

Summary

Therapies Under Review

ICER's report reviewed the clinical effectiveness of five interventions for chronic low back and neck pain, as well as the value of those interventions in chronic low back pain. The interventions reviewed were **acupuncture**, **cognitive behavioral therapy** (a form of psychotherapy that helps develop coping strategies to manage a particular problem -- in this case, pain), **mindfulness-based stress reduction** (a technique that uses a combination of mindfulness meditation, body awareness, and yoga to manage pain), **tai chi**, and **yoga**.

The report was subject to public deliberation during a meeting of the California Technology Assessment Forum.

ICER Evidence Ratings

- **Low Back Pain:** With the exception of tai chi, for which evidence was promising but inconclusive, ICER's review found moderate certainty of at least a small net health benefit for each of the interventions.
- **Neck Pain:** With the exception of acupuncture, for which evidence was promising but inconclusive, evidence was insufficient to determine the benefit of any of the interventions in neck pain.

Cost Effectiveness and Value

- ICER's analyses concluded that each of the therapies had favorable cost-effectiveness ratios, falling within or below commonly accepted thresholds when used in chronic low back pain. Prices align with the benefit provided to patients.
- Due to data limitations, cost-effectiveness was not assessed in chronic neck pain.

Key Policy Recommendations

- The strength of evidence appears adequate to support coverage of acupuncture, CBT, MBSR, and yoga for chronic low back pain. Evidence is far weaker for tai chi.
- Payers may wish to assess requests for coverage of therapies for chronic neck pain on a case-by-case basis, given that there is far less evidence on the effectiveness of these therapies for chronic neck pain.
- Researchers should study the effect of these interventions in reducing or eliminating the use of opioid therapy in patients with chronic pain.

For Chronic Low Back and Neck Pain

Chronic low back and neck pain are two of the most common reasons patients visit their doctors in the US. Total health care costs for these conditions are high, reaching \$87.6 billion in 2013. Many treatments, including opioid pain medications, injections, and surgeries provide modest benefit and pose substantial risk. Non-invasive therapies may provide safer alternatives. ICER’s review focused on five cognitive and mind-body therapies: **acupuncture, cognitive behavioral therapy (CBT), mindfulness-based stress reduction (MBSR), yoga, and tai chi.**

How strong is the evidence that **cognitive and mind-body interventions** improve patient outcomes?

ICER Evidence Ratings

	For Chronic Low Back Pain	For Chronic Neck Pain
Acupuncture	Moderate certainty of at least a small net health benefit	Promising but inconclusive
CBT	Moderate certainty of at least a small net health benefit	Insufficient
MBSR	Moderate certainty of at least a small net health benefit	Insufficient
Yoga	Moderate certainty of at least a small net health benefit	Insufficient
Tai Chi	Promising but inconclusive	Insufficient

The two outcomes that patients said were most important to them were **improvement in function** (i.e., a greater ability to work and do their desired daily activities), and **reduction in pain**. These were the key outcomes assessed in ICER’s review of the evidence.

Back Pain

The majority of trials and analyses of **acupuncture, CBT, MBSR, and yoga** showed **small to moderate improvements in function and pain compared to usual care**. There was substantially less evidence for the effectiveness of tai chi.

In acupuncture, the differences in outcomes were smaller when compared to sham acupuncture instead of usual care, suggesting that much of the benefit of the intervention may result from a placebo effect.

Neck Pain

For acupuncture and CBT, trials found a **small net health benefit** based on improvements in pain and function, with limited harms; however, the small numbers of patients studied, short follow-up, and inconsistent results led to **low certainty in the evidence**. There were no trials of MBSR and yoga that met ICER’s inclusion criteria. A single, small trial of tai chi found no differences comparing tai chi to neck exercises.

How strong is the evidence that **cognitive and mind-body interventions** improve patient outcomes? (continued)

Harms

Each of the five interventions were well-tolerated for both back and neck pain. No serious adverse events that were thought to be related to the intervention were reported in the trials.

Commonly-reported adverse events included bleeding and pain at the site of acupuncture needles, and strains and joint aches in patients receiving the MBSR, yoga, and tai chi interventions. An increase in back and neck pain for up to one month was sometimes reported. No adverse events were reported for CBT.

Other Benefits and Contextual Considerations

ICER's report also considers potential additional benefits that are not adequately captured in the clinical literature. Stakeholders suggested some of these considerations may include:

- Treatment for a condition with a high burden of illness
- Reduced family/caregiver burden
- Return to work or increased job productivity
- Reduction or discontinuation of opioid therapy to manage pain, reducing the risk of associated harms

Controversies and Uncertainties

There are several issues that are important to consider when assessing the evidence base for the cognitive and mind-body interventions.

- **Variation within Interventions:** There are many different approaches to each of the interventions (e.g., different types of yoga). Some forms may offer more benefit than others, but evidence was not sufficient to identify which, if any, of the approaches were most effective. Variation in skill level of the therapist leading the intervention may further affect results.
- **Pain Subtypes:** There are many different causes for chronic low back and neck pain. There may be mind-body interventions that are particularly effective in certain subtypes of low back and neck pain, but current evidence is not sufficient to identify any variation in effectiveness.
- **Placebo Effect:** Some studies found sham acupuncture to be almost as effective as traditional acupuncture or structured acupuncture, suggesting a strong placebo effect. Some argue that this is a worthwhile use of the placebo effect, while others argue that it is unethical to recommend such treatment.
- **Long-term Effects:** The majority of the clinical trials of cognitive and mind-body interventions for chronic pain followed patients for less than a year. For most of these therapies, patients must maintain behavioral changes, which can be challenging. Thus, there remains considerable uncertainty about their long-term benefits, although they are unlikely to have any long-term harms.

Economic Analyses

Long-Term Cost-Effectiveness

Compared to usual care, **all interventions for chronic low back pain met commonly-accepted thresholds for cost-effectiveness of \$50,000-\$150,000 per quality-adjusted life year (QALY) gained.** Due to a lack of evidence on key clinical outcomes, cost-effectiveness analyses were not conducted for chronic neck pain.

Cost-effectiveness for chronic low back pain compared to usual care:

- **Acupuncture:** \$54,000 per QALY
- **CBT:** \$94,000 per QALY
- **MBSR:** \$20,000 per QALY
- **Yoga:** \$4,000 per QALY
- **Tai chi:** \$37,000 per QALY

ICER's Value-Based Price Benchmarks

All the interventions under review are aligned with their benefit to patients at current prices, falling below or within ICER's threshold value range of \$100,000 to \$150,000 per QALY. A majority of the interventions would continue to align with value even if costs increased.

Intervention	Cost per Session	Value-Based Price Benchmark (per session)	Cost within or below benchmark range?
Acupuncture	\$104	\$180-\$262	✓
CBT*	\$212	\$225-\$328	✓
Yoga*	\$18	\$150-\$219	✓
MBSR*	\$60	\$225-\$328	✓
Tai Chi*	\$18	\$39-\$56	✓

*Per-session costs based on group appointments.

Economic Analyses (continued)

Potential Short-Term Budget Impact

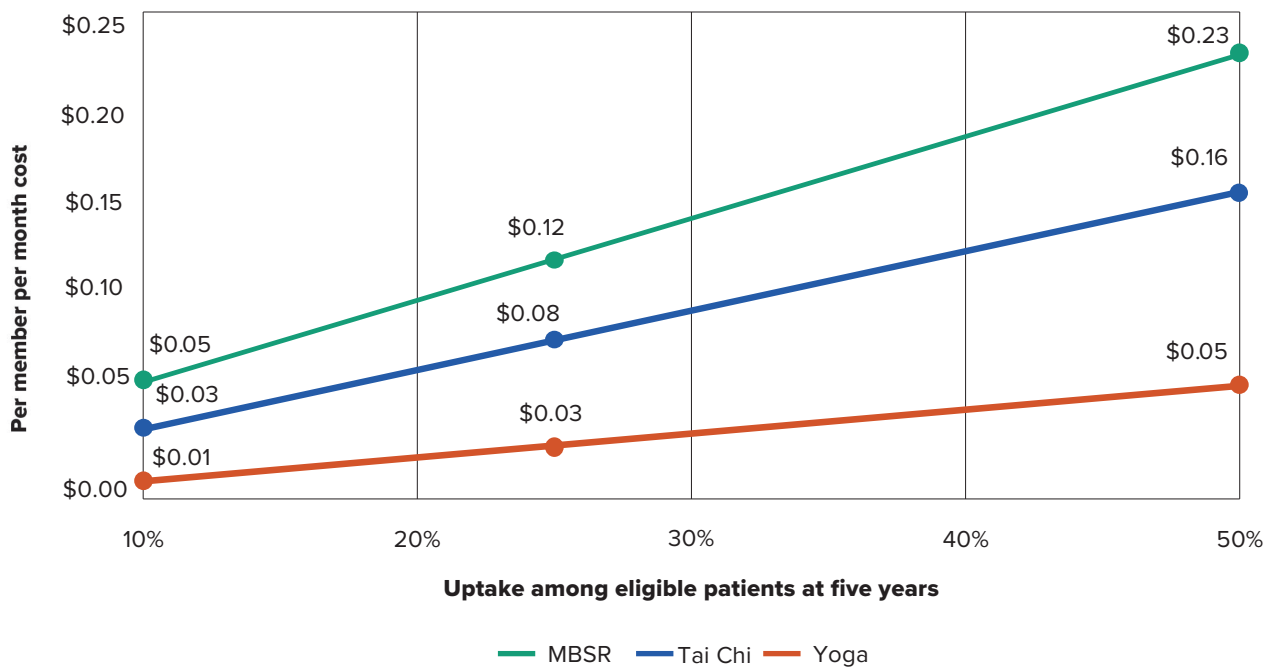
ICER’s review examined the potential budget impact of three interventions that are not commonly covered by insurers: mindfulness-based stress reduction, yoga, and tai chi.

Analyses considered the costs of coverage to a hypothetical health insurance plan covering 1 million members. For example, if the plan were to cover mindfulness-based stress reduction, the most expensive of the three interventions, and 50% of eligible patients took part, monthly costs would increase by \$0.23 per member.

To put that per-member cost in perspective, one large national pharmacy benefits management company spends approximately \$4.46 per member per month on medication costs for treatment of pain/inflammation.

The graph below shows the per member per month expenditures if that hypothetical insurer were to cover each intervention, based on varying levels of member uptake of those services (10% uptake, 25%, and 50%).

Per-Member Per-Month Cost for Yoga, MBSR, and Tai Chi Based on Treatment Uptake Among Eligible Cohort



Voting Results

California Technology Assessment Forum Votes

The California Technology Assessment Forum (CTAF) deliberated on key questions raised by ICER’s report at a public meeting on October 19, 2017. The results of the votes are presented below. These results reflect the voting of a majority of the Panel. More detail is provided in the [full report](#).

	Is evidence sufficient to show net health benefit in chronic low back pain?	Is evidence sufficient to show net health benefit in chronic neck pain?	What is the long-term value for money of treatment in chronic low back pain when added to usual care?
Acupuncture	Yes	Yes	Intermediate
CBT	Yes	Vote not taken due to limitations in data	Intermediate
MBSR	Yes		High*
Yoga	Yes		High*
Tai Chi	No		Insufficient evidence, no vote taken

*MBSR and yoga both had favorable cost-effectiveness ratios that fell well below ICER’s threshold range, signaling a default high value designation without a need for a vote.

Policy Recommendations

CTAF engaged in a moderated discussion with a policy roundtable of subject-matter experts about how best to apply evidence in policy and practice. The roundtable included patient advocates, clinical experts, a private payer representative, and a public payer representative. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants. Below are the top-line policy implications; for more information please see the [full report](#).

Payer Recommendations

Chronic Low Back Pain

- The strength of evidence appears adequate to support coverage of acupuncture, CBT, MBSR, and yoga for chronic low back pain. Evidence is far weaker for tai chi.
- It is reasonable to consider evidence-based boundaries on duration of therapy and on repetitive courses of therapy given the potential for inappropriate overuse of services.
- Payers should consider covering each of these therapies to maximize the chances for positive outcomes. Patients may have strong preferences and respond best to some therapies, but not all.
- Payers may wish to consider requests for concurrent treatment on a case-by-case basis, as there is no evidence on use of multiple therapies at the same time.
- Coverage policies should be clear and efficient so that providers can order these therapies as easily as they order physical therapy or a pain medication, and should ideally be part of the regular medical benefit.
- Reimbursement for cognitive and mind-body therapies needs to be adequate to support a robust network of providers.

Chronic Neck Pain

- Payers may wish to assess requests for coverage on a case-by-case basis, given that there is far less evidence on the effectiveness of these therapies for chronic neck pain than for chronic low back pain.

Provider Group Recommendations

Integrate multiple options for cognitive and mind-body therapies for chronic low back pain into local practices.

Specialty Society Recommendations

- Develop clear guidelines for the use of cognitive and mind-body therapies for chronic pain.
- Develop appropriate licensing and credentialing criteria for practitioners certified to deliver these therapies for chronic low back pain.
- Educate providers about the value of cognitive and mind-body therapies.

Research Recommendations

- Promote long-term studies of functional outcomes for these interventions.
- Study the efficacy of these interventions at reducing or eliminating the use of opioid therapy in patients with chronic pain.
- Study predictors of response to therapy to identify subsets of patients for whom therapies may be most effective, and study the dose response effect of therapies to determine appropriate frequency and intensity of treatment.
- Perform additional high-quality trials of these therapies for chronic neck pain

About ICER

The Institute for Clinical and Economic Review (ICER) is an independent nonprofit research institute that produces reports analyzing the evidence on the effectiveness and value of drugs and other medical services. ICER's reports include evidence-based calculations of prices for new drugs that accurately reflect the degree of improvement expected in long-term patient outcomes, while also highlighting price levels that might contribute to unaffordable short-term cost growth for the overall health care system.

ICER's reports incorporate extensive input from all stakeholders and are the subject of public hearings through three core programs: the California Technology Assessment Forum (CTAF), the Midwest Comparative Effectiveness Public Advisory Council (Midwest CEPAC) and the New England Comparative Effectiveness Public Advisory Council (New England CEPAC). These independent panels review ICER's reports at public meetings to deliberate on the evidence and develop recommendations for how patients, clinicians, insurers, and policymakers can improve the quality and value of health care. For more information about ICER, please visit ICER's website (www.icer-review.org).