June 19, 2018

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Removal of cervical plates

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Orthopedic Physician

REVIEW OUTCOME:

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

X Upheld (Agree)

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

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a XXXX who was diagnosed with dysphagia, chronic cervical radiculopathy and a history of pinched nerve in XXXX low back. The patient underwent a surgery for similar symptoms in XXXX and was doing quite well until XXXX, when XXXX and since then started having increased pain. On XXXX, the patient underwent anterior cervical discectomy and fusion (ACDF) C3-C4 and C6-C7. The patient was noted to have prior fusion from C4 through C6.

From XXXX, evaluated the claimant for musculoskeletal complaints to include low back pain radiating to bilateral lower extremities. Comorbidities were hypertension and hypercholesterolemia. Surgical history was notable for laminectomy and cervical fusion. Diagnoses were lumbar radiculopathy, spondylosis, minimal radicular symptoms and sacroiliitis. Medication regimen included XXXX.

On XXXX, the patient was seen by XXXX, for low back and bilateral leg pain and difficulty swallowing. XXXX denied any neck or arm pain. The general appearance showed the patient appeared uncomfortable. The buccal mucosa was moist. There was no neck tenderness. The suppleness was not decreased. Neck flexion did not produce tingling down the spine/arms. The Hoffman's reflex, deltoid reflex, pectoral reflex, finger flex reflex and cross abduction reflex were abnormal. Clinical impression was lumbar radiculopathy, lumbar spondylosis and dysphagia. Plan included removal of the cervical plate.

On XXXX, XXXX diagnosed cervical radiculopathy and ordered x-rays of the cervical spine and removal of the anterior cervical plate.

Per Utilization Review dated XXXX, the request for cervical plate removal was denied on the basis of the following rationale: *"The submitted clinical records indicate that the patient is status post anterior cervical discectomy and fusion (ACDF). The submitted clinical records indicate that the patient has*

complaints of inadequate production of saliva. The patient was seen by an ENT specialist who told the patient that this was unrelated to the anterior fixation plate. The record provides no imaging studies or other data to suggest that this plate is causing the patient's dysphagia or impairs with the patient's ability to produce saliva. As such, this request is not supported at this time."

On XXXX, XXXX notified XXXX regarding the denial of the requested service.

On XXXX, a correspondence by XXXX indicated the patient had been complaining of dry mouth and mainly swallowing problems. XXXX opined that the association of swallowing problems with cervical plates is a well-described and accepted phenomenon. XXXX had seen numerous patients over the years with these issues, and often despite numerous studies including esophagograms, CAT scans of the cervical spine and dynamic swallowing studies being normal, removing the plate will often relieve the swallowing problems. XXXX further stated that therefore XXXX had no longer ordered the studies when a patient complains of swallowing problems after an ACDF, then request the plate to be removed. XXXX did not feel the added expense of the studies was necessary, in that over 90% of the patients that have had these plates removed despite normal studies, have had considerable improvement in their swallowing difficulties after removing the plate. XXXX opined that since the plate was placed as a part of a XX injury, and clearly there was an indication to remove the plate because of dysphagia and swallowing problems, XX should be covering and approving the requested procedure.

On XXXX, the patient wrote an appeal letter in response to the denial of the requested service. The patient stated when XXXX would lie down the plate would push into XXXX throat. XXXX had to do continuous swallowing (voluntary and involuntary). The throat became sore and agitated, and the saliva stopped secreting and the mouth became dry. XXXX had a burning and tingling sensation all over the mouth and lips with accompanied awful taste in the mouth, especially between the gums and cheeks. On using a soft C-collar to bed, the dryness occurred less frequently but still daily.

Per a Reconsideration dated XXXX, the request for a cervical plate removal was denied on the basis of the following rationale: "The submitted clinical records indicate that the patient is status post ACDF. The submitted clinical records indicate that the patient had complaints of inadequate production of saliva and swallowing difficulty. The patient was seen by an ENT specialist who told the patient that this was unrelated to the anterior fixation plate. The record provides no imaging studies or other data to suggest that this plate is causing the patient's dysphagia or impairs with the patient's ability to produce saliva. As such the medical necessity for removal of the anterior cervical plate is not supported as medically necessary."

On XXXX, XXXX notified XXXX that the denial for requested service was upheld.

On XXXX, the patient wrote an appeal letter with an update of the present condition, in response to the denial. The patient reported worsening of mouth dryness, daily. The patient stated the ENT doctor had told him that the plate was more than likely the cause of the saliva restriction and sour taste, as the ENT could not find any problems with the mouth/nasal/stomach.

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

The two preauthorization denials appear to have been properly formulated, based on ODG criteria, sufficient alone. The denials should be upheld. It is incumbent upon the requesting surgeon to support XXXX rationale with evidence-based arguments; such appears lacking in this case.

Aside from ODG, other rationale and evidence-based literature is available to support denial of the authorization.

There is no objective evidence that the anterior cervical hardware is the cause of the claimant's symptomatology. The rationale for removing the hardware is based on anecdotal personal experience and conjecture. The surgeon has not provided evidence-based data to support XXXX rationale.

Numerous etiologies other than hardware are cited in evidence-based literature, particularly the complications of exposure/approach to the operative site. None of the other more medically probable etiologies has been ruled out as the source of the claimant's symptomatology. The surgeon appears resistant to ruling out the differential diagnosis, for reasons unidentified.

The following excerpts are from a review article by Anderson and Arnold (2013). The article identifies numerous etiologies other than retained hardware that should be part of the differential diagnosis. The differential diagnoses must be ruled out before severely invasive surgery is performed on this claimant—surgery that can potentiate (worsen) XXXX current symptomatology.

XX

13. Chin K R, Eiszner J R, Adams S B Jr. Role of plate thickness as a cause of dysphagia after anterior cervical fusion. Spine (Phila Pa 1976) 2007;32:2585–2590. [PubMed]

27. Lee M J, Bazaz R, Furey C G, Yoo J. Influence of anterior cervical plate design on Dysphagia: a 2-year prospective longitudinal follow-up study. J Spinal Disord Tech. 2005;18:406–409. [PubMed]

28. McAfee P C, Cappuccino A, Cunningham B W. et al. Lower incidence of dysphagia with cervical arthroplasty compared with ACDF in a prospective randomized clinical trial. J Spinal Disord Tech. 2010;23:1–8. [PubMed]

29. Kepler C K, Rihn J A, Bennett J D. et al. Dysphagia and soft-tissue swelling after anterior cervical surgery: a radiographic analysis. Spine J. 2012;12:639–644. [PubMed]

Medically Necessary

X Not Medically Necessary

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

X OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (see references above)