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| Case Number: | CM14-0090218 | | |
| Date Assigned: | 07/23/2014 | Date of Injury: | 06/18/2002 |
| Decision Date: | 05/29/2015 | UR Denial Date: | 05/22/2014 |
| Priority: | Standard | Application Received: | 06/16/2014 |

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. 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: New Jersey, Alabama, California
 Certification(s)/Specialty: Neurology, Neuromuscular 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 57-year-old woman sustained an industrial injury on 6/18/2002. The mechanism of injury is not detailed. Diagnoses include spondylolisthesis, lumbar spinal stenosis, osteoarthritis of spinal facet joint, broad based intervertebral disc protrusion, chronic pain syndrome, lumbar radiculopathy, lumbar facet joint pain, sacroiliitis, lumbar post-laminectomy syndrome, myofascial pain, headache, thoracic outlet syndrome, scapulargia, cervicalgia, and shoulder joint pain. Treatment has included oral medications. Physician notes dated 5/16/2014 show complaints of low back, left leg and arm pain rated 5/10. Recommendations include continue medication regimen, lumbar radio frequency rhizotomy, evaluations for MILD procedure, surgical consultation, and follow up in one month.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topiramate (Topamax) 50mg #180 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topiramate (Topamax).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) TOPIRAMATE Topamax <http://www.rxlist.com/topamax-drug/side-effects-interactions.htm>.

Decision rationale: TOPAMAX(topiramate) Tablets and TOPAMAX(topiramate capsules) Sprinkle Capsules are indicated as initial monotherapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures. It also indicated for headache prevention. It could be used in neuropathic pain. There is no documentation of neuropathic pain in this case. Although the patient was documented to have a migraine headache, there is no documentation of the frequency of headache and the failure of abortive medication and the need for preventive treatment for headache. There is no documentation of neuropathic pain in this case and no evidence of efficacy of topiramate in chronic back pain. Therefore, the prescription of Topiramate (Topamax) 50mg #180 with 3 refills is not medically necessary.

Prescription For Celebrex 200mg #60 With 3 Refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti inflammatory medications Page(s): 27-30.

Decision rationale: According to MTUS guidelines, Celebrex is indicated in case of back, neck and shoulder pain especially in case of failure or contraindication of NSAIDs. There is no clear documentation that the patient failed previous use of NSAIDs. There is no documentation of contra indication of other NSAIDs. There is no documentation that Celebrex was used for the shortest period and the lowest dose. The patient continued to report back pain. Therefore, the prescription of Celebrex 200mg #60 With 3 Refills is not medically necessary.

1 Evaluation for mild procedure: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines- Low Back - Lumbar & Thoracic (Acute & Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mild ½ (minimally invasive lumbar decompression). <http://www.odg-twc.com/index.html>.

Decision rationale: According to ODG guidelines, not recommended. See Percutaneous diskectomy (PCD). Mild (minimally invasive lumbar decompression), from [REDACTED], describes a percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis. In contrast to surgical decompression, the mild procedure is a percutaneous decompressive procedure performed solely under fluoroscopic guidance (e.g., without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc

herniation, should it be required. Due to the unknown impact of these limitations on health outcomes, RCTs in appropriate patients are needed to compare this new procedure with established alternatives. The mild tool kit initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the FDA in 2006, with intended use as a set of specialized surgical instruments. (FDA, 2006) While there are no published prospective studies comparing this with established alternatives, it has received coverage in the general press. (NY Times, 2012) According to CMS, percutaneous image guided lumbar decompression (PILD) for lumbar spinal stenosis is not reasonable and necessary. PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram. The procedure that most closely falls under this description is commercially known as the mild procedure, suggested to offer a minimally invasive alternative to a standard laminotomy-laminectomy. (CMS, 2013) In the first RCT to evaluate the minimally invasive procedure percutaneous laser discectomy (even though it was FDA approved 24 years ago), there was no indication that this minimally invasive surgery is superior to open surgical techniques. (Brouwer, 2015) A systematic review found that current evidence does not support the routine use of minimally invasive surgery for cervical or lumbar discectomy. Minimally invasive surgery had no clinically significant advantage in terms of short- or long-term measures of pain or function. Patients who underwent minimally invasive disc surgery had higher levels of nerve root injury, dural tears, and reoperation. According to the authors, surgeons already perform open discectomies through relatively small incisions, so it is not surprising to find that outcomes are no better with minimally invasive discectomies. (Evaniew, 2014) Another systematic review concluded that, based on lower quality evidence, there are no differences in clinical outcomes between minimally invasive and open discectomy. (Kamper, 2014) A Cochrane systematic review concluded that minimally invasive discectomy may be inferior in terms of relief of leg pain, low back pain, and rehospitalization, but differences in pain relief appear to be small and may not be clinically important. (Rasouli, 2014) There is no documentation that the patient is suffering from solely from a lumbar central canal stenosis and therefore the request is not medically necessary.