1. **Purpose**

The purpose of this policy is to establish the criteria for when surgical spinal fusion (arthrodesis and arthroplasty) may be considered medically necessary.

2. **Definitions**

2.1. Surgical spinal fusion (arthrodesis) involves a surgical procedure which attempts to fuse one or more vertebral segments by inserting bone grafts or bone graft substitutes (with or without instrumentation).

2.2. Surgical spinal arthroplasty (artificial disc replacement) involves a surgical procedure which attempts to replace one or more of the intervertebral discs with an artificial disc (prosthesis).

2.3. The *AMA Guides to the Evaluation of Permanent Impairment* defines segmental instability (loss of motion segment integrity) as an “anteroposterior motion of one vertebra over another that is greater than 3.5 mm in the cervical spine, greater than 2.5 mm in the thoracic spine, and greater than 4.5 mm in the lumbar spine.”

3. **Statement of Policy**

3.1. **Lumbar Fusion**

3.1.1. The determination of medical necessity for the use of lumbar spinal fusion (arthrodesis) with or without instrumentation is always made on a case-by-case basis.

3.1.2. Lumbar fusion (arthrodesis) **is considered medically necessary** in patients who demonstrate unstable vertebral fractures, spinal dislocations or where surgery is being performed for tumor, spinal infection, or other disease processes that have led to or will lead to lumbar segmental instability as defined above.

3.1.3. Lumbar fusion (arthrodesis) **may be considered medically necessary** in patients with severe chronic (at least one year in duration) low back pain with or without radiculopathy which is aggravated by activity and demonstrate:

   - Isthmic spondylolisthesis; or

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• Degenerative spondylolisthesis or degenerative scoliosis with evidence of spinal stenosis with associated neurological findings (radicular pain with or without neurogenic claudication); or

• A pseudoarthrosis (non-union) from a prior spinal fusion; or

• The clinical need for a third lumbar discectomy at the same level; or

• Spinal stenosis which requires decompressive surgery with concomitant lumbar segmental instability; or

• Scoliosis or kyphosis resulting in severe skeletal deformity which compromises the patient’s visceral function, severely interferes with the patient’s ability to carry out their activities of daily living, produces severe pain or documented progression.

3.1.4 Lumbar spinal fusion may be considered not medically necessary if the following criteria have not been met:

• Lumbar segmental instability has been documented at the level(s) being considered for fusion as defined above; and

• The patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; and

• The patient has undergone an MRI or a CT scan with or without myelography within the past 6 months which demonstrates severe disc pathology; and

• The patient has participated in a minimum of 3 months up to 6 months of a supervised active rehabilitation exercise program with appropriate adjunctive care. When comparing the long term outcomes of spinal fusion versus an aggressive rehabilitative exercise program combined with a cognitive behavioral approach, the scientific literature demonstrates comparable outcomes with respect to pain and function. Spinal fusion, however, carries increased risks of serious complications as compared to rehabilitative exercises.; and

• The patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome; and
3.1.5. Lumbar spinal fusion may be considered medically necessary in a carefully selected group of patients with severe single level degenerative disc disease who fulfill the following criteria:

- The patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; and
- The patient has undergone an MRI or a CT scan with or without myelography within the past 6 months which demonstrates severe single level disc pathology; and
- The patient has undergone a discogram by an independent examiner and it must be positive for concordant pain at the proposed single level to be fused with at least one normal control level documented; and
- The patient has participated in a minimum of 6 months of an active supervised rehabilitative exercise program with appropriate adjunctive care. When comparing the long term outcomes of spinal fusion versus an aggressive rehabilitative exercise program combined with a cognitive behavioral approach, the scientific literature demonstrates comparable outcomes with respect to pain and function. Spinal fusion, however, carries increased risks of serious complications as compared to rehabilitative exercises.; and
- The patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome; and
- The patient does not have clinically significant co-morbid factors such as morbid obesity, smoking, diabetes, renal disease, osteoporosis, or other
co-morbid factors which could increase the likelihood of a negative outcome of the surgical procedure while dramatically increasing patient risk.

3.2. **Lumbar Artificial Disc Replacement**

3.2.1 Lumbar artificial disc replacement (arthroplasty) is considered not medically necessary based on the lack of long term efficacy and safety in comparison to standard spinal fusion techniques.

3.3. **Cervical Fusion**

3.3.1 The determination of medical necessity for the use of cervical spinal fusion (arthrodesis) with or without instrumentation is always made on a case-by-case basis.

3.3.2 Cervical fusion (arthrodesis) is considered medically necessary in patients who demonstrate unstable vertebral fractures, spinal dislocations, segmental instability secondary to traumatic injury, or where surgery is being performed for tumor, infection, or other disease processes that have led to cervical segmental instability.

3.3.3 Cervical fusion (arthrodesis) may be considered medically necessary in patients with severe chronic neck pain with or without radiculopathy which is aggravated by activity and fulfill the following criteria:

- Is performed as part of a cervical decompressive procedure; and
- Patient has received an adequate diagnostic evaluation to rule out all other potential causes of pain; and
- Patient has undergone an MRI or CT scan with or without myelography within the past six (6) months which indicates spinal stenosis (central and/or lateral recess) with clear evidence of a neural compressive lesion/nerve root compromise and/or spinal cord compression which correlates with the clinical examination findings; and
- Patient has participated in a reasonable trial of an active rehabilitative exercise program with appropriate adjunctive care; and
• Patient does not have clinically significant co-morbid factors which could potentially increase the likelihood of a negative outcome of the surgical procedure while dramatically increasing patient risk; and

• Patient does not have an active psychological diagnosis or disturbance or psychosocial issues that would substantially reduce the possibility of a successful outcome.

3.3.4 Cervical fusion (arthrodesis) may be considered medically necessary in patients who demonstrate a pseudoarthrosis (non-union) from a prior fusion.

3.3.5. Cervical fusion (arthrodesis) using both an anterior and posterior approach (360° fusion) may be considered medically necessary in patients as an adjunct to an extensive anterior approach procedure or in certain cases of severe instability.

3.4 Cervical Artificial Disc Replacement

3.4.1 Cervical artificial disc replacement (arthroplasty) is considered not medically necessary based on the lack of long term efficacy and safety in comparison to standard spinal fusion techniques.

4. References

4.1. Scientific:

The following scientific references were utilized in the formulation of this medical policy. Triad Healthcare, Inc. will continue to review clinical evidence surrounding spinal fusion (arthrodesis) and artificial disc replacement (arthroplasty) and may modify this policy at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to Triad Healthcare, Inc. so the information can be reviewed by the Academic Advisory Committee (AAC) and the Medical Quality Improvement Committee (MQIC) to determine if a modification of the policy is in order.

References for Spinal Fusion (Arthrodesis):


Fritzell P, Hagg O, Wessberg P, Nordwall A; Swedish Lumbar Spine Study Group, 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from


• Wright IP, Eisenstein SM. Anterior cervical discectomy and fusion without instrumentation. *Spine*. 2007 Apr 1;32(7):772-4; discussion 775.


References for Artificial Disc Replacement (Arthroplasty):


4.2. Related Triad Medical Policies:
- TMMP 18 - Medical Necessity
- TMMP 403 – Discography (62290, 62291)

5. Attachments
- Provider Manual

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