Pure Resolutions LLC
An Independent Review Organization
Phone Number: **(817) 779-3288**
990 Hwy. 287 N. Suite 106 PMB 133
Mansfield, TX 76063
Fax Number: **(817) 385-9613**
Email:pureresolutions@irosolutions.com

Notice of Independent Review Decision

Review Outcome:

A description of the qualifications for each physician or other health care provider who reviewed the decision:

Orthopedic Surgery

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

- ☑ Upheld (Agree)
- ☐ Overturned (Disagree)
- ☐ Partially Overturned (Agree in part / Disagree in part)

Description of the service or services in dispute:

Total Disk Replacement at C3-4

Patient Clinical History (Summary)

The patient is a male who sustained an injury on xx/xx/xx when he fell from a ladder. The patient is status post C4 to C6 anterior cervical discectomy and fusion performed on 04/07/14. The patient did attend postoperative physical therapy and MRI studies of the cervical spine from 06/12/14 noted spondylitic disease and a disc protrusion at C3-4 measuring 4mm with effacement of the central cord and C4 nerve roots with high grade central stenosis. The patient was being followed for postoperative neck pain as well as upper extremity numbness and clumsiness in the hands as well as the feet. The clinical report on 07/17/14 noted ongoing complaints of neck pain that was severe radiating to the upper extremities with an associated numbness and tingling. The patient's physical exam noted numbness throughout the upper extremities with both weakness and clumsiness in the upper extremities. Positive Romberg's signs were noted. Due to myelopathic-type symptoms and the MRI findings of C3-4, the patient was recommended for a total disc arthroplasty at C3-4. The requested artificial disc replacement at C3-4 was denied on 09/15/14. As there was a lack of recommendation within the literature to support artificial disc replacements and multi-level degenerative processes. The request was again denied on 10/15/14 as there was limited evidence for cervical myelopathy and there were limited recommendations within the literature or guidelines regarding the use of artificial disc replacement and multi-level degenerative cases.

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

The patient does present with objective evidence consistent with cervical myelopathy. There is cord contact and compression noted on C3-4 on MRI studies following a 2-level cervical fusion from C4 to C6. The recommendation for an artificial disc replacement at C3-4 would potentially spare motion limitations that is typical from an extended fusion construct and cervical spine. The clinical literature regarding a hybrid type cervical fusion artificial disc replacement construct is very limited. It is currently unclear what the long term safety and efficacy is from the use of an artificial disc replacement adjacent to a previously fused cervical level. In the FDA indications for artificial disc replacements there should evidence of single level degenerative disc disease that is symptomatic which is noted in this case however due to the patient's prior cervical fusion

there is an overall insufficient amount of evidence within the literature to support the use of this procedure in comparison with standard alternative treatment to include multi-level cervical fusion with extension of the cervical fusion at C3-4. As such, it is this reviewer's opinion that the request is not medically necessary due to the experimental and investigational nature of the request 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 um knowledgebase
- ☐ AHCPR-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
- ☐ 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)