# **Complete Summary**

#### **GUIDELINE TITLE**

Treatment of primary headache: chronic daily headache. Standards of care for headache diagnosis and treatment.

## **BIBLIOGRAPHIC SOURCE(S)**

Mathew N, Ward T. Treatment of primary headache: chronic daily headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 73-80. [4 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

#### \*\* 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.

- June 15, 2005, COX-2 Selective (includes Bextra, Celebrex, and Vioxx) and <u>Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)</u>: Labeling revised to include a boxed warning and a Medication Guide, highlighting the potential for increased risk of cardiovascular (CV) events and life-threatening gastrointestinal (GI) bleeding.
- April 7, 2005, Bextra (valdecoxib), Cox-2 inhibitors, Celebrex (celecoxib),
   Non-steroidal anti-inflammatory drugs (NSAIDS) (prescription and OTC,
   including ibuprofen and naproxen: Bextra (valdecoxib) withdrawn from the
   market and labels for other Cox-2 inhibitors and NSAIDS revised to include a
   boxed warning and a Medication Guide, highlighting the potential for
   increased risk of cardiovascular (CV) events and life-threatening
   gastrointestinal (GI) bleeding.

#### **Additional Notices**

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning
  on the prescribing information on all antidepressant medications to include
  warnings about the increased risks of suicidal thinking and behavior in young
  adults ages 18 to 24 years old during the first one to two months of
  treatment.
- <u>April 11, 2007, Zanaflex (tizanidine hydrochloride)</u>: Changes to the product labeling for Zanaflex, a drug used to treat spasticity, to warn against its

- hypotensive and sedative effects when administered with fluvoxamine or ciprofloxacin (CYP1A2 inhibitors).
- <u>July 19, 2006, Triptans</u>: Healthcare professionals and consumers of new safety information regarding taking triptans together with selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs).

## **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

**QUALIFYING STATEMENTS** 

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

### SCOPE

## **DISEASE/CONDITION(S)**

Chronic daily headache (CDH) including:

- Chronic tension-type headache
- Chronic migraine (formerly known as transformed migraine with or without analgesia rebound)
- New daily persistent headache
- Chronic cluster headache
- Hemicrania continua
- Chronic paroxysmal hemicrania
- Hypnic headache
- Idiopathic stabbing headache
- SUNCT (short-lasting, unilateral neuralgiform headaches with conjunctival injection and tearing)
- Cranial neuralgias (e.g., trigeminal neuralgia)

#### **GUIDELINE CATEGORY**

Diagnosis Prevention Treatment

#### **CLINICAL SPECIALTY**

Family Practice Internal Medicine Neurology

#### **INTENDED USERS**

Health Care Providers Physicians

## **GUIDELINE OBJECTIVE(S)**

- To improve the medical treatment of headache
- To help physicians and other health care professionals to:
  - Rule out secondary headache and establish a primary headache diagnosis
  - Set reasonable goals with each patient, identifying expectations and individual needs by tailoring the educational component to the patient's level of active participation and desire
  - Design a treatment plan, combining nonpharmacologic with pharmacologic approaches as necessary to:
    - Minimize symptomatology
    - · Reduce disability
    - Improve quality of life
  - Provide follow-up care for long-term headache management to:
    - Reassess how well the treatment plan is achieving established goals
    - Reevaluate patient needs and specific headache patterns
  - Recognize indications for appropriate and timely referrals to specialists

#### **TARGET POPULATION**

Patients with chronic daily headache (CDH)

#### INTERVENTIONS AND PRACTICES CONSIDERED

### **General Management Strategies**

- 1. Patient education and involvement in treatment plan
- 2. Early consultation with headache specialist
- 3. Screening and counseling patients for medication overuse
- 4. Stopping or tapering medication that is being overused
- 5. Providing measures to cover the withdrawal headache that will ensue upon stopping the overused medication
  - Clonidine (for opioid withdrawal)
  - Temporary substitution of phenobarbital for butalbital (to avoid seizures or other serious withdrawal symptoms)
  - Intravenous (IV) dihydroergotamine (DHE) (for headache relief)

# **Pharmacologic Treatments**

- 1. Acetazolamide
- 2. Amitriptyline
- 3. Botulinum toxin type A
- 4. Divalproex sodium
- 5. Doxepin

- 6. Fluoxetine
- 7. Indomethacin
- 8. Nefazodone
- 9. Phenelzine
- 10. Tizanidine
- 11. Topiramate
- 12. Glucocorticoids, including dexamethasone, prednisone, methylprednisolone
- 13. Dihydroergotamine
- 14. Caffeine
- 15. Codeine
- 16. Oxycodone
- 17. Butalbital
- 18. Propoxyphene
- 19. Butorphanol
- 20. Ergotamine tartrate
- 21. Almotriptan
- 22. Eletriptan
- 23. Sumatriptan succinate
- 24. Naratriptan
- 25. Rizatriptan benzoate
- 26. Zolmitriptan
- 27. Metoclopramide
- 28. Chlorpromazine
- 29. Valproate
- 30. Ketorolac

### **Other Treatments**

- 1. Nerve blocks
- 2. Trigger point injections
- 3. Injections of botulinum toxin
- 4. Inpatient treatment

## **Nonpharmacologic Treatments**

- 1. Biofeedback
- 2. Stress management
- 3. Cognitive behavioral therapy

## **MAJOR OUTCOMES CONSIDERED**

Not stated

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines presented in this monograph represent the consensus of an advisory panel of practitioners chosen by the National Headache Foundation (NHF) for their expertise. In addition to incorporating the US Headache Consortium's recommendations, their conclusions reflect clinical experience and the most recent medical literature.

## 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**

Not stated

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

### **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

## **Chronic Daily Headache (CDH)**

## **Diagnosis and Treatment**

The approach to the patient with CDH is straightforward. First, a diagnosis must be made. There are several diagnostic categories of CDH, including:

- Constant (last all day)
- Daily but not constant (lasting for minutes or hours)
- Secondary (due to an underlying medical illness)
- Primary (not related to structural or systemic illness)

Secondary causes of CDH (see table below titled "Secondary Causes of CDH") must be considered and ruled out. Once a primary form of CDH is diagnosed (see table below titled "Primary Types of CDH"), it is important to educate patients and involve them in the treatment plan. Early consultation with a headache specialist is appropriate.

## **Secondary Causes of CDH**

- Post-traumatic (may mimic any primary headache)
- Cervicogenic (especially C2, C3 upper root entrapment)
- Temporomandibular joint syndrome
- Sinus disease
- Arteriovenous malformation
- Arteritis (including giant cell arteritis)
- Subdural hematoma
- Vascular dissection
- Neoplasm
- Infections
- Intracranial hypertension
- Intracranial hypotension

**Note**: All diagnoses may be confounded by medication overuse.

# **Primary Types of CDH**

- Chronic tension-type headache
- Chronic migraine (formerly known as transformed migraine with or without analgesic rebound)
- New daily persistent headache
- Chronic cluster headache
- Hemicrania continua
- Chronic paroxysmal hemicrania
- Hypnic headache
- Idiopathic stabbing headache
- SUNCT (short-lasting, unilateral neuralgiform headaches with conjunctival

## **Primary Types of CDH**

injection and tearing)

Cranial neuralgias (e.g., trigeminal neuralgia)

## Medication Overuse

Treating patients with CDH can be challenging, particularly if the headaches are complicated by medication overuse. Often, patients may not realize that excessive or frequent self-treatment may actually worsen their condition. Continued overuse of immediate-relief medications, particularly in headache-prone patients, may result in refractoriness to treatment (prophylactic medications may not work), perpetuation of the headaches, and a transformation from a pattern of intermittent migraine to one of CDH. The diagnosis of CDH may be obscured by medication-overuse headache. A 2-month period is required after cessation of medication overuse to establish the diagnosis with certainty.

Virtually any medication used more than 2 to 3 days per week may cause these phenomena, including off-the-shelf remedies such as acetaminophen and prescription agents such as the triptans. Combination products containing caffeine and butalbital may be especially likely to generate "analgesic rebound," whereas drugs with a longer duration of action (i.e., a longer half-life) may be less likely to do so. Clinicians should be careful to screen CDH patients for medication overuse and should make it a point to counsel their patients about the risks of analgesic overuse and rebound headache.

Confounding overuse of medications must be stopped. Many drugs can be abruptly stopped, although measures must be taken to cover the withdrawal headache that will likely ensue. Sometimes a steroid taper and an antiemetic will suffice. Drugs such as narcotics, butalbital, and benzodiazepines in general should not be stopped abruptly but rather should be tapered. The use of clonidine for opioid withdrawal or the temporary substitution of phenobarbital for butalbital to avoid seizures or other serious withdrawal symptoms may be instituted to moderate withdrawal. Intravenous dihydroergotamine (DHE) given over several days may provide sufficient relief of the underlying headache to allow the patient to discontinue the offending acute medications.

## Acute Treatment

Many patients can be helped through outpatient therapy, and the diagnosis will determine the most appropriate choice of acute treatment (see table below). However, limits on acute medication use of 2 to 3 days per week need to be instituted, along with avoidance of the agent that was being overused. For example, if the patient is experiencing chronic migraine, antimigraine agents such as the triptans, nonsteroidal anti-inflammatory drugs (NSAIDs), and DHE can be effective, provided the patient has not previously overused any symptomatic medication. Table 7.5 of the original guideline document provides guidelines for treating intractable migraine, or migraine lasting for more than 24 hours in spite of treatment. Chronic tension-type headache (CTTH) can be effectively managed with analgesics. For hemicrania continua and chronic paroxysmal hemicrania, prompt resolution of the headache with a trial of indomethacin 50 mg 3 times a

day for 48 hours will establish the diagnosis. As with other forms of CDH, secondary forms need to be considered, and confounding medication overuse needs to be addressed. Most patients will have a dramatic response to indomethacin and a lesser response to other NSAIDs.

## **Medications Studied in CDH**

- Acetazolamide
- Amitriptyline
- Botulinum toxin type A
- Divalproex sodium
- Doxepin
- Fluoxetine
- Indomethacin
- Nefazodone
- Phenelzine
- Tizanidine
- Topiramate

Regardless of past medication use, drugs used for the acute treatment of CDH should be strictly limited to reduce the chance of complicating treatment. If a patient regularly seeks medications on a more frequent basis than guidelines suggest (see table below), reevaluation of the diagnosis and assessment for preventive treatment may be indicated.

Limitation Guidelines for Use of Abortive Therapies in Headache	
SUBSTANCE/MEDICATION	GUIDELINES
	Treatment day = 24 hours
Caffeine (often found in combination over-	2 treatment days/week. Both dosage and frequency of u
the-counter [OTC] and prescription	affect development of withdrawal headaches or symptom
medications)	Caffeine from beverage consumption also contributes to
	total dosage.
Codeine	2 treatment days/week
Oxycodone	2 treatment days/week
Butalbital	2 treatment days/week
Propoxyphene	2 treatment days/week
Butorphanol	2 treatment days/week
Ergotamine tartrate: oral (p.o.), rectal,	8 treatment days/month or 2 treatment days/week (or
sublingual	less)
Almotriptan	8 treatment days/month or 2 treatment days/week
Eletriptan	8 treatment days/month or 2 treatment days/week
Frovatriptan	8 treatment days/month or 2 treatment days/week
Sumatriptan succinate: subcutaneous (SQ),	8 treatment days/month or 2 treatment days/week
p.o., rapid-release tablet, intranasal	
Naratriptan hydrochloride: p.o.	8 treatment days/month or 2 treatment days/week
Rizatriptan benzoate: p.o. and orally	8 treatment days/month or 2 treatment days/week
disintegrating tablet	
Zolmitriptan: p.o., oral disintegrating tablet, intranasal	8 treatment days/month or 2 treatment days/week
	1

**Note**: In general, the use of opiates/opioids for the symptomatic management of pain should be limited

Limitation Guidelines for Use of Abortive Therapies in Headache	
SUBSTANCE/MEDICATION	GUIDELINES
	Treatment day = 24 hours

to instances in which acute abortive therapy has failed or is contraindicated. Opioids, as a class, should be limited to no more than 2 days/week, regardless of which agent is used. However, when they are used, they should be administered at a sufficient dose to provide adequate analgesia.

#### Preventive Treatment

Patients with very frequent headaches should be treated primarily with preventive medications (see National Headache Foundation [NHF] guidelines on "Preventive Treatment of Migraine") to reduce the frequency, severity, and duration of the headaches. Choices for prevention of CTTH, new daily persistent headache, and chronic migraine are best made on the basis of concomitant or comorbid conditions. Medications should generally be started at a low dose, followed by gradual increases in dose until efficacy is achieved, side effects become intolerable, or the ceiling dose is reached. Nonpharmacologic therapies such as biofeedback, stress management, and cognitive behavioral therapy should also be considered. Monotherapy is the preferred approach, as the prescription of copharmaceutical treatments should be reserved for physicians specializing in the treatment of headache. Specific therapies exist for chronic paroxysmal hemicrania and hemicrania continua (e.g., indomethacin). The same is true for hypnic headaches, cranial neuralgias, and chronic cluster headache.

Psychiatric comorbidities such as anxiety and depression are common and need to be considered. All forms of psychiatric comorbidities may be complicated by medication overuse, which may limit the effectiveness of preventive medications; therefore, medication overuse also needs to be addressed. It is also critical to communicate realistic expectations to patients, as it may take up to 6 weeks or more for preventive medications to become fully effective.

### **Inpatient Treatment**

For patients who fail to respond to outpatient treatment, or whose conditions are too complicated for outpatient detoxification and treatment, inpatient treatment may be considered. Outpatient treatment is best conducted in a setting with experienced practitioners who can take a multidisciplinary approach to the medical issues. The mainstay of the approach is to resolve medication overuse, cover the withdrawal headache likely to occur in the first several days after admission, address comorbid and coexistent conditions, and institute preventive therapy. Intravenous regimens that have been used for intractable headache include repetitive metoclopramide and DHE, neuroleptics (such as chlorpromazine), valproate, or ketorolac. More information can be found in the NHF guidelines on "Inpatient Headache Treatment."

## **Other Treatments**

Less commonly used treatment modalities for CDH may be best employed by practitioners who are headache experts. These modalities include nerve blocks (e.g., occipital nerve blocks), trigger point injections, and injections of botulinum toxin. The use of botulinum toxin is controversial, with anecdotal reports of

efficacy in some patients with CDH. In some cases of "cervicogenic headache," especially in some cases of post-traumatic headache, some experts advocate procedures directed against the C2 and/or C3 nerve roots, with deep computed tomography-guided blocks said to be diagnostic. Ultimately, the best approach to CDH is to make a clear diagnosis early and to institute treatment early, before disability becomes manifest and the situation becomes complicated by medication overuse and psychiatric issues. Early referral of the patient to a practitioner skilled in the diagnosis and treatment of headache is essential. Patients with refractory headache may need to be admitted for inpatient treatment.

## **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

In addition to incorporating the US Headache Consortium's recommendations, the conclusions reflect clinical experience and the most recent medical literature.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

Appropriate diagnosis and management of chronic daily headache (CDH)

#### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

Drug therapy is constantly evolving as new research, clinical trials, case reports, and opinions are published. Many of the drugs recommended in these guidelines are not approved by the US Food and Drug Administration (FDA) for treatment of headache, nor are they necessarily the same as those therapies recommended by the manufacturer for labeled indications. Their use in headache, however, may be supported by the scientific literature and by the authors' clinical experiences. While efforts have been made to ensure accuracy, the authors and publisher do not assume responsibility for the consistent updating of available information for these guidelines, nor for any errors or omissions, nor for any consequences thereof. The onus is on the practitioner to evaluate recommendations in light of the clinical condition of the patient and recent medical literature. The authors advise the practitioner to consult other sources, especially the manufacturers'

warnings and precautions, before prescribing any drug with which they are unfamiliar. Practitioners are also advised that while these guidelines will address the needs of many patients, there will be circumstances calling for exceptions to these recommendations.

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Chart Documentation/Checklists/Forms
Foreign Language Translations
Patient Resources
Slide Presentation

For information about <u>availability</u>, 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 Living with Illness Staying Healthy

## **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

Mathew N, Ward T. Treatment of primary headache: chronic daily headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 73-80. [4 references]

# **ADAPTATION**

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

# **DATE RELEASED**

2004

## **GUIDELINE DEVELOPER(S)**

National Headache Foundation - Private Nonprofit Organization

## **SOURCE(S) OF FUNDING**

National Headache Foundation

### **GUIDELINE COMMITTEE**

Not stated

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Ninan Mathew, MD, and Thomas Ward, MD

## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- The complete headache chart. Chicago (IL): National Headache Foundation (NHF); 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>
- National Headache Foundation fact sheet. Chicago (IL): National Headache Foundation (NHF); 2004 Oct. 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

#### **PATIENT RESOURCES**

The National Headache Foundation (NHF) has created a variety of educational resources for patients, including informative brochures, a patient diary for migraines, Power Point presentations, and patient guides; many of these resources are available in both Spanish and English. Some of these items are available as print copies for purchase through the <a href="NHF online store">NHF online store</a>. Electronic versions of other resources are available through the consumer education section of the <a href="NHF Web site">NHF Web site</a>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org.

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#### **NGC STATUS**

This NGC summary was completed by ECRI on April 11, 2005. The information was verified by the guideline developer on April 26, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on August 29, 2006, following the U.S. Food and Drug Administration advisory on Triptans, SSRIs, and SNRIs. This summary was updated by ECRI Institute on May 8, 2007, following the U.S. Food and Drug Administration advisory on Zanaflex (tizanidine hydrochloride). This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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