



Treatment Options for Low Back Pain Overview & Key Questions

Overview

Low back pain (LBP) is an exceedingly common complaint, with a lifetime prevalence ranging from 54-80%. Chronic low back pain may be seen in 25-60% of patients one year or longer after an initial episode. The economic impact of low back pain is substantial. It is the fifth most common reason for all physician visits in the U.S., and is responsible for direct medical costs that approach \$30 billion annually. In addition, low back pain is a major cause of lost productivity; it is estimated that 2% of the U.S. work force is compensated for back pain or injury each year.

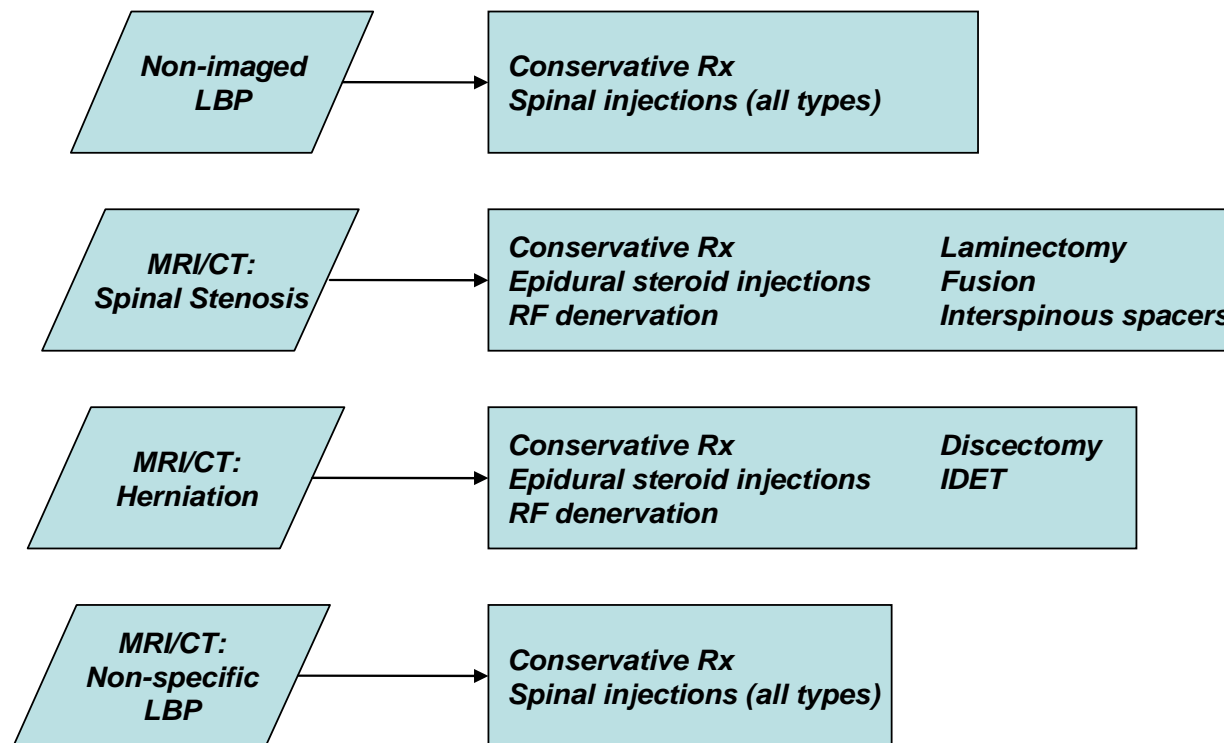
This appraisal will evaluate the evidence on the comparative risks and benefits for four types of patients with chronic low back pain. Our appraisal will include a systematic review of published literature and the creation of a new decision analytic model. The four types of patients, and the specific management strategies to be compared for each type, are depicted in the **Figure** on the following page.

We have framed the patient categories and the list of treatment options to be compared based on our preliminary data review and discussions with clinical experts and policy leaders. The goal of our appraisal is not to be exhaustive; rather, we intend to focus on the key areas of uncertainty and controversy that are the highest priority for patients, clinicians, and policy makers. Consequently, while non-invasive, or “conservative” care is part of this appraisal, we do not plan to perform new assessments comparing the many possible forms of non-invasive management strategies to each other. In part, this decision was driven by the existence of excellent, comprehensive reviews of the various approaches to conservative care that were developed recently to support a joint American College of Physicians/American Pain Society guideline statement. These excellent reviews are included in the separate Appendix document (Appendix F).

The key questions on which we will seek your input during the scoping phase of this appraisal are outlined beginning on page 3. Background information, including descriptions of the management strategies as well as relevant guidelines, coverage policies, and ongoing research can be found in Appendices A-E.

Low Back Pain* Proposed Patient Categories and Treatments for Comparison

**Pain >4 weeks, no systemic symptoms or urgent findings from neurological exam*



LBP: Low back pain; RF: Radiofrequency; IDET: Intradiscal electrothermal therapy

Key Questions: Low Back Pain

General

1. We propose to frame the evidence for 4 distinct patient populations:
 - a. Non-imaged
 - b. Imaged, evidence of spinal stenosis
 - c. Imaged, evidence of disc herniation
 - d. Imaged, non-specific findings

Is there a better way to conceptualize the key patient populations?

2. The **Figure** depicts the proposed set of treatment options we will compare for each patient population. Should any of these treatment options be excluded for any reason? Conversely, have we left out any management options that you think should be high priority for our appraisal?
3. What are the most important outcomes related to the *clinical effectiveness* of the strategies under evaluation that we should focus on in the appraisal (e.g., functional return, pain, lost productivity)?
4. Are there any types of published studies that we should emphasize or de-emphasize in our review for any reason? Have certain techniques evolved such that we should exclude earlier data published before a particular year? Are there additional sources of data other than published studies that should be included in our review?
5. Are there particular patient subgroups within the four categories that we should evaluate separately in the appraisal (e.g., by age, worker's comp)?
6. We perform our cost-effectiveness analyses from the third-party (Medicare) perspective, but we always consider whether additional costs (e.g. productivity, time in treatment) should be included. What costs should we include/exclude for this appraisal?

Treatment-specific

7. We plan to limit our scope to intraspinal injections only (e.g., epidural steroids, facet nerve blocks) and exclude other injections such as botulinum toxin, local injections, and prolotherapy. Are any of the excluded variations of high enough priority to consider including in the scope of the appraisal?
8. Should the appraisal of discectomy include the open procedure as well as microscopic and/or endoscopic approaches?
9. In addition to open laminectomy, are there are other approaches to decompression that we should consider including?
10. We plan to evaluate the evidence on both simple and complex fusion; are there further stratifications of the evidence (e.g., by type of instrumentation) that would be feasible and appropriate?

Description of the Decision Analytic Model

A state transition (Markov) model of management and outcomes of low back pain will be created. In a Markov model, the clinical course of patients is classified into discrete clinical states and patients transition between states at discrete time intervals.

The clinical course of patients will be modeled for low back pain of > 4 weeks duration with no evidence of systemic disease (infection, malignancy) and no evidence of neurological disease requiring immediate surgery. Patients with prior surgery for low back pain will be excluded.

Patient categories and comparative treatment options are displayed in the preceding **Figure**. The proposed clinical outcomes of interest include:

- 1) Resolution of persistent low back pain
- 2) Return to previous level of function
- 3) Limitations in function
- 4) Recurrent episodes of low back pain
- 5) Recurrent surgery
- 6) Adverse effects or complications of treatment
- 7) Death

The systematic review and meta-analysis of published studies will provide important parameters for the probabilities of outcomes of each intervention. Information on clinical epidemiology of low back pain and its treatment will be obtained from the literature, and mortality data will be obtained from US vital statistics and life tables. Information on costs will be obtained using Medicare payment rates as well as acquisition costs of drugs and devices from manufacturers.

The management alternatives will be represented graphically in a decision tree and a cost-effectiveness (cost-utility) analysis will be conducted. The analysis will follow the recommendations of the Panel on Cost-Effectiveness in Health and Medicine. The economic analysis will use costs and quality adjusted life years as summary measures. Costs will include direct medical care costs (i.e., treatment, follow-up and monitoring, complications and side effects) and indirect medical care costs (e.g., work loss). Analyses will be conducted alternatively including and excluding work loss. Uncertainty in parameter estimates will be explored using a variety of deterministic and probabilistic sensitivity analyses.

Model Questions

1. Eligible patients

- a. Patients with previous surgery for low back pain will be excluded. Does this adequately describe the relevant population?
 - b. Patients with occupational low back pain covered by workman's compensation and patients with unresolved disability claims may differ from other patients. How should these subpopulations be classified?
 - i. Should the analysis be *stratified* for these subpopulations?
 - ii. Should the analysis be *restricted* to any subpopulations?
 - iii. Should the analysis *exclude* any subpopulation?
2. **Sources of data and selection bias.** Patients enrolled into studies of low back pain who have had previous low back pain may represent selected low back pain patients, and data on their clinical course and outcomes may reflect substantial selection bias. Similarly, studies from academic and referral centers may also reflect referral bias. What sources of data are available to most accurately model the typical clinical course and outcomes of low back pain?
3. **Time frame.** Low back pain is a chronic and recurrent condition. Previous studies suggest that patients improve after conservative treatment and surgical treatments, and that patients with conservative treatment may have late or delayed surgery and that patients with surgical treatment may have surgery again for low back pain. Previous CEAs and clinical trials with accompanying CEAs have analyzed time periods of 2 years, 5 years and 10 years. We propose to analyze the short-term and long-term outcomes, and project clinical course for 10 years or longer. Which time frame represents the most important to stakeholders?

4. **Clinical states.** The goals of treatment for low back pain are to relieve pain and restore patient to previous level of function. We would propose to describe outcomes as combinations of pain (resolved or persistent) and function (return to previous level of function or new limitations in function). What clinical classification methods are used to report pain and functional outcomes in the published literature? What outcome classifications methods are used to describe outcomes of surgery for low back pain? Are there differences by surgical specialty?
5. **Perspective.** We will analyze outcomes using societal and payer perspectives. Are other perspectives of interest, such as an employer's perspective?