her a copy of American Society of Plastic and Reconstructive Surgeons (ASPRS) pamphlet regarding augmentation mammoplasty as well as a Mentor pamphlet regarding silicone gel filled implants. The patient was to think over this and if she would like to proceed with surgery, then she should go back to her surgeon who accepted Workers Compensation insurance. He also advised the patient to gently massage her breast on a daily basis and take ibuprofen for pain and Soma for muscle spasms.

On February 1, 2012, noted the patient reported that she was worse. She had been wearing the underwire bra consistently. She was interested in surgical repair. She wanted to perform the surgery for reasons of continuity of care. On examination, there was a right inframammary fold 1.0-1.5 cm lower than the left, right appeared actually slightly worse than previous visit, right breast harder indicating developing capsular contracture and a palpable right breast implant. assessed right inframammary fold tear with resultant breast asymmetry, loss of integrity of right inframammary fold and palpable right implant. He recommended removing and replacing both implants and suggested silicone gel to reduce palpability, scar capsule excision and repair of right inframammary fold. He requested the patient's primary surgeon to perform the re-operative surgery, as this was a complicated procedure and out of scope of care and expertise.

Per utilization review dated February 14, 2012, the request for open repair of right inframammary fold and bilateral removal of breast implants was denied. There was no documentation of any conservative treatment. The request was not medically reasonable and necessary and therefore was not authorized.

On April 30, 2012, performed a peer review and noted the following. *“Explanation offered in one of the appeal letters indicated that in this case, it was not supported that a lifting injury such as described as was likely to change the position of the inframammary fold for implants placed seven years previously. He further indicated that implants placed seven years prior would have an established capsule which would not likely be ruptured or affected by a muscle strain. Furthermore, he reported that bilateral removal of the implants with capsulectomies and replacement of the implants was not medically necessary as there was no imaging documentation of implant injury or rupture in the medical records that supported the diagnosis. Furthermore, the injury was confined to only the right breast in this case. Given these issues, medical necessity of this*

request for surgical intervention was not established. He referenced as it related to breast augmentation and implants. also quoted concerning the differences between cosmetic and reconstructive surgery on the breast. An extensive review of considerations for the medical necessity to remove a breast implant was reviewed and these included extrusion of the implant through the breast skin, implants complicated by recurrent infections, implants with Baker IV contracture and associated severe pain, implants with severe contractures that interfered with mammography, intra or extracapsular rupture of silicone gel filled implants and remnant breast cancer or cancer in the contralateral breast. None of these conditions applied to this patient.” agreed with all of conclusion except for the inability of a seven-year breast capsule scar to tear. He diagnosed right pectoral muscle tear/strain secondary to lifting injury on xx/xx/xx, and right breast periprosthetic capsular tissue tear interrupting integrity of the right breast inframammary fold causing inferior migration of saline implant and breast asymmetry.

In response to the questions, opined as follows: (1) The patient more likely than not sustained a right breast pectoralis muscle tear/strain and possibly a periprosthetic capsular tear of the right breast which might have caused disruption of the inferior breast fold resulting in a progressive lowering of the right inframammary fold secondary to the weight of the breast implant. Although very rare, it was known that capsular tears could occur many years after the primary augmentation surgery with certain activities such as gym, other athletic workouts, weightlifting and even certain aerobic poses. With this in consideration, lifting a box which utilized the pectoralis musculature especially in over the shoulder maneuvers could cause tears of the pectoralis muscle and/or the periprosthetic capsule tissue. The mechanism of injury was consistent with these injuries. The patient's symptoms, complaints and physical findings were proximate in timing to the causative event. Right pectoral muscle strain was consistent with the injury or event. While the injury would potentially cause a periprosthetic tear, a magnetic resonance imaging (MRI) of the right breast tissue to objectify signs of recent injury including muscle tear, periprosthetic capsular tear, implant failure, hematoma, seroma, edema and any other findings was indicated. If there were no acute findings of trauma found on the MRI, then the cause of breast asymmetries would not be caused by the alleged injury, but would be associated with other etiologies. Therefore, an MRI of the right breast tissue was indicated and the results of this objective study would definitely assess in determining causation. (2) If there was a confirmed compensable injury of a tear in the right breast inframammary fold documented on the MRI study, the indicated treatment would be a surgical procedure to elevate the fold back into its pre-injury “normal” position. Removal of the existing saline implant was not indicated, however, the standard of care stated that the surgeon have an exact replica of the existing implant in the operating room at the time of the procedure in case anything unexpectedly should happen to the existing implant at surgery. Additional capsule work on the breast, be it capsulectomy or capsulotomy, was not part of the compensable injury or care. Changing the present saline implants to silicone implants was not part of the compensable injury or care. Any work that might be done on the left implanted breast at the time of the procedure was not a part of

the compensable injury either. The follow-up for this procedure would be routine postoperative care per the plastic surgeon's protocol, usually every week to two weeks for the course of the first six weeks postoperatively during initial healing and then at six months and 12 months follow-up visits. The patient would be required to wear a support bra at all time during the day and a night time support bra while sleeping for the rest of her life. No physical therapy (PT), chiropractic manipulations/treatment would be indicated. The patient would be treated with pain medication for the several weeks if surgery became indicated. Again, this was assuming that the MRI confirmed the suspected diagnosis.

On June 7, 2012, MRI of the bilateral breasts with or without contrast revealed that the saline prosthesis were intact. There was no suggestion of malignancy. Background enhancement of fibroglandular elements and patient motion diminished the accuracy of the study somewhat particularly in the right breast. However, on evaluating the first non-subtracted post gadolinium axial sequence, significant right breast pathology was not identified. The impression was BI-RADS category 2-benign findings. The radiologist suggested follow-up.

On July 18, 2012, reviewed the reports and examined the patient and noted that the right inframammary fold was 2 cm lower than the left. He opined that her injury/problem was directly due to the injury at work on xx/xx/xx, and referred the patient to her primary care surgeon for performing the repair.

On August 30, 2012, noted that multiple previous examinations demonstrated further descent of the right breast despite non-operative supportive measures and suggested a surgical correction. He further stated that the temporal relationship and mechanism of injury supported, in all medial probability, that the patient's work injury was a direct causative factor of right inframammary fold disruption causing a right breast implant to break through the fold and descend causing breast asymmetry.

On September 20, 2012, in an addendum assessed right chest wall muscle strain secondary to lifting injury on xx/xx/xx. He concluded that per the MRI reports there was no evidence of acute or chronic trauma to the patient's bilateral breasts resulting from an injury. Any lowering or malposition of the patient's breast implants was not related to the injury occurring on xx/xx/xx. Based on the obtained evidence-based medicine, the patient's initial complaint on the date of injury was a strain to the right breast. He further stated that was recommending a surgery. The compensable injury was right chest wall muscle strain which was a self-limiting medical diagnosis treated with non-steroidal antiinflammatory medications with symptoms lasting from seven to 14 days. No more than two office visits would be indicated for follow-up care. No additional diagnostic tests, surgery, durable medical equipment (DME), physical therapy (PT), chiropractic manipulation/treatment or injections were indicated. did not agree with recommendation for surgery in regards to the injury of xx/xx/xx.

On December 11, 2012, concluded that the patient's current condition of her right breast was directly related to the work injury. The MRI demonstrated that the tear in the capsule did appear to have healed. However, as a result of injury, her right inframammary fold was not supporting her right breast implant and had resulted in a gross and obvious deformity. He further stated that this condition was best described as loss of integrity of the right inframammary fold and hence the right breast implant was now positioned 2 cm below its proper position. The mechanism of injury of lifting boxes overhead was consistent with causing this type of injury.

2013: On February 20, 2013, evaluated the patient. He noted that her current breast size was 36C; she had 330 cc saline implants placed. On examination, the patient's nipple to sternal notch on the right hand side was 21 cm and on the left was 23 cm. Base diameter was 14 cm bilaterally. Nipple to inframammary fold was 10 bilaterally, however, the inframammary fold to the chest wall on the right side was 5 cm and in the left that dimension was 7 cm suggesting that the inframammary fold was somewhat displaced inferiorly on the right relative to the left. There was significantly more bottoming out on the right than the left; however, on the left side the patient did have some descent of the breast implant. The patient had inferior positioning or malposition of her bilateral implants; however, significantly worse on the right side causing a less than pleasing appearance. The patient also related that while vacuuming and using her arm on the right she had discomfort. He felt that this might or might not be related to the relationship of her pectoralis major muscle to the now malpositioned implant. He further opined that taking at face value the patient's report she had significant bruising after lifting boxes and it did seem reasonable that in the course of the duties at work lifting the boxes, she had an inferior capsular tear that caused inferior malposition of the implant on that right side. He discussed with the patient her breast revisionary surgery to replace her implant and have them relocated on a more appropriate and anatomic location. He further suggested that whenever revisionary surgery of this type was considered, bilateral surgery was indicated in order to create the most symmetry. also discussed with the patient that switching to a saline implant might give more control and having a different implant might help facilitate the process of reconstruction or restoration of her breast form and shape symmetry. He informed the patient that the nipple distance would not be equalized, the nipple to sternal notch would not be equalized and that some asymmetry might be residual.

On March 7, 2013, requested an outpatient removal of intact mammary implant, mammoplasty augmentation with implant, acellular dermal matrix implant and open periprosthetic capsulotomy breast to the right breast.

Per utilization review dated March 11, 2013, the request for an outpatient removal of intact mammary implant, mammoplasty augmentation with implant, acellular dermal matrix implant and open periprosthetic capsulotomy breast to the right breast was denied with the following rationale: *"It is the opinion of the reviewing physician that this claimant was injured in xxxx when she was moving boxes and felt a pull in her right breast. Request is for removal of intact mammary implant,*

mammoplasty augmentation with implant, acellular dermal matrix implant and periprosthetic capsulotomy to the right breast. Note from February 20, 2013, shows claimant was originally seen for pain in the right breast with migration. Claimant at the time had a great deal of bruising on that side. At this point claimant has displacement of the right breast versus the left with significantly more bottoming. Claimant has inferior position or mouth position of her bilateral implants which is significantly worse on the right side causing less than a pleasing appearance. The ODG does not directly address this request. Based on the current clinical, a link between surgery and initial industrial accident is not established. Furthermore, the clinical does not describe any functional deficits other than aesthetic appearance. Therefore, at this time and on this Information request is not authorized.”

On March 22, 2012, placed an appeal for an outpatient removal of intact mammary implant, mammoplasty augmentation with implant, acellular dermal matrix implant and open periprosthetic capsulotomy breast to the right breast.

Per reconsideration review dated March 26, 2013, the request for an outpatient removal of intact mammary implant, mammoplasty augmentation with implant, acellular dermal matrix implant and open periprosthetic capsulotomy breast to the right breast was denied with the following rationale: *“It is the opinion of the reviewing physician that, “The patient sustained a work-related trauma to the previously augmented right breast while lifting heavy boxes overhead at work. This was documented as a trauma original injury at the level of inframammary fold. MRI revealed intact implant with significant displacement of the implant secondary to tear of the inframammary fold. Diagnosis was soft tissue disorder and breast disorders, NEC. Request was made for removal of intact mammary implant, mammoplasty augmentation with implant, acellular dermal matrix implant, and open periprosthetic capsulotomy breast to the right breast. This was denied. After reviewing the medical records, in my professional opinion the requested procedure is not medically necessary because her implant is intact and her only issue directly resulted as a result of her work injury would be tear of inframammary crease and secondary mal-positioning of the implant. Therefore, the request for implant replacement and use of acellular dermal matrix at this stage is not medically necessary. There are no Official Disability Guidelines that address this type of issue.”*

A benefit review conference was held on November 6, 2012, followed by a contested case hearing (CCH). The conclusion was: The compensable injury of xx/xx/xx, extends to include a disruption of the right inferior breast fold and lowering of the right inframammary fold. The compensable injury of xx/xx/xx, does not extend to include a right pectoralis tear and a right breast peri- prosthetic capsular tear.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

I went ahead and reviewed the case that was provided including the notes by:

Patient on xx/xx/xx gives a history that while moving boxes at work she experienced pain and bruising on her right breast.

She has a past history on 3/23/2005 of having a bilateral retropectoral augmentation mammoplasty via the inframammary approach with saline implants 330cc.

Originally patient was seen who then referred patient. Patient was then reviewed.

After reviewing the documentation that was provided and results of MRI by history, this patient had a tear of the lower part of the capsular that surrounds the breast implant, the implant descended to 1 to 1 1/2cm to the tear.

The procedure for the tear will be to reconstruct the capsular tear and support the soft tissue and try to make the inframammary lines equal.

There is no indication for removal of the intact saline breast implant. There is no indication to do a capsulotomy or capsulectomy for a 2 baker contraction or for the need of acellular dermal matrix.

Her diagnosis is soft tissue injury in the inframammary creast with secondary decreased of the implant.

The request for is removal if intact mammary implant, mammoplasty augmentation with implant, aellular dermal matrix implant, and open periprosthetic capsulotomy breast to the right breast was denied and no surgery to her left breast is indicated secondary to the trauma on xx/xx/xx.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG does not address this condition or procedure.