



Complete Summary

GUIDELINE TITLE

Acute low back pain.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Acute low back pain. Ann Arbor (MI): University of Michigan Health System; 2003 Apr [rev. Oct 2004]. 13 p. [8 references]

GUIDELINE STATUS

This is the current release of the guideline.

This updates a previous version: University of Michigan Medical Center. Acute low back pain. Ann Arbor (MI): University of Michigan Health System; 1997. 13 p.

This guideline was updated by the guideline developer in October 2004 following the removal of Vioxx (rofecoxib) from the worldwide markets. See the [U.S. Food and Drug Administration \(FDA\) Web site](#) for more information. This guideline was updated again by the guideline developer in December 2004 following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of some non-steroidal anti-inflammatory drug products. See the [FDA Web site](#) for more information.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the [U.S. Food and Drug Administration \(FDA\) Web site](#) for more information.

Subsequently, on April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter

[OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the [FDA Web site](#) for more information.

Most recently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Acute low back pain

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To enable primary care providers to:

- Identify persons at risk for chronic disability and intervene early
- Detect dangerous, but uncommon lesions
- Utilize diagnostic tests efficiently
- Initiate treatment and refer when appropriate

TARGET POPULATION

Adults >18 years of age with pain for <6 weeks

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Focused medical history:
 - Assess for serious disease
 - Assess psychological and social risk for chronic disability
2. Physical examination:
 - General assessment including areas of back tenderness and back mobility, including degree of flexion, extension
 - Focused examination includes the testing of muscle strength, reflexes, and range of motion which may include:
 - L-5 innervated medial hamstring reflex test
 - Reproduction of pain in a specific anatomical structure
 - Palpation of spine and flexion/extension of the spine
 - Straight leg raise test
 - Gordon Waddel's five non-organic pain signs
3. Diagnostic testing as indicated:
 - Complete blood count and erythrocyte sedimentation rate
 - Imaging studies (Magnetic resonance imaging [MRI], computed tomography [CT], CT-myelography)
 - Electromyography (EMG)
 - Plain x-rays (not recommended for routine evaluation, but can be used to rule out fractures)
 - Bone scan

Treatment

1. Non-medication treatments (e.g., ice, stretching)
2. Patient education including:
 - Educational booklets/handouts
 - Self-applied ice and heat

- Medication risks and side effects
 - Minimize activity limitations
3. Treatment options considered but not specifically recommended include:
 - Spinal manipulation for symptomatic relief
 - Exercises (McKenzie exercises, aerobic and back-strengthening exercises)
 - Physical modalities such as ultrasound, diathermy, phonophoresis or iontophoresis of medications, transcutaneous electrical nerve stimulators (TENS)
 - Shock absorbing shoe inserts

Note: Lumbar corsets or belts and traction were considered but not recommended.

4. Medications
 - Non-steroidal anti-inflammatory drugs (NSAIDs)

Note: NSAIDS are recommended over Cyclo-oxygenase-2 (COX-2) inhibitors in most patients

- Medications considered but not specifically recommended include:
 - Acetaminophen
 - Muscle relaxants
 - Opiate analgesics
 - Injections
 - Epidural steroid injections

Note: Trigger point injections with local anesthetic, "dry needling," and botulinum toxin injections were considered but not recommended.

Follow-Up

1. Update history and physical
2. Reduce medications, increase activity
3. Diagnostic testing as indicated (e.g., MRI, EMG)
4. Specialist referrals as indicated:
 - Surgery
 - Physiatry
 - Psychosocial counseling (biofeedback and hypnosis are not recommended)
 - Multidisciplinary rehabilitation

MAJOR OUTCOMES CONSIDERED

- Recovery and recurrence rates
- Patient satisfaction with treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for the current update was based on a supplemental Medline search of literature from 1997 through the fall of 2002. The population was adults and the results were limited to English language. The major keywords were: *low back pain* and *back pain and low back*. Additional search terms were: *chronic disease, chronic back pain, risk, diagnosis, diagnostic use, therapy, therapeutic use, clinical trials, and guidelines*. The search was a single cycle. Also included were guidelines on low back pain listed at the National Guideline Clearinghouse and reviews on low back pain in the Cochrane Database of Systematic Reviews.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership in departments to which the content is most relevant. This guideline was reviewed by members of the following departments: General Medicine; Family Medicine, Physical Medicine and Rehabilitation, Orthopedic Surgery, Neurosurgery, and Obstetrics and Gynecology.

Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text of the original guideline document for detailed information on diagnosis; "red flags" for serious disease; risks for chronic disability; differential diagnoses; assessing muscle strength and reflexes; treatment and medications.

Definitions for the levels of evidence (A, B, C, D) are provided at the end of the Major Recommendations field.

- **Natural History.** Low back pain occurs in about 80% of people [*evidence C*]. Within 6 weeks 90% of episodes will resolve satisfactorily regardless of treatment [*C*]. Of all persons disabled for more than 1 year, 90% will never work again without intense intervention [*C*].
- **Initial Visit**
 - Assess for "red flags" of serious disease (see Table 1 in the original guideline document), as well as psychological and social risks for chronic disability (see Table 2 in original guideline document). Diagnostic tests are usually unnecessary [*C*]
 - Educate about good prognosis [*B*].
 - Treatment options include: ice [*D*], nonsteroidal anti-inflammatory drugs (NSAIDs) [*A*], and return to usual activities - bed rest is not recommended [*A*]. (Cyclo-oxygenase-2 [COX-2] inhibitors are no more effective than traditional NSAID agents and should be reserved for carefully selected patients [see Table 8 in the original guideline document for COX-2 criteria]. [*A*])

Refer to the following tables in the original guideline document for detailed information on:

- Non-Radiating (Axial) Low-Back Pain: Treatment and Follow Up (Pain Not Below the Knee) (Table 5)
- Radiating Low-Back Pain: Treatment and Follow Up (Sciatica - Pain Below the Knee) (Table 6)

- Medications for Low Back Pain (Non-Radiating and Radiating) (Table 7)
 - Close clinical follow up until return to work or key life activities [D].
- **By 2 weeks** (acute). If work disability persists, consider psychiatric consultation [A] especially if psychosocial risks to return to work exist.
- **For radicular pain, by 2-4 weeks:** If no improvement obtain magnetic resonance image (MRI) [B]. If not diagnostic, obtain electromyography (EMG). If pathology proven, consider acute psychiatric evaluation (for injection therapy) or surgical evaluation [A]. If pathology not proven, consider physiatrist referral [D].
- **By 6 weeks** (subacute). **If activities are still limited, consider psychiatric consultation regarding a complex rehabilitation program [A].**
- **By 12 weeks** (chronic). If still disabled from major life activities or work, strongly consider referral to a physiatrist or specialized spinal pain team for a complex rehabilitation team [A].

Special Circumstances (see discussion in original guideline document):

- Primary prevention
- Chronic low back pain
- Recurrent low back pain
- Pregnancy and low back pain

Definitions:

Levels of Evidence

*Levels of evidence for the most significant recommendations.

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

The original guideline document contains a clinical algorithm for diagnosis and treatment of acute low back pain.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations).

Conclusions were based on prospective randomized clinical trials, when possible. In the absence of randomized controlled trials, observational studies were considered. If none were available, expert opinion was used.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of acute low back pain

POTENTIAL HARMS

- Refer to Table 7 "Medications for Low Back Pain (Non-Radiating and Radiating)" in the original guideline document for a listing of medication side effects.
- Consider cyclo-oxygenase-2 inhibitors (COX-2 inhibitors) if patient:
 - has a history of upper gastrointestinal bleeding
 - is receiving chronic, high dose systemic corticosteroids
 - has presence of a bleeding disorder
 - is receiving anticoagulants
 - has a documented intolerance to traditional non-steroidal anti-inflammatory drugs (NSAIDs)
 - is elderly with multiple co-morbidities
- **Note:** Do not prescribe COX-2s to patients with known coronary heart disease. Exercise extreme caution in prescribing to patients with multiple risk factors for coronary heart disease.

CONTRAINDICATIONS

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In general, bone scans, x-rays and computed tomography (CT) scans are contraindicated during pregnancy.

QUALIFYING STATEMENTS

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- These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.
- The medical model of "diagnose, treat, cure" does not easily fit low back pain, given the state of our knowledge. An anatomical diagnosis cannot be made in most persons. Currently no diagnostic test can verify the presence of muscle strains, ligament sprains, or small tears of the annulus fibrosis of the disk, which seem intuitively plausible as causes of pain. Other possible diagnoses such as facet joint asymmetry, or disk "bulges" do not correlate statistically with the presence of pain in large populations or with reproduction/alleviation of pain on examination or injection.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2003 Apr; modified 2004 Oct following FDA drug withdrawal)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Low Back Pain Guideline Team

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Guidelines Oversight Team: Connie Standiford, MD Lee Green, MD, MPH Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member, Company, Relationship

- David Alvarez, DO (none)
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- Connie Standiford, MD (none)
- Amy Tremper, MD (none)

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the use of some non-steroidal anti-inflammatory drug products. See the [FDA Web site](#) for more information.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [University of Michigan Health System Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following are available:

- Low back pain exercises. Ann Arbor (MI): University of Michigan Health System; 2003 Apr. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the [University of Michigan Health System Web site](#).
- Adult low back pain. Patient education handout. University of Michigan Health System; 2003. Various p. Electronic copies: Available from the [University of Michigan Health System Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on January 19, 2004. The information was verified by the guideline developer on February 6, 2004.

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