C-IRO Inc.

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Description of the service or services in dispute:
XX XX shoulder manipulation under anesthesia and XXXX injection to XX major muscle quantity: 1
XX: Manipulation procedures on the shoulder
XX:, aspiration and / or injection

Description of the qualifications for each physician or other health care provider who reviewed the decision:
Board Certified Orthopedic Surgeon

Upon Independent review, the reviewer finds that the previous adverse determination / adverse determinations should be:
☐ Overturned (Disagree)
☑ Upheld (Agree)
☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)
XXXX who was diagnosed with adhesive capsulitis of the XX shoulder. XXXX.

XXXX for XX shoulder pain. The pain was described as intermittent, constant, achy, burning, dull, sharp, shooting, stabbing and tingling. It worsened by activities and stretching. The pain was relieved by heat / ice packs, pain medications and rest. It was rated at 6-7/10 on that day. The pain on the worst day was rated at 10/10 and on the best day was rated at 7/10. The pain had slightly increased due to weather change. The medications were effective. Physical therapy had been ineffective in relieving the pain. XXXX continued to take XXXX, with improvement in XXXX painful condition. XXXX tolerated change to XXXX without any side effects. The examination revealed severe range of motion restriction of the XX shoulder and pain in the XX region. The diagnoses were XX, XX muscle strain, XX rotator cuff dysfunction and encounter for long-term drug use.

XXXX visited XXXX on XXXX for XXXX ongoing complaints of XX shoulder pain. The pain was rated at 7-8/10. XXXX reported the pain remained unchanged since the prior visit. Pain medication and XXXX had been effective. XXXX had discontinued XXXX as it made XXXX sick to XXXX XX. XXXX had seen XXXX, who stated that XXXX had "scar tissue" and had recommended surgery. XXXX continued on XXXX e with benefit. XXXX had difficulty sleeping and significant nausea with XXXX. The examination showed severely range of motion restriction of the XX shoulder and pain in the XX region.

According to the peer review summary by XXXX, XXXX was seen on XXXX for an orthopedic consultation regarding XX shoulder pain and limited range of motion. The XX shoulder symptoms included pain and weakness. XXXX had some early degenerative arthritis in the XX shoulder and some partial rotator cuff tear. XXXX had relief of pain for two weeks and then had an episode of pain and spasms associated with an innocuous movement of the shoulder. XXXX complaints had worsened since then. The examination showed 35 degrees external rotation on the XX and 5 degrees on the XX. Abduction was 90 degrees on the XX and 70 degrees on the XX. The internal rotation was up to XX on the XX. On the XX, XXXX had XX spasms with external rotation and not the whole pectoral muscle, but it got very firm and felt like a mass / pseudo mass on examination. The x-rays post dynamic contrast-enhanced (DCE) imaging showed adequate decompression and mild glenohumeral arthritis. On XXXX, XXXX continued to have pain in the XX chest area. XXXX did have a palpable swelling in the XX muscle that was asymmetric with the opposite side and appeared different than it was a few months prior.

The MRI of the XX major dated XXXX identified no soft tissue abnormality at the site of the markers along the anterior XX chest wall. Mild degenerative changes of the XX, XX and XX joints were noted. A small amount of fluid in the biceps tendon sheath was seen. Per the peer review summary by XXXX, the MRI performed in XXXX did not show any specific pathology in the XX muscle. The MRI of the XX shoulder dated XXXX revealed no evidence of rotator cuff tear or XX tear. There was an acromioclavicular joint arthropathy noted. There was a small amount of XX the vicinity of the rotator cuff XX, which could indicate adhesive capsulitis.

An x-ray of the lumbosacral spine dated XXXX revealed lower thoracic and lumbar spine multilevel severe chronic degenerative changes most marked at the XX-XX level. A XX mm grade 2 anterolisthesis / spondylolisthesis of XX on XX was noted. An MRI of the XX elbow and XX humerus performed on XXXX identified no fracture or acute osseous abnormality of XX humerus or elbow. No significant joint effusion was noted in the shoulder or elbow. Both examinations were mildly limited by continuous patient motion. Probable pseudocapitellar defect posteriorly at the elbow with a subjacent 9 mm subcortical intraosseous cyst was noted, Mild very mild strain of the distal brachialis myotendinous junction and minimal focal tendinosis of the distal biceps at the insertion were noted. Possible mild low-grade sprain of the ulnar collateral ligament proximally was noted. Minimal subcutaneous edema at the posterior medial elbow and likely intermediate grade partial articular sided tear distal subscapularis tendon at the shoulder were noted.

The treatment to date consisted of physical therapy, anti-inflammatory medications, injections, medications including XXXX, heat / ice packs, rest, XX shoulder diagnostic arthroscopy, subacromial decompression, distal clavicle excision, and glenohumeral debridement with debridement of the labral tear and undersurface of the rotator cuff tear on XXXX.

Per an Adverse Determination Letter dated XXXX, the request was noncertified. The letter contained an attached summary outlining the recommendation of the peer reviewer XXXX. Rationale: "Per the guidelines, manipulation under anesthesia is under study as an option in adhesive capsulitis. Guidelines indicated that there was very little evidence available for manipulation under anesthesia (MUA) and most of the studies identified had limitations. Exceptional factors were not identified to warrant the procedure. With XXXX injection to the XX major, XXXX (injection) is not generally recommended for chronic pain

disorders. Studies have found no statistical support for the use of XXXX A for those conditions. Clarification was needed regarding the request and how it might affect XXXX' clinical outcomes."

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The ODG indicates the manipulation under anesthesia is recommended as indicated for primary adhesive capsulitis following failure of conservative management for at least 6 months to include physical therapy, corticosteroid injections, and anti-inflammatories. Additionally, objective findings of passive shoulder flexion and/or abduction of less than 130° is necessary. The most recent progress note from the treating provider indicates that there is severely restricted range of motion on examination of the shoulder, but quantified objective range of motion measurements were not provided. The provider notes use of XXXX, but it is unclear if a recent trial of NSAIDs has been attempted, and there is no documentation indicating recent trial of a corticosteroid injection. The provider notes prior treatments physical therapy, but it is unclear when physical therapy was previously attended. Given the lack of information regarding specific range of motion measurements and no documentation of physical therapy having been attempted with the last 6 months or XXXX, injections or oral NSAIDs, the proposed manipulation under anesthesia would not meet ODG criteria, and insufficient information has been submitted by the treating clinician indicate that an exception from the guidelines would be warranted.

Regarding XXXX injections, the ODG does not have an entry for XXXX injections into the shoulder. The entry from the ODG in the pain section does not typically support XXXX injections. Current clinical literature regarding the use of XXXX injections for management of pectoral muscle spasms is generally limited to plastic surgery literature regarding the use of XXXX for pectoral muscle spasm following mastectomy or breast augmentation surgery. The literature does support the use of XXXX injections for intractable muscle spasms and other regions of the body. This data could be extrapolated to this particular case and it could be stated that XXXX injections can be trialed, the trial and failure of appropriate first-line interventions would be indicated. Given the lack of information regarding conservative treatment in the last 6 months with physical therapy, corticosteroid injections, or NSAIDs direct progression to XXXX injections would not be supported. As such, this portion of the request is also considered not medically necessary.

Given the documentation available, the requested service(s) is considered not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines
- ☐ DWC-Division of Workers Compensation Policies and Guidelines
- ☐ European Guidelines for Management of Chronic Low Back Pain
- ☐ Interqual Criteria
- ☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
- ☐ Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines
- ☑ ODG-Official Disability Guidelines and Treatment Guidelines

Shoulder Chapter
Manipulation under anesthesia (MUA)
Recommended as indicated below, only for primary adhesive capsulitis following failure of conservative management for at least 6 months. Poorer outcomes of manipulation under anesthesia (MUA) following shoulder surgery do not justify recommendation. See also Surgery for adhesive capsulitis. See the Low Back Chapter for Low Back , where MUA is not recommended in the absence of vertebral fracture or dislocation; and the Knee Chapter in the Knee, where MUA is recommended for treatment of arthrofibrosis and/or following total knee arthroplasty.
ODG Indications for Surgery™ -- Manipulation under anesthesia:
Criteria for MUA with or without arthroscopic capsular release require ALL of the following:
1. Conservative Care: Failure to respond after a minimum 6 months of conservative treatment including physical therapy, corticosteroid injection, and nonsteroidal anti-inflammatory drugs.
2. Subjective Clinical Findings: Patient is capable and willing to strictly follow a post-operative rehabilitation protocol; AND has disabling pain and stiffness which significantly limits shoulder function.
3. Objective Clinical Findings: Passive shoulder flexion AND/OR abduction is less than 130 degrees.

Pain Chapter
XXXX (XXXX®; Myobloc®)
Not recommended for most chronic pain conditions. Also, not recommended for the following: tension-type headache; fibromyositis; chronic neck pain; myofascial pain syndrome (MPS); and trigger point injections. Studies have found no statistical support for the use of XXXX A (BTX-A) for those conditions.

Myofascial pain syndrome (MPS): Not recommended: No myofascial analgesic pain relief as compared to saline. (Qerama, 2006) No success as a specific treatment for myofascial cervical pain as compared to saline. (Ojala, 2006) (Ferrante, 2005) (Wheeler, 1998) No success from injection in myofascial trigger points as compared to dry needling or local anesthetic injections. (Kamanli, 2005) (Graboski, 2005). Systematic reviews have stated that current evidence does not support the use of BTX-A trigger point injections for myofascial pain. (Ho, 2007) Or for mechanical neck pain (as compared to saline). (Peloso-Cochrane, 2006) One study found statistical improvement with the use of BTX-A compared to saline. Study patients had at least 10 trigger points and no patient in the study was allowed to take an opioid in the 4 weeks prior to treatment. (Gobel, 2006) Other more recent reviews find inconclusive evidence to support the use of XXXX in the treatment of MPS. (Soares Cochrane, 2014) Contradictory study results regarding the efficacy of XXXX A in MPS associated with neck and back pain do not allow this treatment to be recommended or rejected. (Climent, 2013)
Low back pain: Not generally recommended. If a favorable initial response predicts subsequent responsiveness, may be an option in conjunction with a functional restoration program. Some additional new data suggests that it may be effective for low back pain. (Jabbari, 2006) (Ney, 2006) Botulinum neurotoxin may be considered for low back pain (Level C). (Naumann, 2008) See also the Low Back Chapter.
Cervical dystonia: Recommended: This is a condition that is not generally related to workers' compensation injuries (also known as spasmodic torticollis), and is characterized as a movement disorder of the nuchal muscles, characterized by tremor or by tonic posturing of the head in a rotated, twisted, or abnormally flexed or extended position or some combination of these positions. When treated with BTX-B, high antigenicity limits long-term efficacy. XXXX A injections provide more objective and subjective benefit than trihexyphenidyl or other anticholinergic drugs to patients with cervical dystonia. See the Neck Chapter for cervical dystonia references.
Spinal cord injury: Recommended: urinary incontinence following spinal cord injury. XXXX significantly reduced urinary incontinence and improved urodynamics and quality of life in spinal cord injury and multiple sclerosis patients with neurogenic detrusor overactivity. (Cruz, 2011) XXXX is well tolerated and provides clinically beneficial improvement for urinary incontinence and neurogenic detrusor over activity secondary to spinal cord injury or multiple sclerosis. (Herschorn, 2011) There are other potential roles in spinal cord injury with spasticity. (Marciniak, 2008)
Spasticity following TBI: Recommended: See the Head Chapter.
Migraine: Recommended for prevention of headache in patients with chronic migraine. See the Head Chapter (recently updated to recommend this) for Criteria for use. Chronic migraine is defined as having a history of migraine and experiencing a headache on most days of the month. (FDA, 2010) A systematic review of RCTs concluded that XXXX A compared with placebo was associated with a small to modest benefit for chronic daily headaches and chronic migraines but was not associated with fewer episodic migraine or chronic tension-type headaches per month. (Jackson, 2012) The FDA approved XXXX injection (onabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine. It is recommended as a second-line therapy (since other acute therapies should have been attempted).
Neuropathic pain: According to a RCT, subcutaneous injections of XXXX A provides analgesic relief for neuropathic pain, especially in a subgroup of patients with allodynia. The protocol involved injecting 5 units of XXXX, or placebo, into each site 1.5 to 2 cm

apart, up to a maximum of 60 sites (300 units). The series of injections was repeated after 12 weeks, with the dose being adjusted according to the pain level. The study showed that over 24 weeks, two successive series of injections of XXXX A was superior to placebo (adjusted effect estimate vs placebo, –0.77). Although the proportion of responders, defined as those with at least a 50% reduction in pain intensity, didn't differ between the groups at 24 weeks, the proportion of responders was higher in the botulinum group when a responder was considered to have experienced at least a 30% reduction in pain. After the second injection series, 22% of patients went from non-responders to responders. Patients most likely to benefit from XXXX A injections are those with peripheral pain that is localized to a specific area, those with limited thermal deficits, and those with allodynia. Because the study protocol required lidocaine and prilocaine cream plus sedation, new delivery techniques for the toxin are needed before this method can be widely used in the clinic. (Attal, 2016)

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and Practice Parameters
- ☐ Texas TACADA Guidelines
- ☐ TMF Screening Criteria Manual
- ☐ Peer Reviewed Nationally Accepted Medical Literature (Provide a description)
- ☐ Other evidence based, scientifically valid, outcome focused guidelines (Provide a description)

Appeal Information

You have the XX to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.