



Clinical and Economic Model of Treatment Strategies for Low Back Disorders
ICER Evidence Review Group Call
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Approach

Markov Decision Analysis model:

- Each alternative strategy is represented graphically in a decision tree as a sequence of interventions over time depending on patients' LBP syndrome and response to treatment interventions.
- Patients' conditions are represented as discrete clinical states, and patients transition between the clinical states over time
- LBP states: classification by response to intervention as "improved" (not requiring a subsequent intervention) or as "not improved" (subsequent intervention) based on RCT criteria of successful outcome (when available) or minimally important difference in one or more of pain (≥ 10 point improvement on VAS or equivalent), function (> 10 point improvement on ODI or 2 point on RDQ, or successful return to work)
- Perspectives: Payers' perspective and employers' perspective
- Time: Overall 2-year time horizon
- Probabilities of response to interventions from systematic review: injections, 1 month (allow up to 2 repeats); conservative treatment or multidisciplinary care, 3 months; IDET 3 months, spacers or other surgery, 1 year
- Men and women, age 45; employed, not disabled

Costs

- Direct medical care costs (costs for medical care services)
- Non-medical costs (human capital approach, lost productivity, time costs)

Outcomes

- Pain (VAS, Likert, etc.)
- Disability/Function (RDQ, ODI)
- Subjective improvement, treatment success
- Work loss, limitations in activity
- Employment
- QoL (SF-36, EQ-5D)

Model Assumptions

1. **Low Back or Leg Pain** > 4 weeks initial conservative treatment [patient education, advice on activities, analgesic and/other medications, spinal manipulation, physical therapy].
 - a. No “red flags: No urgent neurological findings (cauda equina syndrome with incontinence, strength < 4/5, pregnancy, trauma, neoplasm, infection, inflammatory spondyloarthropathy)
 - b. No prior LBP surgery, severe scoliosis, or other congenital deformities
2. **Patients**, age 45, male or female. Patients are employed and do not have initial disability or severe comorbid conditions that would limit selection of LBP treatments.
3. **Low Back Pain Syndromes**
 - a. Lumbar Disk Herniation (LDH)
 - b. Lumbar Spinal Stenosis \pm degenerative spondylolisthesis (LSS \pm DS)
 - c. Nonspecific Low Back Pain (NSLBP)
4. **Strategies** apply to patients with LBP > 4 weeks duration and assume pain persists and is severe after initial conservative treatment. Patients have been referred for imaging and are classified based on clinical findings and imaging. Strategies compare management options for each LBP syndrome.
5. **Lumbar Disk Herniation (LDH) Strategies**
 - Continued conservative treatment
 - Intensive multidisciplinary care
 - Epidural steroid injections
 - IDET
 - RF denervation
 - Discectomy
6. **Lumbar Spinal Stenosis (LSS \pm DS) Strategies**
 - Continued conservative treatment
 - Intensive multidisciplinary care
 - Epidural steroid injections
 - Interspinous spacers
 - RF denervation
 - Laminectomy \pm fusion
7. **Nonspecific Low Back Pain (NSLBP) Strategies**
 - Continued conservative treatment
 - Intensive multidisciplinary care
 - Epidural steroid injections or other injections
 - IDET
 - RF denervation
 - Interspinous spacers
 - Laminectomy \pm fusion
8. **Surgery**
 - Surgery may be indicated if severe LBP persists, recurs, or becomes more severe after other minimally invasive or less invasive interventions (epidural steroid injections, IDET, RF neurotomy, or interspinous spacers).
 - Repeat surgery may be required for a complication of a surgical intervention or a minimally invasive intervention and will be included in treatment strategies.
 - A rate of repeat LBP surgery for recurrent symptoms will also be included in treatment strategies. The repeat rate will be derived from the literature.

Key Questions for ERG

1. Model perspective (payers & employers) and duration of follow-up (2 years) appropriate?
2. How can the patients' LBP be classified for use in the interventions in the strategies?
 - a. LBP (mild, moderate severe)?
 - b. LBP (better, same, worse)?
 - c. Patient working, not working due to LBP, or disabled?
3. Are the LBP syndromes (LDH, LSS ± DS, NSLBP) appropriate?
4. Are the interventions for each LBP syndromes appropriate?
5. Are strategies (sequence of interventions) shown in the sample decision trees for each LBP syndrome appropriate?
6. Are assumptions about repeat surgery appropriate?
7. Other costs and outcomes of interest in addition to those listed?
8. For interventions with limited or inconclusive evidence for effectiveness, we intend to conduct "threshold" analyses only (i.e., if intervention A had sufficient evidence, at what threshold of effectiveness would it produce better outcomes than intervention B?) Appropriate?
9. Data permitting, we will assume a probability of repeat minimally-invasive treatments (e.g., injections, RF denervation, IDET) prior to surgery for non-response. Appropriate?





