

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: LOWER BACK PAIN: PHARMACOLOGICAL INTERVENTIONS

Initial HERC approval 6/14/2012
Reaffirmed 11/13/2014

This coverage guidance was created under HERC's 2012 coverage guidance process and does not include strength of recommendation, a GRADE-informed framework or coverage guidance development framework.

As a part of the normal evidence review process, the Evidence-based Guidelines Subcommittee elected in September, 2014 (see Appendix A) to defer action on this coverage guidance until a planned updated version of the original source review is completed. However, the guidance's recommendation language has been altered to be consistent with that of more recent guidances.

HERC Coverage Guidance

Pharmacologic interventions for low back pain are recommended for coverage as follows:

Acute low back pain

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications (NSAIDs) and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines and opioids

Chronic low back pain (>1 month)

- First line: acetaminophen or NSAIDs, tricyclic antidepressants
- Second line: benzodiazepines and opioids
- Skeletal muscle relaxants should not be covered for chronic low back pain

For acute exacerbations of chronic low back pain, the herbal therapies of devil's claw, willow bark, and capsicum are recommended for coverage.

Given the risk profile of opiates and benzodiazepines, there should be a risk assessment prior to initiating therapy, and clear documentation of functional benefit should be required for ongoing prescription coverage.

Systemic steroids are not recommended for coverage for low back pain.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease

- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Chou, R., Huffman, L. *Medications for Acute and Chronic Low Back Pain: A Review of the Evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline*. *Ann Intern Med.* 2007; 147; 505-514. Available at: <http://www.annals.org/content/147/7/505.full.pdf+html>

Chou R., Qaseem, A., Snow, V., Casey, D., Cross, J.T., Jr., Shekelle, P., Owens, D.K.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. *Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society*. *Annals of Internal Med.* 2007; 147(7); 478-491. Available at: <http://www.annals.org/content/147/7/478.long>

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

SUMMARY OF EVIDENCE

CLINICAL BACKGROUND

Low back pain is the fifth most common reason for all physician visits in the United States. Approximately one quarter of U.S. adults reported having low back pain lasting at least 1 whole day in the past 3 months, and 7.6% reported at least 1 episode of severe acute low back pain within a 1-year period. Low back pain is also very costly: Total incremental direct health care costs attributable to low back pain in the U.S. were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. work force compensated for back injuries each year.

Many patients have self-limited episodes of acute low back pain and do not seek medical care. Among those who do seek medical care, pain, disability, and return to work typically improve

rapidly in the first month. However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity. Approximately 5% of the people with back pain disability account for 75% of the costs associated with low back pain.

Many options are available for evaluation and management of low back pain. However, there has been little consensus, either within or between specialties, on appropriate clinical evaluation and management of low back pain. Numerous studies show unexplained, large variations in use of diagnostic tests and treatments. Despite wide variations in practice, patients seem to experience broadly similar outcomes, although costs of care can differ substantially among and within specialties.

EVIDENCE REVIEW

Medications in several classes have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For example, acetaminophen is a slightly weaker analgesic than NSAIDs but is a reasonable first-line option for treatment of acute or chronic low back pain because of a more favorable safety profile and low cost. Nonselective NSAIDs are associated with well-known gastrointestinal and renovascular risks, and there is an association between exposure to cyclooxygenase-2–selective or most nonselective NSAIDs and increased risk for myocardial infarction. Opioid analgesics or tramadol are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and NSAIDs. Because of substantial risks, including aberrant drug-related behaviors with long-term use in patients vulnerable or potentially vulnerable to abuse or addiction, potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy. Failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation.

For *skeletal muscle relaxants*, although the antispasticity drug tizanidine has been well studied for low back pain, there is little evidence for the efficacy of baclofen or dantrolene, the other FDA-approved drugs for the treatment of spasticity. Other medications in the skeletal muscle relaxant class are an option for short-term relief of acute low back pain, but all are associated with central nervous system adverse effects (primarily sedation). Tricyclic antidepressants are an option for pain relief in patients with chronic low back pain and no contraindications to this class of medications. Antidepressants in the selective serotonin reuptake inhibitor class and trazodone have not been shown to be effective for low back pain, and serotonin–norepinephrine reuptake inhibitors (duloxetine and venlafaxine) have not yet been evaluated for low back pain.

Gabapentin is associated with small, short-term benefits in patients with radiculopathy and has not been directly compared with other medications or treatments. There is insufficient evidence to recommend for or against other antiepileptic drugs for back pain with or without radiculopathy. For acute or chronic low back pain, benzodiazepines seem similarly effective to skeletal muscle relaxants for short-term pain relief but are also associated with risks for abuse, addiction, and tolerance. Herbal therapies, such as devil's claw, willow bark, and capsicum, seem to be safe options for acute exacerbations of chronic low back pain, but benefits range from small to moderate. Systemic corticosteroids are not recommended for treatment of low

back pain with or without sciatica, because they have not been shown to be more effective than placebo.

OVERALL SUMMARY

Medications in several classes, including NSAIDs, opioids, tramadol, skeletal muscle relaxants, antidepressants and antiepileptics, have been shown to have moderate, primarily short-term benefits for patients with low back pain. Each class of medication is associated with unique trade-offs involving benefits, risks, and costs. For most patients, first-line medications are acetaminophen or NSAIDs. Systemic corticosteroids are ineffective. Several herbal therapies demonstrate small to moderate benefit.

PROCEDURE

Pharmacologic therapy

DIAGNOSES

Low back pain

APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
V10.3	Personal history of malignant neoplasm, breast
V16.3	Family history of malignant neoplasm, breast
V76.10	Special screening for malignant neoplasms, breast, unspecified
V76.19	Special screening for malignant neoplasms, breast, other screening breast examination
V84.01	Genetic susceptibility to malignant neoplasm of breast
CD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
77058	MRI breast, with or without contrast, unilateral
77059	MRI breast, with or without contrast, bilateral
HCPCS Level II Codes	
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8904	Magnetic resonance imaging without contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8907	Magnetic resonance imaging without contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral

Note: Inclusion on this list does not guarantee coverage

APPENDIX A

SCANNING RESULTS

One AHRQ review that addresses pharmacological interventions for low back pain is expected to be published in late 2015 or early 2016.

Agency for Healthcare Research and Quality (2014). Noninvasive Treatments for Low Back Pain: Research Protocol. Oct. 8, 2014. Retrieved from <http://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1983>

SUMMARY

The Evidence-based Guidelines subcommittee will perform a search of trusted sources and update the coverage guidance upon completion of the report referenced above.