Local Coverage Determination (LCD)

Cervical Fusion

L39758

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

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Issue

Issue Description

This policy is developed as a multi-MAC collaboration to provide an evidence-based policy for cervical fusion.

CMS National Coverage Policy

This LCD supplements but does not replace, modify, or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for cervical fusion procedures for pain management. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify, or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations, and rules for Medicare payment for EPIDURAL procedures for pain management and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  ~ Chapter 13, 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Code of Federal Regulations (CFR) References:

CFR, Title 42, Ch. IV, § 410.74 Physician assistants' services, §410.75 Nurse practitioners' services and § 410.76 Clinical nurse specialists' services.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and General Information

Covered Indications

A. Cervical fusion surgery is considered medically reasonable and necessary for the decompression of symptomatic cervical nerve root impingement when all of the following requirements are met:

1. Persistent or recurrent moderate or severe arm pain (4 or more on the visual analog scale or equivalent) present for a minimum of 12 weeks within the current episode of arm pain with documented failure to respond to multimodal conservative management (as tolerated) in the absence of exceptional circumstances (below) **AND**
2. Nerve compression negatively impacts activities of daily living **AND**
3. All other potential sources of pain/neurological deficit have been excluded **AND**
4. Imaging (MRI or CT) evidence of central, lateral recess or foraminal stenosis at the level corresponding with clinical myotome signs or symptoms and including at least one of the following:
    a. Cervical degenerative disc disease as indicated by the presence of one or more of the following findings: herniated nucleus pulposus, narrowing of the intervertebral disc, disc osteophytes, facet hypertrophy, or synovial cysts.
    b. Tumors (primary or metastatic)
    c. Post infection radiographic findings
    d. Spinal instability as defined by subluxation or translation more than 3.5 mm on static lateral views or dynamic radiographs OR sagittal plane angulation of more than 11 degrees between adjacent segments.[1]

Limitations

The following is considered not reasonable and necessary for the decompression of symptomatic cervical nerve root impingement:

1. Isolated chronic axial cervical pain

Exceptions to conservative therapy requirement for decompression of symptomatic cervical nerve root impingement:

1. Concomitant myelopathy or myeloradiculopathy
    1. Cervical myelopathy class III or above **OR**

2. Progression of neurological deficits during the trial of conservative treatment.

2. Isolated radiculopathy
   a. Presenting with progressive motor weakness **OR**
   b. Significant motor weakness interfering with ADLs **OR**
   c. Severe radicular pain defined as pain limiting ability to perform activities of daily living (AOLs) and ≥7/10 on VAS or equivalent scale2 AND associated with confirmatory imaging (computed tomography, magnetic resonance imaging) and clinical-radiological correlation.
3. Loss of bowel or bladder control due to cervical spinal cord compression.

B. Cervical fusion surgery is considered reasonable and necessary for the decompression of symptomatic cervical canal stenosis when the following requirements are met:

1. Persistent or recurrent moderate or severe arm pain (4 or more on the visual analog scale or equivalent) present for a minimum of 12 weeks within the episode of arm pain with documented failure to respond to multimodal conservative management (as tolerated) in the absence of exceptional circumstances (below) **OR**

2. Nerve compression negatively impacts activities of daily living **OR**

3. Spastic gait, loss of manual dexterity, problems with sphincter control **AND**

4. All other potential sources of pain/neurological deficit have been excluded **AND**

5. Imaging (MRI or CT) evidence of central stenosis at the level corresponding with clinical signs or symptoms and including at least one of the following:

   a. Cervical degenerative disc disease as indicated by the presence of one or more of the following findings: herniated nucleus pulposus, narrowing of the intervertebral disc, disc osteophytes, facet hypertrophy, or synovial cysts.
   b. Congenital short pedicles
   c. Tumors (primary or metastatic)
   d. Post infection radiographic findings
   e. Ossification of the posterior longitudinal ligament.
   f. Spinal instability as defined by subluxation or translation more than 3.5 mm on static lateral views or dynamic radiographs OR sagittal plane angulation of more than 11 degrees between adjacent segments.
   g. Cord compression with or without increased cord signal.

Limitations

The following are considered not reasonable and necessary for decompression of symptomatic cervical canal stenosis:

1. Isolated chronic axial cervical pain.
2. Asymptomatic myelopathy (regardless of severity on imaging findings).

Exceptions to conservative therapy requirement for decompression of symptomatic cervical canal stenosis:

1. Myelopathy
    1. Cervical myelopathy class III or above **OR**
    2. Progression of neurological deficits during the trial of conservative treatment.
2. Radiculopathy
    a. Presenting with progressive motor weakness **OR**
    b. Significant motor weakness interfering with ADLs **OR**
    c. Severe radicular pain defined as pain limiting ability to perform activities of daily living (AOLs) and ≥7/10 on Visual Analog Scale (VAS) or equivalent scale[2] AND associated with confirmatory imaging (computed tomography, magnetic resonance imaging) and clinical-radiological correlation.

3. Loss of bladder or bowel function due to cervical spinal cord compression.

C. Cervical fusion surgery is considered reasonable and necessary for the decompression or stabilization of the cervical spine for the following indications:

1. Traumatic injuries including fractures, dislocations, fracture-dislocations, or traumatic ligamentous disruption when[3]:

    a. Fractures or dislocations which are likely to result spinal instability without neurological defects **OR**
    b. Fractures or dislocations associated with neurological defects at the affected level **OR**
    c. Instability is present.

2. Spinal tumors involving the spine or spinal canal when:[3]

    a. Malignant or benign tumors which have caused instability or neurologic deficit where treatment of the tumor will likely require stabilization of the spine.[4] **OR**
    b. Expected treatment of the tumor whether by chemotherapy or radiation therapy or surgery will likely cause spinal instability or neurologic deficits.[4] **OR**
    c. Instability is present.

3. Infection involving the spine in the form of discitis, osteomyelitis, or epidural abscess when[3]:

    a. Imaging or other studies (MRI, biopsy, bone aspirate) demonstrating infection **AND**
    b. Imaging evidence of vertebral body destruction OR documentation that spinal debridement will cause vertebral instability[5,6] **OR**
    c. Instability is present.

4. Deformities that include the cervical spine including when[3]:

    a. Cervical kyphosis associated with cord compression or Atlantoaxial (C1-C2) subluxation or Basilar invagination of the odontoid process into the foramen magnum; *or* Subaxial (C2-T1) instability kyphosis, head drop syndrome, post-laminectomy deformity OR
    b. Symptomatic pseudarthrosis (non-union of prior fusion) with radiological (e.g., CT or MRI) demonstration of non-union of prior fusion (lack of bridging bone or abnormal motion at fused segment) after 12 months since fusion surgery *or* with radiographic evidence of hardware failure (fracture or displacement). OR
    c. Spinal instability after laminectomy **OR**

d. Rheumatoid arthritis with associated instability **OR**
e. Cervical degenerative spondylolisthesis with spinal instability (Anterolisthesis/Posterolisthesis) **AND**
f. Substantial functional limitation is present such as severe neck pain or difficulty ambulating or decrease ability to perform ADLs or ability to maintain forward gaze. **OR**
g. Progression of deformity

Limitations

Cervical Fusion for the decompression or stabilization of the cervical spine is not reasonable and necessary when all the above criteria are not fulfilled.

Provider Qualifications

The Medicare Program Integrity Manual states services will be considered reasonable and necessary only if performed by appropriately trained providers.

Patient safety and quality of care mandate that healthcare professionals who perform cervical fusion are appropriately trained and credentialed by a formal residency/fellowship program. Credentialing or privileges are required for procedures performed in inpatient and outpatient settings.

All aspects of care must be within the provider's medical licensure and scope of practice. Reimbursement for procedures utilizing imaging techniques may be made to providers who meet training requirements for the procedures in this policy only if their respective state allows such in their practice act and formally licenses or certifies the practitioner to use and interpret these imaging modalities (ionizing radiation and associated contrast material, magnetic resonance imaging, ultrasound). At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

Notice: Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, all existing CMS national coverage determinations, and all Medicare payment rules.

Definitions

Acute Pain – an unpleasant sensory and emotional experience associated with actual or potential tissue damage which is present for up to 6 weeks.[7]

Baseline Pain- An initial measurement of the pain which is taken at a specified time point and used for comparison over time to look for changes in the pain levels.

Cervical Radiculopathy- Pain in a radicular pattern in one or both upper extremities related to compression and irritation of one or more cervical nerve roots.[8]

Chronic Pain – The temporal definition of pain persisting at least 12 weeks after the onset of the acute pain.

Conservative Therapy – Consists of an appropriate combination of medication in therapeutic dosages (e.g., non-steroidal anti-inflammatory [NSAIDs], serotonin and norepinephrine

reuptake inhibitors (SNRIs), analgesics, etc.) administered for a sufficient amount of time to determine efficacy, in combination with either physical therapy, spinal manipulation therapy, cognitive behavioral therapy (CBT), home exercise program, acupuncture, or other interventions based on the individual's specific presentation, physical findings, and imaging results.

Consistent Improvement – The progressive, incremental, and clinically meaningful improvement of physical signs or symptoms.

Disability – Activity limitations or participation restrictions in an individual with a health condition, disorder or disease.[9]

Functional Impairment - A physical or functional or physiological impairment causing deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired or delayed capacity to move, coordinate actions or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.[9]

GRADE – A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible, and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.

Hangman's Fracture - a bilateral fracture traversing the pars interarticularis of cervical vertebrae 2 (C2) with an associated traumatic subluxation of C2 on cervical vertebrae 3 (C3).[10]

Multidisciplinary Biopsychosocial Rehabilitation (MBR) – Targets physical as well as psychological and social aspects of pain and involves a team of healthcare providers with different professional backgrounds and training.

Myelopathy- An inclusive term describing a compression of the spinal cord resulting in neurological deficits e.g., spasticity (sustained muscle contractions), hyperreflexia, pathologic reflexes, paresthesia affecting the extremities, muscle weakness, digit/hand clumsiness, or gait disturbance.[11,12]

Nonspecific low back pain – Back pain that cannot be attributed to a specific disease or spinal pathology.

Session- A session is a time period, which includes all procedures (e.g., SIJIs and RFA ablations) that are performed during the same day.

Sustained and Constant Pain Relief - The pain relief must continue for the defined time period and without interruption or regression to the primary (index) pain.

Symptomatic pseudarthrosis- (non-union of prior fusion) with radiological (e.g., CT or MRI) demonstration of non-union of prior fusion (lack of bridging bone or abnormal motion at fused segment) 12 months or more since fusion surgery *or* with radiographic evidence of hardware failure (fracture or displacement).[13]

Unstable Spine- cervical spinal instability has been defined as destruction of either the anterior or posterior elements of the spine making them nonfunctional, more than 3.5 mm of

displacement of one vertebra in relation to another or greater than 11 degrees of rotational difference between adjacent vertebrae.[1,14]

Contractor Advisory Meeting

A Multi-MAC Contractor Advisory Committee (CAC) Meeting was hosted by Noridian and included Noridian Healthcare Solutions, CGS Administrators, National Government Services, Palmetto GBA, WPS Government Health Administrators, First Coast Service Options and Novitas Solutions on August 16, 2023. The transcript and audio for this meeting is posted on each MACs website. Feedback from the subject matter experts is included through the evidence summary.

Summary of Evidence

Conservative Treatment

Treatment of cervical radiculopathy can range from conservative management to surgery. Conservative care is considered initial management for cervical radiculopathy from degenerative disorders as most cases will be self-limited and resolve spontaneously over a variable length of time without specific intervention.[8] Conservative management for cervical radiculopathy may include oral analgesics or short course of oral glucocorticoids, avoidance of provocative activities, short term immobilization with cervical collar or pillow, active physical therapy, manual therapy, and cervical traction.[15,16] In a published analysis of clinical practice guidelines for neck pain and radiculopathy the following interventions were listed as recommended components of conservative therapy[16]:

- Pharmacotherapies: analgesics, Paracetamol (Acetaminophen), NSAIDs (non-steroidal anti-inflammatory drugs), SNRIS, opioids (including tramadol), topical medications including NSAIDS.
- Non-Pharmacologic Interventions: exercise programs/physical therapy, thermotherapy, manual therapy (combined with other treatment), acupuncture, epidural steroid injection.

Studies have shown that surgery and conservative interventions achieve similar long-term results, and that conservative treatment is often the preferred option because it avoids the risks of surgical treatment.[8,17] A systematic review found sufficient low-quality evidence to support the role of conservative measures as a first-line approach for the management of cervical radiculopathy.[18] Observational data reports 40-80% of patients with cervical radiculopathy will improve with conservative measures.[15] Exercise alone or in combination with other treatments was shown to be beneficial for cervical radiculopathy in a systematic review and meta-analysis.[19] Physical therapy accompanied by home exercise for 6 weeks has been shown in a randomized trial to substantially reduce neck and arm pain for patients with cervical radiculopathy.[20] A RCT compared cervical collar or physical therapy and found improvement over a wait and see approach suggesting that an active treatment approach results in better outcomes.[21] A RCT demonstrated that patient who proceed to surgery for management of cervical radiculopathy had more rapid resolution of symptoms compared to those who remained in physical therapy but outcomes at 2 years were similar and conclude structured physiotherapy should be considered first line management.[22] Further investigation with the same author reported anterior cervical decompression and fusion (ACDF) plus PT was superior to PT alone.[23] Subject matter experts agreed that conservative therapy is an acceptable first line approach and that there are modifiable risk factors such as diabetes management, smoking cessation and weight loss that can impact disease course and surgical outcomes.[24]

NASS Guidelines state: “As the majority of patients with cervical radiculopathy will improve with nonoperative treatment, particularly within three months from onset, most practitioners would agree that a 6- to 12-week period of nonoperative care seems reasonable. Specific provisions of

what should be included during the course of nonoperative treatment were not outlined as there is no universally agreed upon group of modalities. The types of treatment that one would consider, however, should include physical therapy, anti-inflammatory pain medications and epidural steroid injections."[3]

A multi-disciplinary, international panel established consensus-based guidance on effective nonsurgical treatment modalities for individuals in different stages (i.e., acute, subacute, and chronic) of cervical radiculopathy.[25] These guidelines include patient education with positive reinforcing and non-nocebo content, spinal manipulative therapy, exercise, sustaining pain-relieving positions, cognitive behavioral therapy, general aerobic exercise, strength training, postural education and workplace and vocational/ergonomic assessment.

Berman, et al compared the American College of Radiology appropriateness criteria for MRI to the specific criteria in 56 commercial policies and clinical management organizations in the USA, for neck pain both with and without radicular symptoms.[26] While the focus was on coverage criteria for MRIs, the study also summarized organizational positions on conservative care.

- Different definitions of conservative care are used e.g., "a multimodality approach consisting of a combination of active and inactive components" and "a combination of strategies to reduce inflammation, alleviate pain, and improve function."
- All organizations require the failure of at least six weeks of conservative management. Some organizations require conservative management within the preceding 3 or 6 months, while others do not specify how recently conservative treatment needs to take place.
- Conservative interventions are 'provider-directed treatment' that includes education, activity modification, nonsteroidal anti-inflammatory (NSAIDs), narcotic and non-narcotic analgesic medications, oral or injectable corticosteroids, a provider-directed home exercise/stretching program, cross-training, avoidance of aggravating activities, physical/occupational therapy, spinal manipulation, interventional pain procedure, and other pain management techniques. Only a single organization requires two separate forms of conservative treatment, although the guidelines do not specify what these are.

Imaging Modalities

North American Spine Society (NASS)[8] Evidence-Based Clinical Guidelines on the Diagnosis and Treatment for Cervical Radiculopathy from Degenerative Disorders state MRI is the recommended study for correlative compressive lesions in cervical spine patients who have failed conservative therapy and being considered for intervention based on Grade B recommendation. The consensus of the group was that CT can be considered in those who have a contraindication to MRI. Computed tomography myelography was recommended for patients with discordant findings on MRI or contraindication to MRI based on Grade B Recommendation. There was insufficient evidence to make a recommendation for or against the use of electromyography (EMG) for cervical radiculopathy evaluation.

Cervical Radiculopathy

Cervical radiculopathy is a common condition that usually occurs when a nerve root is inflamed by a herniated disc or bone spur. As a result, the inflamed nerve root may result in neck pain,

numbness or muscle weakness and sensory symptoms. This condition impacts approximately 85 out of 100,000 people.[27]

Clinical Outcomes

Seven evidence syntheses with publication dates ranging from 2016-2022 that assessed clinical outcomes were identified.[28-34] Two reviews included only RCTs.[28,30] Four studies included both non-randomized studies of interventions (NRSI) and a small number (range 1-6) of RCTs.[29,31-33] The number of primary studies in the syntheses ranged from 7-23, with generally small sample sizes. Half the studies diagnosed participants with single-level, unilateral cervical radiculopathy. Comparators included different fusion techniques, foraminotomy, arthroplasty, and conservative interventions. Anterior cervical discectomy and fusion was an intervention in each study. Timing to follow-up ranged from 24 to 47 months.

Broekema, et al. (2020)conducted a systematic review with meta-analysis that included 1,567 participants described in 21 RCTs.[28] Thirteen of the studies had data from less than 100 participants. The clinical effects of ACDF were compared with posterior cervical foraminotomy (PCF), anterior cervical discectomy without intervertebral spacer (ACD), ACD with poly-methylmethacrylate as an intervertebral spacer (PMMA), autologous bone graft (ABG), ACDF with autologous bone graft plus plating (ABGP), cervical disc arthroplasty (CDA), and physical therapy. ACDF had a significantly better success rate compared to ACD. Among the remaining comparisons, there were no significant differences in success rates. Six subgroup comparisons found no significant differences in work status across interventions. Aside from a significant effect favoring ACDF over CDA, there were no differences in disability outcomes at mean follow-up. Improvement in arm pain favored ACDF with a cage over ABGP, ACD over ACDF with a cage, and ACDF over CDA. The clinical significance of these differences was not described. Limitations in this evidence synthesis included an overall high risk of bias (only 3 of 21 included studies had a low risk of bias), indirectness (the mean age across studies was 43.8 years), and imprecision due to the small sample sizes across sizes, with 62% of studies having less than 100 participants.

Fang, et al. (2020) included 3 RCTs and 12 NRSI with a total of 52,705 (~51K from a single cohort study) participants diagnosed with single-level unilateral cervical radiculopathy in a systematic review with meta-analysis. Outcomes comparing ACDF with PCF were measured at a mean of 47 months.[29] No statistically significant differences were identified for measures of disability (function), neck pain, arm pain, or satisfaction. Limitations impacting the certainty of the evidence included inherent drawbacks due to most of the primary study designs (12 of 15 studies were retrospective cohort designs) and the 3 RCTs either did not contribute to or contributed minimally to the pooled analyses, indirectness (the mean ages across studies ranged from 39 to 53.8 years), and significant heterogeneity was observed in subgroup analyses of ACDF vs. PCF using open and minimally invasive techniques.

In a network meta-analysis, Gao, et al. (2022) performed direct and indirect comparisons of ABG, ACD, ACF, PCF, ACDFP (ACDF plus plating), CDA, PMMA, and physical therapy.[30] Twenty-

three RCTs (N=1,844) were assessed at a mean of 26 months. There were no statistical differences among the different interventions in measures of success rate, arm/neck pain, or disability. There were limitations in this network meta-analysis including an overall high risk of bias (only 13% [3 of 23] of the studies had a low risk of bias), indirectness (the mean/median age among the included studies ranged from 41 to 50.5 years and only 2 of 23 studies were conducted within the United States), imprecision (sample sizes were small [27-209]), and inconsistency (clinical and statistical heterogeneity).

Goedmakers, et al. (2020) systematically reviewed 6 RCTs and 2 NRSI (N=777) in comparing ACDF with CDA.[31] Timing to follow-up in the studies ranged from 1-7 years. A single study reported a statistically significant difference between interventions for disability; however, the difference did not achieve clinical relevance. Another five studies found no significant difference between CDA and ACDF. None of the studies reported a significant difference in neck pain after 2 years post-surgery. Limitations of this systematic review included all articles showed intermediate to high risk of bias, indirectness (mean age was ~45 years), imprecision (sample sizes were small [41-209]), and inconsistency (high heterogeneity precluded pooling the results of individual studies).

A systematic review with meta-analysis of 658 patients (1 RCT; 11 NRSI) with single-level cervical radiculopathy compared traditional ACDF vs. stand-alone ACDF vs. CDA.[32] The reviewers found no statistically significant differences in disability measures at a minimum of 1 year for the different interventions. Limitations included the drawbacks inherent in observational studies (11 of 12 included studies were cohort designs), uncertainty about the internal validity of the studies (risk of bias of the included studies was not assessed), imprecision (the mean sample size was 54.8), and inconsistency (high heterogeneity was present in the pooled analysis for disability outcomes).

Liu, et al. (2016) produced a systematic review of 1,336 patients with cervical radiculopathy (3 RCTs, 7 NRSI) who underwent either ACDF or PCF.[33] At a mean of 3.7 years following the procedure, there were no between-group differences in patient-reported measures of pain and disability. Based on a single study, ACDF showed a significantly higher success rate (93.6%) than the PCF group (85.1%). Limitations of this review included the drawbacks inherent in observational studies (7 of the 10 studies were retrospective cohort designs), all the RCTs were judged to have a high risk of bias, and indirectness (the mean age of the included participants was ~46 years [39-53.3]).

Zou, et al. (2022) conducted a systematic review with a meta-analysis of 1,175 patients with unilateral cervical radiculopathy.[34] One RCT and 6 NRSI compared clinical outcomes for groups receiving ACDF or MI-PCF (minimally invasive posterior cervical fusion). At a mean post-surgical follow-up of 47 months, no statistically significant differences were observed in patient-reported disability, neck pain, or arm pain. Limitations in this evidence synthesis included those inherent in observational study designs, indirectness (the mean age of the participants was 48.9 years), and inconsistency (high heterogeneity was reported for arm pain outcomes).

In aggregate, the clinical effects associated with the different surgical and conservative interventions did not result in statistically significant or clinically relevant differences. The only exception was ACDF, which showed a better success rate than ACD. Overall, the certainty of the evidence was determined to be very low. Limitations included those inherent in observational study designs, high risk of bias in most RCTs, indirectness, imprecision, and heterogeneous outcomes.

Surgical Outcomes

Three evidence syntheses reported on perioperative measures. Operative time was assessed in all studies.[29,30,34] Length of stay (LOS) was included in two reviews.[29,34] A single study analyzed blood loss.[29]

Fang, et al. (2020) compared ACDF with open PCF or MI-PCF for patients with single-level, unilateral cervical radiculopathy in a systematic review with meta-analysis.[29] The reviewers reported that compared to ACDF, open PCF had a shorter operation time, while there was no difference between ACDF and MI-PCF. Based on data from 2 studies, there was no significant difference in blood loss among the surgical techniques. The PCF group was associated with a significantly shorter length of hospitalization than the ACDF group. Limitations impacting the certainty of the evidence included inherent drawbacks due to most of the primary study designs (12 of 15 studies were retrospective cohort designs) and the 3 RCTs either did not contribute to or contributed minimally to the pooled analyses, indirectness (the mean ages across studies ranged from 39 to 53.8 years), and significant heterogeneity was observed in subgroup analyses of ACDF vs. PCF using open and minimally invasive techniques.

Gao, et al. (2022) assessed operative time for different surgical procedures in a network meta-analysis.[30] Direct and indirect comparisons showed ABGP, ACD, ACDF, and ACDFP had shorter surgery times compared with ABG. ACDF had a shorter surgery time compared with PMMA. There were limitations in this network meta-analysis including an overall high risk of bias (only 13% [3 of 23] of the studies had a low risk of bias), indirectness (the mean/median age among the included studies ranged from 41 to 50.5 years and only 2 of 23 studies were conducted within the United States), imprecision (sample sizes were small [27-209]), and inconsistency (clinical and statistical heterogeneity).

Zou, et al. (2022) performed a systematic review with meta-analysis comparing ACDF with MI-PCF.[34] The analysis did not find any significant difference in operative time between the two cohorts. Data from 3 retrospective studies observed a statistically significant difference in LOS favoring MI-PCF. Limitations in this evidence synthesis included those inherent in observational study designs, and indirectness (the mean age of the participants was 48.9 years).

In summary, the observed perioperative results varied by the comparators and the type of outcome. Compared to open PCF, ACDF had significantly longer operative time and LOS. MI-PCF also had a significantly less LOS than ACDF. When ACDF was compared to other surgical techniques, no significant differences were found in operative time and blood loss. The overall

certainty of the evidence was rated as very low due to the high risk of bias in the included RCTs, limitations inherent in observational studies, and uncertainty about the applicability of the results to the U.S. Medicare population (indirectness).

Radiographic Outcomes

Two evidence syntheses described post-surgical radiographic results associated with individuals diagnosed with cervical radiculopathy.[32,33]

Katsuura, et al. (2019) performed a systematic review with meta-analysis that compared traditional ACDF vs. stand-alone ACDF vs. CDA.[32] At a minimum of 1-year post-surgical follow-up, no significant differences in the C2-C7 (Cobb) angle were observed. Limitations of this evidence synthesis included the drawbacks inherent in observational studies (11 of 12 included studies were cohort designs), uncertainty about the internal validity of the studies (risk of bias of the included studies was not assessed), and imprecision (the mean sample size was 54.8).

Liu, et al. (2016) systematically reviewed data from 3 RCTs and 7 NRSI, encompassing 1,335 patients; however, only a single RCT provided data regarding radiographic outcomes.[33] The postoperative ROM of the caudal adjacent segment was 11.33° ± 5.07° in the ACDF group and 8.73° ± 5.92° in the PCF group. The significance of this difference was not described. Limitations of this review included the drawbacks inherent in observational studies (seven of the ten studies were retrospective cohort designs), all the RCTs were judged to have a high risk of bias, and indirectness (the mean age of the included participants was ~46 years [39-53.3]).

Overall, there was limited evidence concerning radiographic outcomes following cervical fusion in patients diagnosed with cervical radiculopathy. No significant between-group differences were reported for Cobb angle or ROM. The overall certainty of the evidence was judged as very low due to a high/unknown risk of bias, study design limitations, imprecise data, and indirectness.

Undesirable Effects

Six evidence syntheses described undesired effects associated with cervical fusion surgery.[28,30,31,33-35] Assessment timeframes ranged from 24 to 57 months.

Broekema, et al. (2020) performed a systematic review with meta-analysis of 1,567 participants diagnosed with cervical radiculopathy who underwent anterior or posterior surgical interventions and were compared with other surgical techniques.[28] There was a higher complication rate in the group with ABG from the iliac crest. This effect disappeared when donor-site complications were left out. No other significant effect was observed in the comparison between ACDF with ABG and ACDF with a cage. Subgroup comparisons found no significant differences in reoperation rate across the different surgeries. Limitations in this evidence synthesis included an overall high risk of bias (only 3 of 21 included studies had a low risk of bias), indirectness (the mean age across studies was 43.8 years), and imprecision due to the small sample sizes across sizes, with 62% of studies having less than 100 participants.

Gao, et al. (2022) conducted a network meta-analysis of 23 RCTs that included direct and indirect comparisons of ACDF, ABG, ACD, ACF, PCF, ACDFP, CDA, PMMA, and physical therapy.[30] There were no statistical differences among the various interventions, including physical therapy for complication and reoperation rates. There were limitations in this network meta-analysis including an overall high risk of bias (only 13% [3 of 23] of the studies had a low risk of bias), indirectness (the mean/median age among the included studies ranged from 41 to 50.5 years and only 2 of 23 studies were conducted within the United States), imprecision (sample sizes were small [27-209]), and inconsistency (clinical and statistical heterogeneity).

Goedmakers, et al. (2020) systematically reviewed 777 participants with cervical radiculopathy from 6 RCTs and 2 NRSI in comparing CDA to ACDF.[31] The authors concluded the reporting on the level of reoperation is heterogeneous and incomplete; however, the results suggested reoperations were most frequent at the adjacent level for the ACDF group and at the index level for the CDA group. Four articles described adjacent segment disease (ASD), of which only one article described a significantly higher incidence of ASD in ACDF patients. No other statistically significant differences in complication rates were described between groups. Limitations of this systematic review included all articles showed intermediate to high risk of bias, indirectness (mean age was ~45 years), imprecision (sample sizes were small [41-209]), and inconsistency (high heterogeneity precluded pooling the results of individual studies).

Gutman, et al. (2018) performed a systematic review with meta-analysis that focused on the comparative undesired effects of participants with single-level cervical radiculopathy who prospectively underwent ACDF, CDA, or MI-PCF.[35] The rate of revision surgery following ACDF (14.46) was greater than double that of MI-PCF (7.00) and CDR (6.49). Compared to ACDF (21.29), the rate of adverse events was significantly less for MI-PCF (3.00), but greater for CDA (27.27). Limitation in this review included the risk of bias of the primary studies was not assessed, indirectness (the mean age for each of the included studies was less than 50 years [43-49.3]), imprecision (the number of studies was few [4], with small sample sizes), and uncertainty concerning inconsistency (heterogeneity was not assessed).

Liu, et al. (2016) assessed the overall complication rate in a systematic review that compared patients who had received either ACDF or PCF.[33] The mean complication rate was 7% in the ACDF group and 4% in the PCF group. The difference was not statistically significant. Limitations of this review included the drawbacks inherent in observational studies (seven of the ten studies were retrospective cohort designs), all the RCTs were judged to have a high risk of bias, and indirectness (the mean age of the included participants was ~46 years [39-53.3]).

Zou, et al. (2022) employed a systematic review with meta-analysis of 1,175 patients who underwent either ACDF or PCF.[34] In the ACDF group, complication rates ranged between 1.8% and 10.5%. In the MIS-PCF group, the rate was between 0% and 14.3%. The between-group difference was not significant. The reoperation rate was between 0-7.5% in the ACDF group and 0 -14.3% in the MIS-PCF group. The difference was not significant. Limitations in this

evidence synthesis included those inherent in observational study designs, and indirectness (the mean age of the participants was 48.9 years).

In aggregate, the complication rates associated with different surgical procedures and physical therapy are generally similar; however, the rate of adverse events with ACDF appears to be greater than MI-PCF, and the rate of ASD is lower with CDA vs. ACDF. The overall results of the different evidence syntheses were heterogeneous concerning reoperation rates. No significant differences were found among the surgical interventions studied apart from a small systematic review (Gutman, et al.; 2018) that concluded the revision surgery rate of ACDF was double that of CDA and MI-PCF. The credibility of these findings was very low due to a lack of quality appraisal (risk of bias) for the included RCTs, the small numbers of studies (4) and participants (506), uncertain applicability to the U.S. Medicare population, and omitting an assessment of heterogeneity. Overall, the certainty of the evidence was judged to be very low due to multiple limitations i.e., study designs, high/unclear risk of bias, indirectness, imprecise results, and unexplained heterogeneity.

Societal Input

The North American Spine Society (NASS) has published appropriateness criteria for cervical fusion surgery as a treatment for cervical radiculopathy.[3]

Cervical radiculopathy: from degenerative disorders (either from disc herniation or bony stenosis), as an adjunct to disc excision, that meets ALL the following criteria:

- Pattern of radiculopathy explained by imaging.
- Six to 12 weeks of an appropriate course of nonoperative treatment.
- The following can mitigate the need for an initial nonoperative trial:
    - Severity of symptoms prevents the patient from working.
    - Functionally limiting motor weakness.

Cervical fusion may NOT be indicated in cases that do not fulfill the above criteria including cervical radiculopathy from isolated foraminal stenosis treated with a partial medial facetectomy/foraminotomy.

Degenerative Cervical Myelopathy

Clinical Outcomes

Six evidence syntheses with publication dates ranging from 2014-2022 that assessed clinical outcomes were identified.[36-41] Three of the syntheses included only non-randomized studies of an intervention (NRSI).[37,39,40] Three studies included both NRSI and a small number (1-4) of RCTs.[36,38,41] The number of primary studies in the syntheses ranged from 5-18, with generally small sample sizes. Participants were mostly diagnosed with multilevel cervical spondylotic myelopathy (CSM). Comparators included different fusion techniques, arthroplasty, and hybrid

surgery. Anterior cervical discectomy and fusion was an intervention in each study. Timing to follow-up was variable (1-60+ months).

Fei, et al. (2015) conducted a systematic review with meta-analysis that compared two fusion techniques, ACDF and ACCF (anterior cervical corpectomy and fusion).[36] Eighteen primary studies (1 RCT, 17 NRSI) were included in the review. Outcomes were assessed at a minimum of 6 months post-operation. Neurological status (success) and pain intensity outcomes were similar between surgical groups. There were several limitations in this study including those associated with observational studies (17 of 18 studies were cohort or case-control designs), indirectness (17 of 18 studies included participants located in China or South Korea, and all the studies had a mean/median between 32-59 years), imprecision (all studies had small sample sizes with confidence intervals that crossed the indicator for no effect), and inconsistency of effects across studies (significant heterogeneity for all secondary outcomes).

In a systematic review with meta-analysis, Han, et al. (2014) reported on 14 NRSI that compared ACDF and ACCF.[37] At a postoperative minimum of 24 months, all clinical measures (success rate, neurological status, pain, and function [disability]) were statistically similar (p >0.05). Limitations of this review involved the inclusion of only low-quality studies (all included studies were observational cohort or case-control designs), indirectness (mean ages ranged from 44-58.74 yrs.), imprecision (all studies had small sample sizes and pain outcomes had small numbers of pooled data), and high statistical heterogeneity (inconsistency) was present for functional outcomes.

Li, et al. (2019) performed a network meta-analysis that included 4 RCTs and 12 NRSI.[38] The analysis included direct and indirect comparisons of ACDF, ACCF, cervical disc arthroplasty [replacement] (CDA), and hybrid surgery. At a mean of 33.3 months following surgery, CDA demonstrated a statistically significant difference in disability outcomes compared to the other surgical procedures. The clinical significance of these results was not described. Limitations in this network meta-analysis were associated with low-quality studies (12 of 16 studies were case-control designs), indirectness (indirect comparisons were a core component of the methodology and 14 studies took place in Asia [China, South Korea, Singapore]), and imprecision (all studies had small sample sizes).

Montano, et al. (2019) systematically reviewed and meta-analyzed 5 NRSI (487 participants) with multilevel CSM.[39] No difference in neurological status was found between ACDF and laminoplasty at a mean of 35.4 months post-surgery (MD = -0.053; 95% CI, -0.511 to 0.404; p = 0.819). Limitations involved the low-quality of all included studies (observational cohort or case-control designs), indirectness (all studies had mean ages between 54 and 56.8 years.), imprecision (too few events for all outcomes and wide confidence intervals for all pooled outcomes measured).

A systematic review without meta-analysis of 11 primary studies (2 RCTs, 9 NRSI) included a total of 570 participants with single or multilevel CSM.[41] Clinical outcomes were assessed between 12 and 60 months postoperatively. No statistically significant differences in ACDF and

ACCF were found for neurological status, pain, or function (disability). Review limitations included the overall low-quality primary study designs (9 of the 11 included studies were observational cohort or case-control), indirectness (none of the studies were performed in the United States and all studies had a mean age between 46.8 and 57.7 years), imprecision (all the studies had small sample sizes), and inconsistency (I^2 test revealed high heterogeneity [>75%] across studies for all outcomes).

Wang, et al. (2022) included 14 NRSI with wide variation in sample sizes (40-2188) that comparatively assessed ACDF and ACCF.[40] There was no between-group difference in patient-reported function; however, improvement in neurological status at 1-60+ months follow-up favored ACDF (OR = 0.49, 95% CI: 0.06 to 0.91; $p = 0.02$). Limitations involved the selection of low-quality studies (all studies were retrospective observational cohorts or case-control designs) and indirectness (11 of the studies were conducted in Asia [China, South Korea]).

Primary Studies

One RCT that was not included in any evidence synthesis was identified. El-Ghandour, et al. (2020) compared ACDF with posterior laminectomy with or without fusion in the management of degenerative cervical myelopathy (DCM).[42] Sixty-eight patients (mean age 53 years) were enrolled in a 1:1 randomized trial. Clinical outcomes were assessed after 1 year. There were significantly better outcomes in patient-reported disability (function) and pain scores in the ACDF group compared to posterior surgical approaches. The Nurick myelopathy grading scale showed a nonsignificant improvement with using the posterior approach. The authors noted several methodologic limitations including a high risk of bias in the randomization process, small sample size, and short-term follow-up.

In aggregate, clinical outcomes were found to be largely equivalent regardless of surgical technique. The overall certainty of the evidence was judged to be very low due to limitations inherent in the included study designs, indirectness (uncertainty about the applicability to the US Medicare population), imprecision (variability within studies in the direction and clinical relevance of effects), and inconsistencies across studies in the magnitude of effect.

Surgical Outcomes

A total of seven evidence syntheses evaluated surgical (perioperative) outcome measures.[36-40,43,44] All syntheses included NRSI, while RCTs were represented in two reviews.[4,5] Sample sizes were small, patients were diagnosed with multilevel CSM, comparisons were between surgical interventions, and follow-up assessments were variable.

Fei, et al. (2015) reported on data from 1,246 patients included in 18 primary studies (1 RCT, 17 NRSI).[38] Compared to ACCF, patients who underwent ACDF had superior perioperative outcomes (length of stay [LOS], operative time, and blood loss). Limitations included the preponderance of low-quality studies (17 of 18 studies were of observational designs), indirectness (17 of 18 studies included participants located in China or South Korea, and all the

studies had a mean/median between 32-59 years), imprecision (all studies had small sample sizes with confidence intervals that crossed the indicator for no effect), and inconsistency (significant heterogeneity for all secondary outcomes).

Han, et al. (2014) included 15 NRSI (1,372 participants) in comparing ACDF and ACCF.[37] No significant difference in operative time was found (MD = -9.34, 95% CI = -42.99 to 24.31; p = 0.59). LOS (MD = -5.60, 95% CI = -7.09 to - 4.11; p<0.00001) and blood loss (MD = -151.35, 95% CI = -253.22 to -49.48; p = 0.004) were both less (better) in the ACDF group vs. the ACCF group. Limitations involved the low-quality of all included studies (observational cohort or case-control designs), indirectness (mean ages ranged from 44-58.74 years), imprecision (all studies had small sample sizes), and inconsistency (high statistical heterogeneity was present for blood loss and operative time).

A network meta-analysis that included 1,639 patients with multilevel CSM found that ACDF resulted in a shorter operative time compared (directly and indirectly) to other surgical techniques (ACCF, CDA, and hybrid surgery).[38] Limitations included low-quality studies (12 of 16 studies were case-control designs), indirectness (indirect comparisons were a core component of the methodology, 14 studies took place in Asia [China, South Korea, Singapore], and only a single study included a U.S. population), and imprecision (all studies had small sample sizes).

Montano, et al. (2019) compared the results of ACDF and laminoplasty in 5 NRSI (487 patients).[39] There was a statistically significant difference favoring ACDF regarding blood loss (MD = -131.381; 95% CI, -259.522 to -3.240; p = 0.044). No between-group difference was seen in operative time (MD = -10.231; 95% CI, -58.612 to 38.149; p = 0.679). Limitations related to the low-quality of included studies (all were observational cohort or case-control designs), indirectness (all studies had mean ages between 54 and 56.8 years), imprecision (too few events for all outcomes and wide confidence intervals for all pooled outcomes measured), and inconsistency (high heterogeneity involving operative time and blood loss).

A total of 5,249 patients from 14 NRSI provided data on surgical outcomes for a systematic review with meta-analysis.[40] Compared to ACCF, blood loss was significantly less in patients that underwent ACDF (OR = -528.63, 95% CI: -586.86, -470.39; p < 0.00001). Operative time was comparable between the two surgical groups. Limitations were due to the low-quality of the included studies (all studies were retrospective observational cohorts or case-control designs) and indirectness (11 of the studies were conducted in Asia [China, South Korea]).

Xu, et al. (2017) pooled data from 6 NRSI (379 patients) in comparing ACDF with posterior laminoplasty (LAMP).[43] No significant differences between the two surgical groups were found for operative time (MD = 32.81, 95% CI = -26.76 to 92.38; p = 0.28) and blood loss MD = -24.16, 95% CI = -174.47 to 126.15; p = 0.75). Limitations included the low-quality study designs (All studies were retrospective observational cohorts or case-control), indirectness (all studies had mean ages between 44.7 and 67 years), imprecision (data were derived from small studies with

wide confidence intervals that crossed the indicator for no effect), and inconsistency (very high unexplained heterogeneity).

A systematic review with meta-analysis of 669 participants (4 NRSI) assessed surgical outcomes between ACDF and hybrid surgery.[44] Blood loss significantly favored ACDF over hybrid surgery (SMD = -30.29, 95% CI = -45.06, -15.52; *p* <.00001), while operative time was similar. The limitations of this review involved the low-quality study designs (all studies were retrospective observational cohorts or case-control designs), and indirectness (none of the studies were performed in the United States, and the mean age among studies ranged from 46.1 to 54.36 years).

Primary Studies

One RCT that was not included in any evidence synthesis was identified. El-Ghandour, et al. (2020) compared ACDF with posterior laminectomy with or without fusion in the management of degenerative cervical myelopathy (DCM).[42] Sixty-eight patients (mean age 53 years) were enrolled in the 1:1 randomized trial. The mean operative duration was significantly longer in the ACDF group (p < 0.001). The mean hospital stay was significantly longer in the posterior group (p < 0.001). The authors noted several methodologic limitations including a high risk of bias in the randomization process, small sample size, and short-term follow-up.

Overall, the observed perioperative results varied by the comparators and the type of outcome. Compared to open PCF, ACDF had significantly longer operative time and LOS. MI-PCF also had a significantly less LOS than ACDF. When ACDF was compared to other surgical techniques, no significant differences were found in operative time and blood loss. The overall certainty of the evidence was rated as very low due to the high risk of bias in the included RCTs, limitations inherent in observational studies, and uncertainty about the applicability of the results to the U.S. Medicare population (indirectness).

Radiographic Outcomes

Five evidence syntheses included assessments of radiographic outcomes (fusion rate, range of motion [ROM], alignment, and lordotic.[36,37,39,40]

Fusion rate was recorded in a systematic review with meta-analysis of 18 primary studies (1 RCT, 17 NRSI).[36] After a minimum of 6 months post-surgery, the authors found the fusion rate was 100% for patients that underwent ACDF and ACCF. Review limitations involved the low-quality of selected studies (17 of 18 studies were of observational designs), indirectness (17 of 18 studies included participants located in China or South Korea, and all the studies had a mean/median between 32-59 years), imprecision (all studies had small sample sizes with confidence intervals that crossed the indicator for no effect), and inconsistency (there was significant heterogeneity for all secondary outcomes except fusion rate).

In another systematic review with meta-analysis, Han, et al. (2014) also reported no difference in fusion rates between ACDF and ACCF (OR = 1.17, 95% CI = 0.34 to 4.11; *p* = 0.80).[37] Cobb

and segmental angles were measured at a minimum of 24 months follow-up. ACDF showed statistically significant outcomes compared to ACCF. The limitations in this review included the low-quality of the selected studies (all studies were observational cohort or case-control designs), indirectness (mean ages ranged from 44-58.74 years), imprecision (all studies had small sample sizes), and inconsistency (high statistical heterogeneity was present for fusion rate and Cobb angle).

Montano, et al. (2019) conducted a systematic review with meta-analysis that compared radiographic outcomes reported in 5 NRSI between ACDF and laminoplasty.[39] The Cobb angle (cervical lordosis) results were significantly better for the ACDF group (MD = 5.63; 95% CI, 1.663-8.469; $p = 0.004$), while ROM favored laminoplasty (MD = -5.399; 95% CI, -10.584 to -0.214; $p = 0.041$). Limitations included the low-quality of analyzed studies (all were observational cohort or case-control designs), indirectness (all studies had mean ages between 54 and 56.8 years) imprecision (too few events for all outcomes and wide confidence intervals for all pooled outcomes measured), and inconsistency (high heterogeneity involving cervical lordosis and ROM.

A systematic review with meta-analysis of 14 NRSI (5,249 patients diagnosed with multilevel CSM) reported statistically significant results favoring ACDF versus ACCF in sagittal and segmental angles, as well as fusion rate.[40] Limitations were due to the low-quality of the included studies (all studies were retrospective observational cohorts or case-control designs) and indirectness (11 of the studies were conducted in Asia [China, South Korea]).

Zhao, et al. (2018) evaluated the radiographic effects of ACDF compared to hybrid surgery.[44] The meta-analysis of 669 patients (4 NRSI) found no significant differences in fusion rate and C2-C7 (Cobb) angle at 24 to 38 months post-surgery. Review limitations included the low-quality of the selected studies (all were retrospective observational cohorts or case-control designs), indirectness (none of the studies were performed in the United States and the mean age among studies ranged from 46.1 to 54.36 years), imprecision (wide confidence angles that represented variable outcomes were found in the pooled data fusion rate), and inconsistency (heterogeneity of effects in the pooled analyses for C2-C7 angle and fusion rate).

In aggregate, radiographic outcomes – obtained at variable time points – showed equitable or favorable results in fusion rate, angular measurements, and alignment for ACDF compared to ACCF, laminoplasty, and hybrid surgery. Laminoplasty was superior to ACDF in preserving ROM. The certainty of the evidence was determined to be very low due to the types of included study designs (mostly retrospective NRSI), uncertainty about the generalizability to the U.S. Medicare population, imprecise results, and heterogeneity of findings.

Undesirable Effects

Six evidence syntheses provided findings regarding a range of undesirable effects associated with cervical fusion surgeries.[36-40,44] Four reviews focused on the total or overall complication

rate.[36-39] In addition to the total complication rate, two syntheses detailed the results of a range of undesirable effects.[40,44]

Fei, et al. (2015) reported that the total complication rate was significantly lower for individuals with ACDF than ACCF (RR= 0.51, 95% CI: 0.33, 0.80; p = 0.003).[36] This result was based on a meta-analysis of 1,246 patients, with a minimum of 6 months follow-up. Limitation of this evidence synthesis were the low-quality of the selected studies (17 of 18 studies were of observational designs), indirectness (17 of 18 studies included participants located in China or South Korea, and all the studies had a mean/median between 32-59 years), imprecision (all studies had small sample sizes with confidence intervals that crossed the indicator for no effect), and significant heterogeneity was present.

Another systematic review with meta-analysis of 1,372 patients diagnosed with multilevel CSM also determined the incidence of overall complications was significantly greater in the ACCF group compared to those who had ACDF surgery (OR = 0.50, 95% CI = 0.35 to 0.73; p = 0.0003).[37] In this review the minimum follow-up period was 24 months. Limitations involved the low-quality of all included studies (observational cohort or case-control designs), indirectness (mean ages ranged from 44-58.74 years), and imprecision (all studies had small sample sizes)

A network meta-analysis calculated both direct and indirect comparisons of overall complications for patients who had undergone ACDF, ACCF, CDA, or hybrid surgery.[38] At a post-operative mean of 33.3 months, CDA resulted in a lower incidence of complications than different types of cervical fusion procedures. The limitations of this network meta-analysis included the low-quality of most study designs (12 of 16 studies were case-control designs), indirectness (indirect comparisons were a core component of the methodology, and only a single study included a U.S. population), and imprecision (all studies had small sample sizes).

A systematic review with meta-analysis included 5 NRSI (N=487) that compared outcomes (mean 35.4 months) between ACDF and laminoplasty.[39] There was no statistically significant difference regarding the complication rate (OR = 1.604; 95% CI, 0.972-2.648; p = 0.065). Limitations included the low-quality of the selected studies (all included studies were observational cohort or case-control designs), indirectness (all studies had mean ages between 54 and 56.8 years), and imprecision (wide confidence intervals for all pooled data).

Wang, et al. (2022) included data from 5,249 participants (14 NRSI) in a systematic review with meta-analysis.[40] The number of total complications was significantly less for individuals that received ACDF compared to ACCF (OR=0.56, 95% CI: 0.48-0.65; p < 0.00001). This study provided additional details about specific undesired effects. No significant difference between ACDF and ACCF was found for dysphagia, hoarseness, cerebrospinal fluid (CSF) leakage, infection rate, epidural hematoma, axial pain, hardware breakage, and pseudoarthrosis. ACDF demonstrated statistically superior outcomes regarding the event rate of C5 palsy, revision surgeries, graft subsidence, and graft dislodgement. The limitations of this review were related to the low-quality of all the selected studies (retrospective observational cohorts or case-control designs), and indirectness (11 of the studies were conducted in China or South Korea).

Zhao, et al. (2018) compared ACDF to hybrid surgery, pooling data from 4 NRSI that comprised 669 patients.[44] Post-surgical outcomes were captured between 24 and 38 months. There was a significant difference in total complications favoring ACDF (OR = 0.66, 95% CI = 0.44-0.98; P = .04). At the discrete outcome level, there was no significant difference between ACDF and hybrid surgery seen for graft subsidence, C5 palsy, infection, CSF leakage, dysphagia, or epidural hematoma. Limitations related to the low-quality of all the selected studies (retrospective observational cohorts or case-control designs), and indirectness (none of the studies were performed in the United States, and mean age among studies ranged from 46.1 and 54.36 years), and imprecision (wide confidence intervals, representative of variable outcomes, were found in the pooled data subgroup analyses for graft subsidence, infection rate, and CSF leakage).

Primary Studies

One RCT that was not included in any evidence synthesis was identified. El-Ghandour, et al (2020) compared ACDF with posterior laminectomy with or without fusion in the management of degenerative cervical myelopathy (DCM).[42] Sixty-eight patients (mean age 53 years) were enrolled in the 1:1 randomized trial. No significant difference in postoperative complications was found, except postoperative dysphagia was significantly higher in the anterior group ($p < 0.05$). The authors noted several methodologic limitations including a high risk of bias in the randomization process, small sample size, and short-term follow-up.

A retrospective cohort compared the short-term outcomes for laminoplasty, laminectomy with fusion, and ACDF.[45] Data from 546 patients resulted in the authors concluding that laminectomy with fusion carries the highest risk for morbidity, mortality, and unplanned readmissions in the short-term postoperative period. Laminoplasty and ACDF cases carry similar short-term complications and risks. Study limitations include the retrospective design, short-term (30-day) outcomes, and clinical heterogeneity.

Overall, apart from CDA, the complication rate favored ACDF over other types of fusion and non-fusion surgeries. The certainty of the evidence was judged to be very low due to inherent study design limitations, indirectness, imprecision involving subgroup analyses, and significant heterogeneity.

Cervical Myeloradiculopathy (Mixed)

Cervical myelopathy occurs when there is compression of the spinal cord in the neck area. Patients present with issues with fine motor skills, pain or stiffness in the neck and loss of balance. Causes of cervical myelopathy may include Rheumatoid arthritis, cervical spine trauma, spinal infection, spinal tumors or cancer.[46]

Myelopathy and cervical spine instability severity is classified based on the criteria put forth by Ranawat.[47,48]

- Class I – No neurologic deficit

- Class II – Subjective weakness with hyperreflexia and dysesthesia
- Class IIIA – Objective weakness with long-tract signs; remains ambulatory
- Class IIIB – Objective weakness with long-tract signs; nonambulatory and quadriparetic

Clinical Outcomes

Four evidence syntheses with publication dates ranging from 2013-2022 that assessed clinical outcomes were identified.[49-52] All the syntheses included only randomized controlled trials. The number of primary studies in the syntheses ranged from 8 to 30, with generally small sample sizes. The eligibility criteria included participants that were diagnosed with single or multilevel cervical radiculopathy, myelopathy, or both (myeloradiculopathy). All reviews compared the effects of ACDF to CDA. Timing to follow-up was variable (29 months to ~8 years).

Núñez, et al. (2022) published a systematic review with meta-analysis that comprised 9 RCTs with sample sizes ranging from 44 to 541.[49] Clinical outcomes were assessed at a mean of 7.8 years post-surgery. The overall success rate in the CDA group was significantly higher than in the ACDF group (OR = 1.98, 95% CI: 1.57–2.49, p < 0.001) with moderate heterogeneity (I^2 = 36%, p = 0.16). There were no significant differences between the 2 groups regarding neck pain (SMD = – 0.17, 95% CI: – 0.37–0.04, p = 0.11) with high heterogeneity (I^2 = 74%, p = 0.002). Patient-reported arm pain results significantly favored the CDA group (SMD = – 0.16, 95% CI: – 0.29 to – 0.04, p = 0.01) with moderate heterogeneity (I^2 = 31%, p = 0.20). The physical SF-36 (quality of life) component significantly favored the CDA group (SMD = 0.13 95% CI: 0.03–0.23, p = 0.01) with very low heterogeneity (I^2 = 1%, p = 0.40). No significant differences were found between the 2 groups in the mental SF-36 component (SMD = 0.19, 95% CI: – 0.03–0.41, p = 0.10), with substantial heterogeneity (I^2 = 69%, p = 0.02). Limitations of this review included a high or unclear risk of bias involving all RCTs, indirectness (the mean age across studies was ~44.5 years), some imprecision involving overall treatment success, significant heterogeneity was present in all pooled clinical results.

Peng, et al. (2022) produced a systematic review with meta-analysis of 9,329 participants with single or multilevel cervical radiculopathy or myelopathy. At multiple follow-up time points, overall success favored CDA (total, OR 1.91, 95% CI 1.73 to 2.11, p=0.000).[50] Neurological success results also favored CDA in all follow-up periods (total, OR 1.74, 95% CI 1.49 to 2.04, p = 0.000). Disability results in all follow-up periods favored CDA (total, OR 1.70, 95% CI 1.49 to 1.94, p = 0.000). Limitations of this analysis included all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age among the studies ranged between 40-50 years), and imprecision (all pooled analyses for each follow-up period had confidence intervals that crossed the null value).

Xing, et al. (2013) included 8 RCTs with sample sizes ranging from 19 to 541. Participants (N=1,617) had single-level cervical radiculopathy or myelopathy [Xing]. Outcomes were measured between 24 and 48 months. For overall success, CDA was significantly superior to ACDF (OR = 1.84, 95% CI = 1.43 to 2.36; p < 0.00001), with no heterogeneity (I^2 = 0%). The neurological success rate results showed CDA was significantly superior to ACDF (OR = 1.75,

95% CI = 1.20 to 2.55; p = 0.004), with no heterogeneity (I^2 = 0%). There was no significant difference between the two treatment groups concerning disability measures. For arm pain, there was a significant difference between the two groups favoring CDA (MD = -4.86, 95% CI = -6.42 to -3.30; p < 0.00001) with low heterogeneity (I^2 = 8%). There was a significant difference between the two groups favoring CDA (MD = -7.90, 95% CI = -10.36 to -5.44; p < 0.00001) with no heterogeneity (I^2 = 0%) regarding neck pain outcomes. Limitations of this evidence synthesis included all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age of included studies was 43 years), imprecision (six of eight [75%] of studies had sample sizes smaller than 400 and all pooled analyses exhibited confidence intervals that crossed the null value), and inconsistency (moderate heterogeneity in the pooled results for disability).

Zhang, et al. (2020) included 1,238 participants from 13 RCTs in a systematic review with meta-analysis.[52] Outcomes were assessed at a mean of 83 months. The overall success rate significantly favored the CDA group compared to the ACDF group (OR = 1.68, 95% CI: 1.29–2.19, p < 0.001) with low heterogeneity (I^2 = 0%, p = 0.62). The CDA group had significantly higher neurological success than the ACDF group (OR = 1.54, 95% confidence interval [CI]: 1.14– 2.08, p = 0.004) with moderate heterogeneity (I^2 = 34.0%, p = 0.18). For disability results, the CDA group was significantly improved versus the ACDF group (MD = – 0.20, 95% CI: – 0.36 to – 0.05, p = 0.009), with moderate heterogeneity (I^2 = 37.8%, p = 0.20); however, the effect size did not reach clinical relevance. Measures of quality-of-life were better in the CDA group; however, neither statistical nor clinical significance was achieved. Both neck and arm pain were significantly better in the CDA group than in the ACDF group (MD = – 0.20, 95% CI: – 0.35 to – 0.05, p = 0.01 and MD = – 0.23, 95% CI: – 0.38 to – 0.07, p = 0.004, respectively), with low heterogeneity (I^2 = 31.6%, p = 0.23 and I^2 = 24.3%, p = 0.27, respectively). Limitations of this evidence synthesis included studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age across studies was ~44.5 years), imprecision (confidence intervals crossed the null effect), and inconsistency (moderate to substantial heterogeneity was found in the pooled analyses for neurological success and disability outcomes).

In aggregate, CDA demonstrated statistically significant improvement across clinical outcomes apart from quality-of-life measures, which were similar to ACDF. The clinical significance of the results was not described when assessing most pooled results for specific outcomes. Overall, the certainty of evidence was judged to be very low. All the included RCTs were rated as having unclear (some concerns) or a high risk of bias. The mean age among the studies ranged between 40-50 years and clinical relevance was not usually assessed (indirectness). More than 50% of studies had small sample sizes and wide confidence intervals suggesting variable effects (imprecision).

Surgical Outcomes

A single evidence synthesis provided data regarding surgical results.

Peng, et al. (2022) conducted a systematic review with meta-analysis of 30 RCTs.[50] Participants (N=9,329) with single or multilevel cervical radiculopathy or myelopathy randomly underwent ACDF or CDA. The pooled data showed ACDF had a significantly longer operative duration (OR, – 0.28; 95% CI, – 0.37 to – 0.2; p = 0.000). There were no significant differences between CDA and ACDF for blood loss and LOS (OR, 0.63; 95% CI, – 2.83 to 4.1; p = 0.72; OR, – 0.01; 95% CI, – 0.08 to 0.05; p = 0.68, respectively). The limitations of this analysis included all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age among the studies ranged between 40-50 years), and imprecision (all pooled analyses for each follow-up period had confidence intervals that crossed the null value).

Based on limited data, CDA demonstrated more than a 25% reduction in operative time compared to ACDF. There were no other perioperative outcomes that revealed significant differences between CDA and ACDF. The certainty of the evidence was rated as very low. All included primary studies had unclear (some concerns) or a high risk of bias. There was uncertainty about the applicability of the results to the U.S. Medicare population (indirectness). All pooled analyses for each follow-up period had confidence intervals that crossed the null value (imprecision).

Radiographic Outcomes

Three evidence syntheses reported on radiographic results in comparing ACDF with CDA.[49,51,52]

Núñez, et al. (2022) systematically reviewed and meta-analyzed data from 9 RCTs (N=2,664) who received either ACDF or CDA.[49] The fusion rate was 94.06% in the ACDF group, with no data for CDA. The heterotopic ossification rate for CDA = 10.3%, with no data for ACDF. The ROM rate in the CDA group was significantly higher (SMD = 1.86, 95% CI: 1.63–2.08, p < 0.001) with no heterogeneity (I^2 = 0%, p = 0.52). Less superior adjacent segment disease (ASD) was reported in the CDA group (OR = 0.33, 95% CI: 0.17–0.65, p = 0.001) with substantial heterogeneity (I^2 = 81%, p < 0.001). Less inferior ASD was reported in the CDA group (OR = 0.31, 95% CI: 0.15–0.66, p = 0.002), with substantial heterogeneity (I^2 = 75.1%, p = 0.05). Limitations of this review included a high or unclear risk of bias involving all RCTs, indirectness (the mean age across studies was ~44.5 years), and inconsistency (significant heterogeneity was present in all pooled results except ROM).

Xing, et al. (2013) measured radiological success as part of a systematic review with meta-analysis.[51] There was no significant difference between the ACDF and CDA groups (OR = 0.87, 95% CI = 0.36 to 2.09; *p* = 0.76). Limitations of this evidence synthesis included all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age of included studies was 43 years), and imprecision (six of eight {75%} of studies had sample sizes smaller than 400 and all pooled analyses exhibited confidence intervals that crossed the null value).

Zhang, et al. (2020) pooled data from 13 RCTs (N=1,238) in assessing ROM between patients who had ACDF or CDA.[52] The CDA group had significantly larger ROM than the ACDF group

(MD = 1.76, 95% CI: 1.57– 1.94, p < 0.001) with low heterogeneity (I^2 = 0%, p = 0.38). Limitations of this evidence synthesis included all studies having unclear (some concerns) or high risk of bias, indirectness (the mean age across studies was ~44.5 years), imprecision (confidence intervals crossed the null effect), and inconsistency (moderate heterogeneity regarding ASD outcomes).

Overall, apart from overall success, CDA demonstrated statistically greater radiological results when compared to ACDF. The certainty of the evidence was determined to be very low. Limitations included high or uncertain risk of bias across all included trials, indirectness, imprecision, and heterogeneity (ASD outcomes).

Undesirable Effects

Four evidence syntheses reported the pooled results of undesirable effects associated with cervical spine surgeries. All studies were conducted as systematic reviews with meta-analysis of RCTs.[49-52]

Núñez, et al. (2022) described outcomes for 2,664 participants obtained from 9 RCTs.[49] For overall complication rate, no significant differences were found between CDA (33.1%) and ACDF (38.9%) (OR = 0.84, 95% CI: 0.56–1.27, p = 0.42), with moderate heterogeneity (I^2 = 37%, p = 0.13). (p = 0.42). Reoperations occurred in 4.4% of CDA patients, a significantly lower rate compared with 15.6% of the ACDF group (OR = 0.26, 95% CI: 0.19–0.37, p< 0.001), with no heterogeneity (I^2 = 0.0%, p = 0.97). The limitations of this review included a high or unclear risk of bias involving all RCTs, indirectness (the mean age across studies was ~44.5 years), and inconsistency (significant heterogeneity was present in the pooled results).

Peng, et al. (2022) included 30 RCTs (N=9,329) in the review comparing ACDF with CDA.[50] In assessing implant events, no significant difference was found between the CDA and ACDF groups in short-term, mid-term, and long-term follow-up and total analysis (total, OR 1.14, 95% CI 0.92 to 1.42, p = 0.23). The incidence of ASD was higher in the ACDF group in long-term follow-up and total analysis (total, OR 0.71, 95% CI 0.55 to 0.94, p = 0.01). The incidence of dysphagia and dysphonia was higher in ACDF in short-term follow-up. There were no significant differences in total, mid- and long-term follow-up between CDA and ACDF (total, OR 0.9, 95% CI 0.73 to 1.09, p = 0.28). The reoperation rate was higher in ACDF in all follow-ups (total, OR 0.37, 95% CI 0.29 to 0.46, p = 0.000). This analysis had limitations including all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness (the mean age among the studies ranged between 40-50 years), and imprecision (all pooled analyses for each follow-up period had confidence intervals that crossed the null value).

Xing, et al (2013) compared the overall complication rates of ACDF and CDA for a mixed (cervical radiculopathy or myelopathy) population.[51] The meta-analysis found there was no significant difference between the two surgical methods (RR = 0.77, 95% CI = 0.48 to 1.23; p = 0.27) with moderate heterogeneity (I^2 = 39%). Limitations of this evidence synthesis included all primary studies were rated as having unclear (some concerns) or high risk of bias, indirectness

(the mean age of included studies was 43 years), and imprecision (six of eight {75%} of studies had sample sizes smaller than 400 and all pooled analyses exhibited confidence intervals that crossed the null value).

Zhang, et al. (2020) provided a comprehensive meta-analysis of undesired effects for 1,238 participants who underwent ACDF or CDA.[52] The difference in complication rates was not significant between the two groups (OR = 1.01, 95% CI: 0.77–1.32, p = 0.96), with low heterogeneity (I^2 = 8.4%, p = 0.37). For reoperations at the index level, the rate was significantly lower in the CDA group than in the ACDF group (OR = 0.41, 95% CI: 0.25–0.69, p = 0.001), with substantial heterogeneity (I^2 = 61.0%, p = 0.004). For reoperation at an adjacent level, the rate was significantly lower in the CDA group than in the ACDF group (OR = 0.34, 95% CI: 0.26–0.46, p < 0.001), with low heterogeneity (I^2 = 23.4%, p = 0.22). Limitations of this evidence synthesis included all studies having unclear (some concerns) or high risk of bias, indirectness (the mean age across studies was ~44.5 years), imprecision (confidence intervals crossed the null effect), and inconsistency (substantial heterogeneity regarding the reoperation rate).

In aggregate, ACDF and CDA demonstrate similar overall complication rates; however, CDA resulted in fewer reoperations and less ASD. ACDF and CDA result in equitable long-term dysphagia and dysphonia outcomes. The overall certainty of the evidence was determined to be very low due to the high or unclear risk of bias in the included RCTs, indirectness, imprecise results, and inconsistency (heterogeneity) affecting multiple outcomes.

Societal Guidance

North American Spine Society (NASS)[3] appropriateness criteria for cervical fusion surgery as a treatment for cervical myelopathy states “While there are some non-fusion procedures available to decompress the spinal canal such as laminoplasty and anterior cervical discectomy without fusion, the workhorses of surgical treatments for cervical spondylotic myelopathy (CSM) are ACDF, anterior corpectomy and fusion, and posterior laminectomy and fusion. It is well-accepted that non-operative care is acceptable in patients with mild myelopathy and that surgery should be considered in most. Anterior cervical decompression and fusion has become the most common surgical approach and technique for treating patients with CSM. With the availability of modern posterior cervical screw fixation, posterior cervical laminectomy and fusion has become an additional workhorse for treatment of CSM, with equivalent results as anterior surgery.”

Cervical myelopathy: (either from disc herniation, bony stenosis, or ossification of posterior longitudinal ligament [OPLL]) may be considered as an adjunct to decompression when anterior cervical discectomy, corpectomy or posterior laminectomy is planned for decompression of the spinal cord.

A multidisciplinary expert panel defined appropriate use criteria (AUC) of cervical fusion for the treatment of degenerative conditions of the cervical spine [Reitman]. Appropriate use criteria were developed using the RAND/UCLA appropriateness methodology. All scenarios included a

surgical plan as either cervical fusion (nonspecific) or specified as anterior cervical fusion (ACF), posterior cervical fusion (PCF), or combined (APCF). Clinical scenarios involving myelopathy was most strongly associated with an "Appropriate" rating. A total of 92% of scenarios with myelopathy, and well controlled medical or mild psychosocial comorbidities, or smokers, received a final rating of "Appropriate." All (100%) scenarios with myelopathy and poorly controlled medical or mild psychosocial comorbidities, or smokers, received a final rating of "Appropriate" for cervical fusion surgery.

AOSpine North America and the Cervical Spine Research Society[53] published clinical practice guidelines that outline recommendations about how to best manage (1) patients with mild, moderate, and severe myelopathy and (2) nonmyelopathic patients with evidence of cord compression with or without clinical symptoms of radiculopathy.

Recommendations based on 5 systematic reviews of the literature concerning the value of surgery and nonsurgical approaches for CSM were as follows: (1) "We recommend surgical intervention for patients with moderate and severe DCM." (2) "We suggest offering surgical intervention or a supervised trial of structured rehabilitation for patients with mild DCM. If initial nonoperative management is pursued, we recommend operative intervention if there is neurological deterioration and suggest operative intervention if the patient fails to improve." (3) "We suggest not offering prophylactic surgery for nonmyelopathic patients with evidence of cervical cord compression without signs or symptoms of radiculopathy. We suggest that these patients be counseled as to potential risks of progression, educated about relevant signs and symptoms of myelopathy, and be followed clinically." (4) "Non-myelopathic patients with cord compression and clinical evidence of radiculopathy with or without electrophysiological confirmation are at a higher risk of developing myelopathy and should be counseled about this risk. We suggest offering either surgical intervention or nonoperative treatment consisting of close serial follow-up or a supervised trial of structured rehabilitation. In the event of myelopathic development, the patient should be managed according to the recommendations above."

The World Federation of Neurosurgical Societies (WFNS) The Spine Committee of the World Federation of Neurosurgical Societies (WFNS) formulated an evidence-based consensus meeting on the management of CSM to develop recommendations for global applicability.[54] With some adaptations, the WFNS Spine Committee endorsed the guidelines of AOSpine North America and the Cervical Spine Research Society.[53] Additional recommendations include: using mJOA or its regional modifications to classify CSM as severe, moderate or mild and suggest offering surgical intervention or rehabilitation for patients with mild CSM (modified Japanese Orthopedic Association scale [mJOA] score 15–17. They state there is a consistent lack of evidence regarding the value of nonoperative treatment of cervical myelopathy in the literature hence nonoperative treatment may not be the final decision in most cases. They also share that predicting factors that indicate a possible deterioration during nonoperative, important predictors of myelopathy development include the presence of symptomatic radiculopathy, prolonged motor evoked potentials and somatosensory evoked potentials and

electromyography signs of anterior horn cell lesions (low evidence), patients are likely to achieve a better result after surgery if they have a shorter duration of symptoms (low evidence) and a call for additional RCTs.

World Federation of Neurosurgical Societies (WFNS) Spine Committee recommendations include:

- In patients with CSM, the indications for surgery include persistent or recurrent radiculopathy nonresponsive to conservative treatment (3 years); progressive neurological deficit; static neurological deficit with severe radicular pain when associated with confirmatory imaging (computed tomography, magnetic resonance imaging) and clinical-radiological correlation.
- The indications of anterior surgery for patients with CSM include straightened spine or kyphotic spine with a compression level below.

They clarify in the elderly age groups with bony ankylosis due to osteophytes at C5–6–7, CSM may manifest at higher levels where motion segments are preserved, especially the C3–4 level and also at lower levels such as the C7–T1 level. These guidelines provide directives for future research with suggested outcome measures, variabilities to consider as well as patient and surgery selection guidance.

The Italian Neurosurgical Society (SINch)[55] analyzed and proposed their own recommendations for the management of CSM in accordance with the recommendations published by the spine committee of the WFNS. The majority of WFNS recommendations were adopted with a few modifications.

The Japanese Orthopaedic Association (JOA) published 2023 clinical practice guidelines on the management of cervical spondylotic myelopathy(CSM).[56] The recommendations relevant to this evidence analysis are reported here:

- For mild cases of CSM, conservative treatment is primarily selected; however, at present there is insufficient evidence regarding treatment outcomes. Surgery is considered suitable for progressive myelopathy in which conservative treatment is unsuccessful.
- It is possible that conservative treatment can delay the progression of mild-to-moderate CSM, and therefore, performing conservative treatment is weakly recommended. For severe and progressive CSM, surgery is likely the first choice of treatment. However, there are few reports regarding the choice of treatment for mild and moderate CSM, and thus, it is difficult to draw a conclusion.
- There is no clear recommendation regarding which surgeries to perform

Additional Systematic Review/Meta-Analysis

Youssef[57] et al. conducted a systematic review and meta-analysis to evaluate the patient-reported and clinical outcomes of adult patients who underwent subaxial posterior cervical fusion with decompression for spondylosis, spinal stenosis and degenerative disc disease

resulting in radiculopathy or myelopathy. PubMed and Embase were searched for applicable literature resulting in a total of 33 and 31 articles which included in the systematic review and the meta-analysis, respectively. Changes in values of preoperative to postoperative patient-reported outcomes (visual analog scales for arm pain and neck pain, Neck Disability Index (NDI), JOA score, modified JOA score, and Nurick pain scale) were evaluated. Patient reported outcomes, successful fusion, revision surgeries, and complications/adverse events were considered. A subgroup analysis was performed in two instances; one for studies that included surgical indications for only myelopathy or radiculopathy (or combination) and another for studies that included surgical indications for only myelopathy or ossifications of the posterior longitudinal ligament (or combination). Cumulative changes in PROMs improved for all surgical indications including the two subgroup analyses. All surgical indications resulted in pooled outcomes rates of 98.25% for successful fusion, 1.09% for revision, and 9.02% for complications/adverse events. Axial pain, C5 palsy, transient neurological worsening, and wound infection were the most common complications. Limitations include high risk of bias, reporting bias, confounding, high heterogeneity, included 20/31 retrospective studies, and combining of different PROMs. Authors report many conflicts of interest but none that seem to impact this study; however, the study was funded by Providence Medical Technology, Inc.

Unstable Spine

Systematic Review/Meta-Analysis Mahmoud[58] and colleagues conducted a systematic review comprised of 627 patients and 36 articles to review the surgical indications, complications, and functional outcomes of different approaches for hangman fractures. Selected literature contained at least one of the primary outcomes: functional outcomes, complication rates, operation time, and blood loss. Minimally invasive surgery, C2 direct pedicle screw, C2- C3 fusion, and ACDF techniques were reviewed. VAS scores fell in all four groups when comparing pre- and postoperative scores, with the lowest VAS scores observed in the minimally invasive surgery group. In unstable fracture patterns, the literature showed that ACDF was preferred. Complications remained low in all groups with the greatest blood loss occurring in the posterior approach (255.9 mL in open posterior approach, 75.8 mL in MIS, and 64.3 mL in ACDF). Authors concluded if indicated, posterior approach may be preferred due to lower blood loss and disc access. When considering posterior approach, MIS may improve outcomes and have fewer complications. Limitations of the present study are inclusion of studies with retrospective study design, variations in reporting methods making data points challenging to categorize and lack comparative outcome studies.

Lee[59] and associates performed a meta-analysis comparing biomechanical and clinical outcomes between anterior-only and combined anterior and posterior fusions to determine which method of cervical fusion yielded better results for unstable cervical injuries. Ultimately, the analysis included 12 studies (eight biomechanical and four clinical studies) which included published dates between 2000-2019. Authors concluded cervical stability can be successfully restored following subaxial cervical injuries by anterior-only and combined anterior and posterior methods. No significant differences in clinical outcomes were observed while some

advantages were associated with combined fusion in terms of biomechanical stability. Selective use of methods should be determined based on type of injury. Authors also note need for control of technical factors of surgery that may have impacted results of cervical fusion. Limitations include a small sample size, in vitro studies, low number of studies included for analysis, and risk of bias.

Prospective

Yang[60] et al. performed a prospective study to propose a novel classification and scoring system called the posterior ligament-bone injury classification and severity score (PLICS) that offers a quantitative score to guide the need for posterior stabilization in addition to anterior reconstruction for subaxial cervical fracture dislocations (SCFDs). The study included 456 SCFD patients. High risk patients were defined as having PLICS ≥ 7 together with extremely unstable lateral mass fracture (EULMF). All others were defined as low-risk patients. Anterior only reconstruction was performed in the low-risk patients and additional posterior lateral mass fixation and fusion was performed after anterior reconstruction in the high-risk patients. The visual analogue score (VAS), the NDI, the American Spinal Injury Association (ASIA) impairment scale were utilized for outcomes. At 12 month follow up, 321 patients in the low-risk group and 49 patients in the high-risk group were still participating. VAS scores from preoperative to 12 months significantly improved (from 6.1 + 0.3 to 1.1 + 0.2 in the low-risk group, $P < 0.001$; from 6.4 + 0.2 to 1.4 + 0.2 in the high-risk group, $P < 0.001$). In the low-risk group at 12 month follow up the average NDI score was statistically low 8.8 + 2.5 vs 13.8 + 3.4, $P = 0.034$). With regards to the ASIA scale, 80.5% of patients experienced ≥1 grade improvement. Authors concluded for SCFD patients, EULMF and a PLICS score of 7 or greater may serve as a threshold for posterior stabilization in addition to anterior reconstruction. Limitations include the study design, patient selection methods, and exclusion of ankylosing spondylitis (AS) patients.

Madan[61] et al. conducted a prospective cohort study to assess the functional, neurological, and radiological outcomes of the patients with traumatic cervical spine instability. A total of 99 patients with subaxial cervical spine injuries were admitted and operated on at a single center between February 2014 and February 2016 and included prospectively. In all patients, bony fusion, neurological recovery, NDI and complications were assessed during the mean follow up period of 27 months (range 12–42 months). Corpectomy procedures that involved 1 level were 77.8% (n=77), 2 levels were 19.2% (n=19) and 3 levels were 3% (n=3). Neck Disability Index resulted in a mean of 7.57 ± 5.42. Grade 1 fusion was reported in 64.6% of cases. The most frequent adverse event was dysphagia 79.8% (n=79). Authors concluded an appropriate treatment option for subaxial cervical spine injuries is anterior cervical corpectomy and stabilization with cage filled with bone and cervical reflex locking plate. Authors further state this procedure is associated with favorable fusion rates and is likely a procedure of choice for posttraumatic multiple disc prolapse. Limitations of this study include study design, single center inclusion, risk of bias and sample size.

A prospective cohort study sponsored by the International Spine Study Group (ISSG) followed 77 patients surgically treated for adult cervical deformities for 1-year.62 Diagnoses included cervical sagittal imbalance (56%), cervical kyphosis (55%), proximal junctional kyphosis (7%) and coronal deformity (9%). Posterior fusion was performed in 85% (mean levels = 10), and anterior fusion was performed in 53% (mean levels = 5). At 1 year after surgery the cohort reported statistically significant improvement in neck pain, ability to perform usual activities and reduced pain and discomfort measured by standardized scales. Limitations include lack of control group, short term follow-up, performance at high volume centers with experienced surgeons that can reduce generalizability, and lack of standardized selection for surgery.

Retrospective

Zheng[63] and associates conducted a single center, retrospective, observational study comprised of 79 patients to investigate the role of ACDF in alleviating symptoms in patients with cervical vertigo associated with cervical instability. A significant relief of vertigo and dizziness was reported following anterior cervical surgery during the 2 year follow up period.

Yang[64] and associates performed a retrospective chart review to investigate the efficacy and safety of halo vest application before and during surgery in 25 patients with AS and severe thoracic kyphosis who underwent surgical treatment of cervical fracture-dislocation. Posterior or combined anterior-posterior surgery was performed on all patients. Authors conclude that use of the halo vest before and during the surgery is safe and effective while assisting with positioning, awake nasoendotracheal intubation, nursing, and the procedure by providing satisfactory reduction and immobilization.

Wang[65] et al. performed a retrospective chart review comprised of 36 patients to investigate the safety and efficacy of the halo-vest in the treatment of cervical fracture in patients with ankylosing spondylitis (AS) and kyphosis. Authors concluded The AS patient should undergo early surgical stabilization utilizing a halo-vest to aid in spinal deformity correction and to avoid neurological decline.

Skeppholm[66] and associates conducted a cohort study of 28 patients with artificial disc replacement (ADR) or anterior cervical decompression which were recruited from a larger RCT cohort to evaluate in vivo motion and stability of implanted artificial discs. Authors concluded most of the ADRs resulted in favorable mobility and proper attachment years after implantation with instability detected in only 8% of patients.

Rustagi[67] and colleagues conducted a retrospective chart review of 29 patients to present a series of posterior-only operated occiput-cervical fixation (OCF) cases following metastasis to the upper cervical spine (UCS) and craniocervical junction (CCJ). Authors concluded posterior OCF without tumor resection and anterior reconstruction can effectively manage symptomatic metastasis while offering pain relief and improved quality of life.

Luksanapruksa[68] and associates conducted a retrospective cohort study of 33 patients to evaluate surgical outcomes and complications of cervical spine fractures in ankylosing spondylitis (CAS) patients who were treated using either the posterior (P) or combined approach after experiencing neck pain after a fall. Authors conclude, although not statistically significant, posterior surgery was associated with lower blood loss, rate of complications, and shorter length of stay as compared to the combined approach. Limitations include study design, small sample size, and moderate lost to follow up rate.

Li[69] et al. conducted a retrospective study comprised of 38 consecutive patients to describe the authors' method of anterior discectomy/corpectomy and fusion combined with internal fixation for the treatment of unstable hangman's fractures and to evaluate the clinical and radiological outcomes. Authors conclude study results indicate to address unstable hangman's fractures, an anterior discectomy/corpectomy and fusion combined with internal fixation is a favorable approach.

Lee[70] and associates conducted a retrospective review of radiologic images of patients (n=34) who underwent C1-2 fusion. Patients were divided into one of two groups (the C-arm group or O-arm group). Authors concluded in cases of unstable C1-2 pathologies posterior fixation can reduce the operative time by utilizing intraoperative cone-beam CT scans for spinal navigation.

Lang[71] and colleagues conducted a cohort study comprised of 33 patients to assess the radiological and mid-term patient-reported outcome of traumatic subaxial cervical fractures treated with different plate systems. Authors concluded regarding a fragile fracture, that dynamic plate provided adequate stability with no significant loss of reduction when compared to the rigid plates. Patient-reported outcome were satisfactory in both groups.

Kong[72] and associates retrospectively analyzed clinical data of 46 patients who underwent C2-3 ACDF combined with internal fixation for unstable hangman's fractures to investigate the changes in the sagittal parameters of the cervical spine and the clinical efficacy of C2-3 ACDF combined with internal fixation. Authors conclude that anterior reconstruction of the anterior and middle columns with plate internal fixation can successfully achieve stability, correct displacement and angulation of C2, and restore sagittal balance while maintaining a high rate of fusion with few complications.

Kim[73] and colleagues conducted a retrospective analysis of 65 patients who were treated for a C1 fracture at single site between 1999 and 2016. Authors concluded type 3 fractures are most likely to be unstable while type 2 fracture and MVC are associated with higher rates of fusion failure. Most fractures were managed conservatively.

Bakhsheshian[74] systematic case review comprised of eight case series and 64 patients was performed to evaluate studies that utilized C2 lag screw placement in patients with traumatic spondylolisthesis of the axis (TSA). Authors concluded while freehand placement of C2 pedicle lag screws may be a reasonable option in some cases, C2 lag screw fixation resulted in positive fusion in most TSA patients. However, this study does not demonstrate superiority over

conservative treatment or other surgical methodologies and evidence is limited to level IV studies.

Jin[75] et al. conducted a retrospective clinical study to assess clinical outcomes and sagittal balance after unstable hangman fracture in 45 patients. Authors concluded that both anterior and posterior approaches are effective in treating unstable hangman fractures. They further state recovery of cervical sagittal balance was achieved by utilizing the posterior approach as compared to the anterior approach.

Garrido[76] and colleagues conducted a retrospective data review of 71 cases to assess the clinical outcomes of both rigid and nonrigid occipitocervical (OC) fusion constructs of a multicenter cervical spine study group. Authors conclude a statistically significant decrease in complication rates are associated with rigid occipitocervical construct as compared to nonrigidly fixed.

Dagtekin[77] et al. conducted a single center retrospective study comprised of 88 patients were included to evaluate OCJ injuries and to discuss the treatment modalities of these traumas and examine cadaveric studies for a better understanding. Authors concluded while it is essential to consider fracture pathophysiology and fracture type, they believe the most appropriate modality for atlantoaxial stabilization is C1-C2 segmental stabilization.

Clark[78] et al. conducted a retrospective chart review comprised of 43 consecutive patients to evaluate 30-day and 1-year mortality rates and review complications associated with posterior C1–2 fusion in an octogenarian cohort. Authors conclude in the octogenarian population a greater mortality rate is associated with Initial fracture displacement. Lower mortality rates resulted with posterior C1-2 fusions with unstable type II odontoid fractures as compared to nonoperative management mortality rates.

Candura[79] et al. performed a retrospective case series on 64 consecutive patients with Type II odontoid fractures. who presented to the Vertebral Surgery Unit. Authors conclude odontoid Type II fractures can be successfully treated with conservative treatment modalities in elderly patients.

Aldrian[80] et al. conducted a retrospective chart review on 46 patients to evaluate outcomes following surgical or nonoperative treatment of Hadley type IIA odontoid fractures. Authors conclude following nonoperative management, Hadley type IIA odontoid fractures are associated with increased risk for secondary loss of reduction and bony nonunion.

Surgical Approach

Multiple studies have compared surgical approaches and have not demonstrated superiority of one approach over another. A RCT compared ventral to dorsal surgical approach for CSM and found among 163 subjects the approaches shared similar outcomes at one year.[81] Other studies report similar results with some advantages and disadvantages found for each approach. A meta-analysis reports on 4,348 subjects and concludes that laminectomy and

fusion techniques offer comparable clinical outcomes.[82] A 2023 systematic review and meta-analysis also found no significant difference in functional outcomes from ACDF vs. posterior discectomy (PD) with moderate evidence per GRADE analysis.[83] The subject matter experts summarize that an individualized approach should be tailored to the individual patient's pathology to determine the optimal surgical route.

A 2023 systematic review on cervical degenerative disease treatment by the Agency for Healthcare Research and Quality[84] included 57 RCTs, 56 nonrandomized studies and one systematic review that enrolled patients with radiculopathy and/or myelopathy at one or more levels and analyzed various surgical approaches used. They report there were few comparative studies of non-operative treatments, and most studies were rated moderate risk of bias with most evidence rated lower insufficient strength to draw conclusions on comparative benefits and harms. They included ACDF, anterior versus posterior approach, standalone cage versus plate and cage in ACDF, and laminoplasty versus laminotomy with fusion. They conclude there were few differences in benefits between surgical approaches and techniques for the treatment of cervical degenerative disease however there was some differences in the frequency of adverse events for some comparison.

The Washington State Dept. of Labor & Industries' Industrial Insurance Medical Advisory Committee (IIMAC) published a "Guideline for Diagnosis and Treatment of Cervical Radiculopathy and Myelopathy" Labor & Industries[85] and states: "The ideal surgical approach for radiculopathy related to herniated disc remains a matter of debate. Various studies have compared the different surgery types and found no significant difference among them. Cervical surgeries can be divided into 2 major approaches: anterior (with or without fusion) and posterior. Except for hybrid surgeries, the choice of surgical procedure is left to the discretion of the surgeon. Hybrid surgeries combine artificial disc replacements and anterior cervical discectomy with fusion at select vertebral bodies (adjacent or non-adjacent) in a single procedure. They state there is insufficient evidence in medical literature to permit conclusions on its safety and efficacy."

North American Spine Society (NASS) Evidence-Based Clinical Guidelines on the Diagnosis and Treatment for Cervical Radiculopathy from Degenerative Disorders agrees that there is a lack of evidence that one surgical approach is superior. They reviewed multiple surgical approaches and found outcomes comparable with a Grade B Recommendation.[8]

Axial Neck Pain

Background

Axial neck pain is a prevalent condition that causes significant morbidity and productivity loss.[86] Nonspecific (primary) axial neck pain is distinguished from neck pain associated with specific causes (e.g., radiculopathy, myelopathy, stenosis, fracture). The pain distribution is localized to the neck and immediate surrounding structures and does not involve dysfunction of the arms, hands, fingers, or other body regions. It is characterized primarily by dull, achy pain in the nuchal region (posterior) neck.[87] The pain can sometimes travel to the base of the skull, shoulder, or scapulae. Other symptoms may include neck stiffness, headaches, and localized areas of muscle pain or paresthesia. Most axial neck pain is diagnosed based on ruling out

specific causes of neck pain. There is a wide range of pharmacologic and non-pharmacologic treatment options for axial neck pain. The appropriateness of surgery for axial neck pain is uncertain.[88] The purpose of this analysis is to summarize the evidence on the impact of fusion surgery procedures for the management of primary axial neck pain.

Literature Analysis

In a systematic review with meta-analysis, van Middelkoop, et al. (2012) identified 10 RCTs that compared additional fusion upon anterior decompression surgical techniques. The reviewers found there was no additional benefit of fusion techniques applied within an anterior discectomy procedure in patients with neck pain without radiculopathy on pain, recovery, and return to work. For recovery, the pooled risk difference in the short-term follow-up was -0.06 (95% CI -0.22 to 0.10) and -0.07 (95% CI -0.14 to 0.00) in the long-term follow-up. The pooled risk differences for pain and return to work all demonstrated no differences.[89]

Riew, et al. (2010) conducted a systematic review that examined the clinical outcome in patients undergoing ACDF for axial neck pain without radicular or myelopathic symptoms.[90] No comparative studies were identified; however, three case series were evaluated. All studies showed a mean improvement of pain of at least 50% approximately 4 years following surgery. Functional outcomes improved between 32% and 52% from baseline. Most patients reported satisfaction with surgery, 56% in one study and 79% in another. Complications varied among studies ranging from 1% to 10% and included pseudoarthrosis (9%), nonunion and revision (3%), and screw removal (1%). The authors concluded, “There is low evidence suggesting that patients with axial neck pain without radicular or myelopathic symptoms may receive some improvement in pain and function following ACDF. However, whether this benefit is greater than nontreatment or other treatments cannot be determined with the present literature.” The authors reported several limitations in their review. These included low-quality primary study designs (noncomparative case series), indirectness (the mean age of patients ranged from 42-56 years) imprecise data (small sample sizes, and the proportion of patients who achieved a clinically meaningful improvement in pain and function >30% was not reported), and inconsistency regarding the selection of fusion levels and integrity of discs adjacent to the operated levels, and the role of provocative testing)

As part of a Neck Pain Task Force, Carragee, et al. (2008) conducted a best-evidence synthesis of literature from 1980 through 2006 on surgical interventions for neck pain alone in the absence of serious pathologic disease. The reviewers found that cervical fusion for neck pain without radiculopathy was not supported by current evidence.[91] The literature search identified 4 frequently cited studies, which were deemed to be scientifically inadmissible, pertaining to cervical Fusion for non-radicular neck pain with only common degenerative changes.

- Palit, et al. (1999) retrospectively reported on the outcomes of 38 patients out of a possible 175 subjects (22%) who underwent ACDF for neck pain and degenerative disc disease (DDD).[92] No concurrent, historical, or retrospective controls were identified. Fusion levels were determined by a painful and concordant response to disc injections. An unknown

number of patients were excluded by the authors or declined surgery. Some potential patients (again, the number is unknown) were excluded because of psychological risk factors. The number of subjects lost to follow-up or who refused follow-up was not reported. There was no apparent standard assessment interval, and the intervals between the surgery and the reported assessment varied widely, from 2 to 7 years. Other interventions that the subjects might have received during this period— which could have affected outcomes—are not reported. Of the reported cases, the mean numerical pain rating after surgery remained greater than 4 (of 10), and the Oswestry Disability Index score showed moderate-to-serious impairment in most of the select group of patients followed. No neck-specific functional outcomes were assessed. Only 18 patients out of an unknown number (between 38 and 175) who were operated on by the authors for neck pain and degenerative disc disease said that the surgery had 'met their expectations'.

- Garvey, et al. (2002) reported on 87 of 112 (78%) retrospectively identified patients who underwent ACDF for a diagnosis of 'mechanical cervical spine pain' (defined by the authors as patients who had more neck pain than arm pain).[93] Patients were evaluated 5 to 10 years after surgery. The number of patients evaluated or considered for surgery is unknown. The selection process and screening were not detailed. Other treatments received were not reported. The group was heterogeneous for diagnosis: an unknown proportion of patients had some radiculopathy, radiographic instability, or cervical deformity. The validity of the outcomes reported is uncertain. For example, it is not clear if pain and functional impairment measurements were recorded both before and after surgery; if validated functional assessments for neck pain were used; and whether subjects considered the occurrence of surgery to have been advantageous to their litigation claim (78%). Only 58 of these 112 patients (52%) reported feeling 'somewhat better' or 'much better' than they did before their surgery; only 25 patients (23%) reported feeling at least 'somewhat satisfied' with their neck condition on follow-up. The authors cited historical controls treated by nonoperative care of neck pain alone, 21% of whom reported complete pain relief and 49% who reported partial relief. These cited 'control' outcomes were similar to the authors' reported surgical outcomes.

- Two additional studies are frequently cited to support surgical treatment of neck pain.[94,95] Both are retrospective case series with poorly reported recruitment procedures and follow few acceptable study design methods for outcome evaluation. For example, in these studies surgical outcomes are based solely on surgeons' perceptions of patient improvement as opposed to validated outcome instruments. Simmons, et al. report that the operating surgeon determined that 30 of 31 (97%) patients undergoing ACDF for neck pain were "all found to have immediate lessening" of symptoms after surgery; they further state that in every case "all pain was gone in a week after surgery"[95] This observation is unlike any recorded by validated outcomes measures or collected by independent examiners.

Carragee, et al.[96] go on to state, "It is well documented that neck pain without serious underlying disease shows wide and spontaneous variations in severity and any accompanying impairment. Thus, none of these frequently cited, uncontrolled studies can confidently estimate

how much, if any, of the reported improvement was due to a surgical intervention, how much was due to natural history, and how much might be explained by various nonspecific and unidentified factors. Although these studies are frequently cited as demonstrating clear efficacy of cervical fusion for primary neck pain, none of these were found to be scientifically admissible by the Neck Pain Task Force. Instead, after critical review of the methods and data we found no clinical evidence, even in the best-known studies purporting definitive efficacy, to support the use of either cervical fusion or cervical disc arthroplasty in patients with neck pain without radiculopathy or serious underlying pathology."

In addition to the methodological shortcomings of these studies described by Carragee, et al. (2008), there were further limitations. There was indirectness regarding the Medicare population (mean ages ranged from 42 to 45 years) and the target condition, nonspecific axial neck pain, (the study authored by Simmons, et al. included mostly [64%] of participants with specific causes of neck pain i.e., fracture, radiculopathy, myelopathy). All the studies had small sample sizes (n= 34-84) producing imprecise results.

In addition to these earlier primary studies, a single more recent RCT compared anterior fusion surgery with multidisciplinary rehabilitation for the treatment of individuals who were refractory to conservative treatment for chronic whiplash-associated disorders (WAD).[97] This study included 49 patients (mean ages were 38 and 40 years for the surgery and rehabilitation groups, respectively) with predominate midline neck pain, who had no neurological abnormalities and no specific changes seen on X-ray and MRI. The primary endpoint was the patient's perceived change in neck pain assessed on the follow-up, using the disease-specific Balanced Inventory for Spinal Disorders (BIS) questionnaire. Follow-up evaluations were performed at variable time points ranging from 17 to 50 months. Analyses were performed by intention-to-treat and per-protocol. At follow-up, 67% of the patients in the surgery group and 23% (95% CI 15 to 64) in the rehabilitation group assessed improvements in the ITT analysis. Corresponding proportions in the per-protocol analysis were 83% and 12%, respectively. This study was judged to have a high risk of bias due to the lack of blinding or incomplete blinding, and the outcome measurement (self-reported change in pain perception) was likely to be influenced by the lack of blinding. Additionally, there was very serious indirectness (all participants had neck pain caused by a motor vehicle accident and the mean ages were well below the Medicare population), and imprecision (small sample size and wide confidence intervals suggesting variable effects).

Taking into consideration all the relevant studies, the certainty of evidence was judged to be very low due to study design and execution limitations, indirectness, and imprecision.

Appropriate Use Criteria/Coverage Recommendations

The North American Spine Society (NASS) assessed the appropriateness of cervical fusion for axial neck pain without stenosis and concluded that the surgical procedure was never considered appropriate.[98] The authors additionally commented, "There was a trend to be rarely appropriate for 2 or greater level fusions, whereas there was more uncertainty for 1 level

fusions. Although uncertain, anterior procedures were overall favored over posterior or anterior and posterior procedures."

In the 2023 NASS Coverage Recommendations[3]), the committee states "Concerning the scenarios in which cervical fusion is not indicated, recent evidence-based medicine reviews have concluded that there is little to no evidence that fusion is an effective treatment for axial neck pain without neurological symptoms." [3]

Evidence-based, clinical practice decision-support guidance explicitly does not recommend surgical intervention for the management of non-radicular neck pain in adults due to a lack of high-quality data demonstrating benefit and the possible risk of harm.[99]

Analysis of Evidence (Rationale for Determination)

Cervical fusion alone or in combination with other spine surgical procedures is often performed for the management of multiple spinal conditions. There are three overall categories: cervical radiculopathy, cervical myelopathy, and unstable spine. There are multiple etiologies which can be revealed on imaging including herniated disc, spinal stenosis, spinal degeneration, synovial cyst and symptomatic pseudoarthrosis from non-union of prior fusion. In all cases the history, physical exam findings and imaging must correlate with the neurological deficits attributable to the affected region of the cervical spinal cord and other causes must be excluded.

The natural disease course of cervical radiculopathy is improvement with time and conservative measures so surgical management is reserved for refractory cases or when motor weakness creates significant functional limitations necessitating escalation of treatment. While the evidence supporting conservative therapy is low quality there are multiple RCTs and systematic review/meta-analysis as well as societal input and subject matter expert agree on a trial of conservative measures prior to surgical interventions. There is a paucity of data on how long the conservative period should be with reports ranging from 6 weeks to 3 or more months. As the data on disease course finds most improvement within the first 3 months a 12-week trial of conservative management is established, however the policy does acknowledge the need for some patients with progression during this time to shift to surgical management.

Cervical myelopathy (degenerative and mixed) is typically treated surgically due to the higher rate of neurological symptoms and risk of progression. In mild cases resolution with conservative therapy is possible and a trial of conservative treatment is indicated with education on progressive symptoms and intervention if worsening. Guidelines consist of a 6–12-week trial and 12 weeks was selected to allow time for the natural history of resolution or progression to determine if surgical intervention is necessary. In cases where there are progressive symptoms with neurological deficits surgical intervention prior to the 12-week time period can be considered.

In cases of unstable spine surgical intervention is necessary and there are few alternative options to consider. Malignant or benign spinal tumors leading to intractable pain or instability or anticipated instability due to treatment may necessitate stabilization with fusion. In some cases, spinal infection with destruction of bone and cervical kyphosis with cord compression may require surgical intervention to stabilize the spine.

There is not sufficient evidence to support surgical intervention for axial neck pain. Systematic review evaluating outcome for ACDF for axial neck pain with and without radiculopathy or

myelopathy reported low quality evidence and the benefit of the surgery over time could not be established as compared to nonsurgical treatment options. The remaining evidence reviewed concludes very low quality and therefore this is not considered reasonable and necessary. This is consistent with societal guidelines.

Investigation into the optimal surgical procedure has explored outcomes with various approaches. While there are clear benefits and disadvantages of the various approaches the overall outcome is largely equivalent. As there is no evidence to support one surgical approach over another the decision for the optimal surgical approach is determined by the surgeon and patients with consideration of the pathology and evaluation of risk and benefits of the various approaches. This is consistent with societal guidance and expert opinion.

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
09/11/2025	R2	**Revision Effective Date:** 09/11/2025 CONTRACTOR INFORMATION: **Added:** JF contractor information This update is to consolidate JE and JF to have one unified document and policy number. Pursuant to the 21st Century Cures Act, this revision does not require notice and comment because this update is considered non-substantive and does not alter the intent of coverage or non-coverage outlined in any LCD.	• Change in Affiliated Contract Numbers
01/30/2025	R1	Revisions effective 1/30/2025: Corrected typographical errors.	• Typographical Error

Associated Documents

Attachments
N/A

Related Local Coverage Documents
Articles

A59624 - Billing and Coding: Cervical Fusion

A59796 - Response to Comments: Cervical Fusion

A59797 - Response to Comments: Cervical Fusion

LCDs

DL39758 - Cervical Fusion (MCD Archive Site)

Related National Coverage Documents

NCDs

N/A

Public Versions

Updated On	Effective Dates	Status	
09/02/2025	09/11/2025 - N/A	Currently in Effect	You are here
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