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Description of the service or services in dispute:
Cervical bone growth stimulator. CPT: E0748 - Osteogenesis stimulator, electrical, non-invasive, spinal applications

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

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 is a XX-year-old XX who was diagnosed with pseudarthrosis after fusion or arthrodesis (ICD-M96.0) with the date of injury XXXX. The ongoing medical problems were asthma, unspecified (493.90); other affections of shoulder region, not elsewhere classified (726.2); reflux (530.81); laryngeal mass (478.79); tobacco abuse (305.1); rotator cuff tear (727.61); tear of right rotator cuff, unspecified tear extent (M75.101); rotator cuff tear arthropathy, not elsewhere classified left shoulder (M12.812) and other cervical disc displacement, mid-cervical region (M50.22).

On XXXX, XXXX was evaluated by XXXX, M.D. (Neurosurgery) for a follow-up visit. Per report, XXXX left C6 radiculopathy for which XXXX had seen XX in XXXX had spontaneously resolved. The symptoms had returned with neck and right lateral upper extremity pain with right middle finger pain. XX quit smoking for the prior four months. On examination, it was difficult to opine if there were any areas of true particular myotomal weakness. XX did raise both upper extremities above XX shoulders marginally with certainly functional strength throughout multiple myotomes. Per the examination, there might be a trace area of weakness throughout multiple myotomes but again XX had functional strength.

Treatment to date consisted of medications, physical therapy and surgical treatments.

A cervical CT scan with myelogram dated XXXX revealed re-demonstration on anterior metallic fusion involving C4 through C6 levels and posterior metallic fusion spanning C4 through C6 levels; postoperative changes were grossly stable without evidence for interval significant hardware complications; a slight degree of perihardware lucency about the posterior C6 level metallic screws was grossly stable; multilevel degenerative changes spanning C3-C3 through C6-C7 re-demonstrated without significant interval detrimental changes; no evidence of significant central canal stenosis within the levels; previously documented moderate-to-severe left C5-C6 level neural foraminal probably on the basis of uncinate process hypertrophy and or lateralized osteophyte formation; and the cervical spinal cord was grossly stable in caliber and contour. Per impression, there was no significant interval detrimental change when compared to XXXX cervical spine myelogram, with postoperative and degenerative findings as detailed above.

X-rays of the cervical spine dated XXXX revealed anterior metallic fusion of C3-C4 and C5-C6, with posterior metallic fusion spanning the C4 through C6 levels; intradiscal space device centered at C5-C6; and multiple postoperative osseous fusion involving the cervical spine at the C3-C4 and the C5 through C7 segments. The evaluation of flexion and extension positioning revealed no significant translational motion.

On XXXX, the patient underwent a cervical spine myelogram for indication of cervical radiculopathy.

Per the utilization review dated XXXX by XXXX, the request for cervical stim bone growth stimulator was denied. Per principal reasons for the determination, with regard to the cervical stim bone growth stimulator, according to a pre-authorization request form on XXXX, there was documentation that XXXX had a multilevel fusion from C3-C6 on XXXX and a bone growth stimulator is being requested for a failed fusion. However, there was no current clinical documentation available for review from the provider detailing XXXX subjective and objective findings and why the stimulator is being requested almost two years' post-op and whether any previous treatment with a stimulator post-op was done, which should be established in order to help facilitate the appropriate treatment plan. Therefore, this request is non-certified.

Per the utilization review appeal peer reviewer's response dated XXXX by XXXX (Neurosurgery), the request for Cervical Stim bone growth stimulator was not recommended. Per the review, Official Disability Guidelines-Treatment in Worker's Compensation Neck & Upper Back procedures stated that bone growth stimulators were under study. However, Official Disability Guidelines- Treatment in Worker's Compensation Low Back, Lumbar and Thoracic (Acute and Chronic) procedures identifies criteria for use of invasive or non-invasive electrical bone growth stimulators. Either invasive or noninvasive method of electrical bone growth stimulation might be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion including one or more previous failed spinal fusion(s); grade III or worse spondylolisthesis; fusion to be performed at more than one level; current smoking habit, diabetes, renal disease, alcoholism; or significant osteoporosis which had been demonstrated on radiographs. In the case, the patient underwent C3, C4, C5, and C6 assessment of fusion, right C5 foraminotomy, and left C6 foraminotomy with hemilaminectomy right C4-C5 and hemilaminectomy at left C5-C6, screw rod fixation at C4, C5 and C6, and arthrodesis with local bone autograft obtained from same incision and allograft at C4-C5 and C5-C6 on XXXX. The provider indicated that the XXXX left C6 radiculopathy spontaneously resolved in XXXX but it returned with neck and right lateral upper extremity pain with right middle finger pain. The patient had just begun to develop more of a fusion process at C5-C6 based on the electrodiagnostic testing results along with cervical spine x-rays, and CT myelogram of the cervical spine. The patient did not meet the criteria for use of bone growth stimulator as there was no evidence that the patient had any significant risk factors for failed fusion to support this request. There was also no submitted updated diagnostic imaging study of the cervical spine which outlines the ongoing status of the patient's fusion at C4-C5 and C5-C6. The medical necessity of the cervical bone growth stimulator purchase was not established. Non-certification was recommended.

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

XXXX has been recommended for a bone growth stimulator to address pseudoarthrosis following a previous anterior cervical discectomy and fusion. However, XXXX prior fusion was completed in XXXX. At this point in time, even with a bone growth stimulator, it is highly unlikely that XXXX will have any further progress in bone consolidation. Therefore, it is this reviewer's opinion that medical necessity is not established, and the prior denials are upheld.

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

Neck and Upper Back Chapter
Bone Growth Stimulators
Under study. See the Low Back Chapter for more information about use in spinal fusion.
Low Back Chapter
Bone Growth Stimulators
Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high-risk cases).
Also see Fusion for the limited indications for spinal fusion surgery. See the Knee and Leg Chapter for more information on use of bone-growth stimulators for long bone fractures, where they are recommended for certain conditions.
Criteria for use for invasive or non-invasive electrical bone growth stimulators:
Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion:
(1) One or more previous failed spinal fusion(s);
(2) Grade III or worse spondylolisthesis;
(3) Fusion to be performed at more than one level;
(4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor);
(5) Diabetes, Renal disease, Alcoholism; or
(6) Significant osteoporosis which has been demonstrated on radiographs.
(Kucharzyk, 1999) (Rogozinski, 1996) (Hodges, 2003)
Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high-risk cases (e.g., revision pseudoarthrosis, instability, smoker). (Mooney, 1990) (Marks, 2000) (Akai, 2002) (Simmons, 2004) There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. (Resnick, 2005)

☐ 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)