

**Proposed Local Coverage Determination (LCD)
Epidural Procedures for Pain Management (DL39015)**

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No relevant conflicts of interest

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Publications: Over 550 articles and 12 books

Editorial Peer Review: 25 journals

LCD Development Process

- LCDs will be developed, in keeping with CMS directives:
 - A validated widespread problem; (Data, MR, CERT findings)
 - A significant risk to the Medicare trust fund (high dollar and/or high volume services);
 - Assuring beneficiary access to care;
 - Frequent denials issued or anticipated;
 - Multi-state contractor creating uniform LCDs across its jurisdiction

21st Century Cures Act of 2016

- Enacted as law in December 2016
- Multiple areas of health care affected
- Revision of Program Integrity Manual, (PIM) Chapter 13 – Local Coverage Determinations (Pub 100-08)
- LCD process updated to provide greater transparency, consistency and patient engagement
- The revised PIM, engaged directly with stakeholders to solicit ideas to improve the Medicare program aligning with process changes, is already underway as a result of the statutory mandates of 21st century cures.

Medicare Program Integrity Manual

Chapter 13: Local Coverage Determinations

Evidentiary Content

- The target Medicare population
- In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines.
- MACs shall explain the rationale that supports their coverage determination of covered, noncovered, or limited coverage. The rationale is the reasoning leading to the coverage determination.

**Procedures may only be eliminated with
overwhelming negative evidence.**

Issues with Epidural Proposed LCDs

1. Deleted percutaneous adhesiolysis
2. Deviates from existing LCD without evidentiary basis
3. Rigid criteria
 - Only radiculopathy, neurogenic claudication included
 - Inconsistent approved codes
4. Repeat procedures
 - Treatment beyond one year questionable
5. Restriction on multiple region treatments in one setting

Percutaneous Adhesiolysis

- Evidence with:
 - Relevant moderate to high-quality randomized trials
 - Relevant moderate to high-quality systematic reviews
- Multi-jurisdictional assessment score 3.21
- Cost utility \$3,710 per QALY

Existing LCDs vs. Proposed LCD

- Deletion of multiple covered conditions and codes
 - Degenerative disc disease
 - Discogenic pain without facet joint pain
 - Spinal stenosis without radiculopathy
- Number of procedures
- Removal of initial and therapeutic phases
- Lack of ability to perform multiple procedures

Rigid Criteria

- Radiculopathy and neurogenic claudication
- Herpes zoster
- Deletion of:
 - Degenerative disc disease without radiculopathy
 - Discogenic pain without facet joint pain – Score 3.43
 - Spinal stenosis without radiculopathy
 - Inconsistent approved codes
- No opportunity to treat with epidural:
 - CRPS
 - Neuropathic pain
 - Cervicogenic headache

Repeat Procedures

- Second procedure after 3 months with $\geq 50\%$ relief
- Limit of 4 per year per region
- No initial and therapeutic phases
- No evidentiary basis

Average relief by injection numbers for all conditions over a period of 2 years

(Based on 13 Randomized Control Trials)

Injection number	Successful	Failed	Combined
1 st procedure relief	6.60 ± 8.71 (1,254)	1.20 ± 1.85 (256)	5.69 ± 8.23 (1,510)
2 nd procedure relief	11.22 ± 12.89 (1,237)	0.93 ± 1.56 (165)	10.02 ± 12.57 (1,402)
3 rd procedure relief	14.35 ± 12.38 (1,124)	5.39 ± 5.79 (63)	13.87 ± 12.29 (1,187)
4 th procedure relief	13.75 ± 7.86 (979)	9.24 ± 11.23 (37)	13.59 ± 8.05 (1,016)
5 th procedure relief	13.77 ± 5.56 (852)	16.05 ± 12.97 (20)	13.82 ± 5.83 (872)
6 th procedure relief	13.94 ± 5.32 (744)	11.77 ± 3.78 (16)	13.90 ± 5.30 (760)
7 th procedure relief	13.58 ± 3.28 (628)	13.18 ± 0.60 (11)	13.58 ± 3.25 (639)
8 th procedure relief	13.45 ± 2.24 (450)	13.11 ± 0.33 (9)	13.44 ± 2.22 (459)
9 th procedure relief	13.41 ± 4.78 (149)	13.20 ± 0.45 (5)	13.41 ± 4.70 (154)

Average Relief for First Procedure

(Based on 13 Randomized Control Trials)

Procedure	Condition	Successful	Failed	Combined
Cervical Epidural	Disc Herniation	7.24 ± 11.21 (103)	0.33 ± 0.58 (17)	6.26 ± 10.66 (120)
Cervical Epidural	Discogenic without Facet joint pain	7.47 ± 6.72 (111)	0.67 ± 0.95 (9)	6.96 ± 6.71 (120)
Cervical Epidural	Central Spinal Stenosis	9.57 ± 19.56 (61)	0.58 ± 1.02 (19)	7.44 ± 17.49 (80)
Cervical Epidural	Post Laminectomy	5.99 ± 5.05 (100)	0.86 ± 0.83 (16)	5.28 ± 5.02 (116)
Thoracic Epidurals	Disc Herniation and Discogenic pain	8.30 ± 7.44 (106)	0.75 ± 1.16 (8)	7.77 ± 7.44 (114)
Lumbar Transforaminal	Disc Herniation	4.68 ± 7.05 (94)	1.27 ± 1.61 (26)	3.94 ± 6.44 (120)
Lumbar Interlaminar	Disc Herniation	6.18 ± 8.57 (109)	0.91 ± 0.83 (11)	5.70 ± 8.31 (120)
Lumbar Interlaminar	Discogenic without Facet joint or SI pain	6.31 ± 4.06 (109)	0.66 ± 0.89 (11)	5.79 ± 4.21 (120)
Lumbar Interlaminar	Central Spinal Stenosis	6.64 ± 10.47 (104)	0.86 ± 1.10 (16)	5.87 ± 9.95 (120)
Caudal Epidural	Disc Herniation	5.87 ± 4.92 (97)	1.64 ± 2.21 (23)	5.06 ± 4.82 (120)
Caudal Epidural	Discogenic without Facet joint or SI pain	6.82 ± 5.41 (78)	1.95 ± 2.35 (42)	5.12 ± 5.13 (120)
Caudal Epidural	Central Spinal Stenosis	7.05 ± 12.72 (74)	1.24 ± 2.00 (26)	5.54 ± 11.27 (100)
Caudal Epidural	Post Laminectomy	4.85 ± 4.47 (108)	1.55 ± 2.68 (32)	4.09 ± 4.35 (140)
Average of first injection for all conditions		6.60 ± 8.71 (1,254)	1.20 ± 1.85 (256)	5.69 ± 8.23 (1,510)

Average Relief for Second Procedure

(Based on 13 Randomized Control Trials)

Procedure	Condition	Successful	Failed	Combined
Cervical Epidural	Disc Herniation	12.65 ± 15.61 (100)	1.00 ± 1.00 (11)	11.50 ± 15.22 (111)
Cervical Epidural	Discogenic without Facet joint pain	11.30 ± 10.44 (110)	0.67 ± 0.82 (6)	10.75 ± 10.44 (116)
Cervical Epidural	Central Spinal Stenosis	11.05 ± 12.62 (59)	0.50 ± 0.87 (10)	9.65 ± 12.29 (69)
Cervical Epidural	Post Laminectomy	12.20 ± 17.29 (98)	0.43 ± 0.50 (10)	11.11 ± 16.82 (108)
Thoracic Epidurals	Disc Herniation and Discogenic pain	15.06 ± 18.12 (104)	0.17 ± 0.41 (6)	14.25 ± 17.94 (110)
Lumbar Transforaminal	Disc Herniation	8.25 ± 4.76 (91)	1.08 ± 1.42 (18)	7.07 ± 5.13 (109)
Lumbar Interlaminar	Disc Herniation	8.31 ± 4.11 (107)	0.22 ± 0.44 (9)	7.68 ± 4.51 (116)
Lumbar Interlaminar	Discogenic without Facet joint or SI pain	10.57 ± 10.51 (109)	0.86 ± 1.05 (5)	10.14 ± 10.46 (114)
Lumbar Interlaminar	Central Spinal Stenosis	12.07 ± 15.94 (103)	0.58 ± 0.79 (12)	10.87 ± 15.48 (115)
Caudal Epidural	Disc Herniation	12.13 ± 14.17 (97)	0.94 ± 2.55 (18)	10.38 ± 13.66 (115)
Caudal Epidural	Discogenic without Facet joint or SI pain	12.22 ± 11.57 (78)	1.57 ± 1.85 (34)	8.99 ± 10.86 (112)
Caudal Epidural	Central Spinal Stenosis	11.12 ± 14.89 (73)	0.76 ± 1.71 (12)	9.66 ± 14.27 (85)
Caudal Epidural	Post Laminectomy	9.13 ± 7.34 (108)	1.11 ± 1.79 (14)	8.21 ± 7.38 (122)
Average of second injection for all conditions		11.22 ± 12.89 (1,237)	0.93 ± 1.56 (165)	10.02 ± 12.57 (1,402)

Multiple Treatments

- 60% with 2 region involvements
- Significantly restricted
- Patient inconvenience (transportation, copays, multiple COVID-19 testings)
- Provider increased workload and costs
- More expensive
 - 150% instead of 200%
- Unintended consequences
 - All Medicare Advantage plans with high copays and deductibles – doubling the pain
 - All government plans follow Medicare
 - Medicaid
 - Commercials
 - Significant access reduction

Long-Term Treatment

- Treatment beyond one year restricted

Summary of Issues

- **Severe access issues**

- Adhesiolysis deleted in 2 jurisdictions

- **Rigid criteria**

- Reduces eligible population by 30%
- $\geq 50\%$ improvement for 3 months – eliminates 70% eligible

Overall leads to:

- Reduction in access
- Patient inconvenience & cost
- Increasing costs to patients, providers & Medicare
- Moving to expensive treatment
- Increasing opioid utilization
- Increasing disability
- Affecting most significantly vulnerable population
 - Elderly
 - Disabled
 - Poor
 - Minorities

Thank You

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