Miles for Migraine: Education Day

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Larner College of Medicine
University of Vermont

May 9, 2020
• **AHDA Mission** – to advocate for the interests of patients with headache disorders and the field of Headache Medicine

• **Major Annual Event:** “Headache on the Hill” Congressional advocacy

• Incorporated 2008; non-profit status 2013

• **Funding** – Member organizations and private donors.

  No corporate donors. No campaign contributions.

• **AHDA Membership** – 13 US non-profit organizations

  - Alliance for Patient Access
  - American Academy of Neurology
  - American Headache Society / American Migraine Foundation
  - CHAMP
  - Clusterbusters
  - Cluster Headache Support Group
  - Headache Cooperative of New England
  - Headache Cooperative of the Pacific
  - Migraine Research Foundation
  - Miles for Migraine
  - National Headache Foundation
  - Spinal Fluid Leak Foundation
  - Southern Headache Society
2007
45 advocates
29 states
136 congressional offices

2020
173 advocates
45 states
225 congressional offices
MIGRAINE: THE LEAST NIH FUNDING RELATIVE TO BURDEN

<table>
<thead>
<tr>
<th>NIH Funding ($ Millions)</th>
<th>Disease Burden (DALYs)</th>
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<tbody>
<tr>
<td>20M</td>
<td>5,000,000</td>
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<tr>
<td>214M</td>
<td>500,000</td>
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<tr>
<td>674M</td>
<td>5,000</td>
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<tr>
<td>1,684M</td>
<td>1,000</td>
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<tr>
<td>Digestive</td>
<td>100</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>10</td>
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<tr>
<td>Arthritis</td>
<td>1000</td>
</tr>
<tr>
<td>Migraine</td>
<td>10,000</td>
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NIH Funding for Headache Research

• 2007 – NIH underfunding was original impetus for 1st HOH, and every year since
  • Since 2008, 15 supportive statements in Appropriations Committee Reports

• 2016 - “STOP Pain Act” introduced and enacted
  
  authorized NIH to increase pain research – including headache disorders research

• 2017 – “Opioids and STOP Initiative Act” introduced
  
  would appropriate $1B / year for 5 years to increase opioids and pain research.

• 2018 – Congress appropriates $500M / year for opioids and pain research
  
  “Helping End Addiction Long-term (HEAL) Initiative”

• It has not yet appreciably increased migraine and headache research
2019 House Appropriations Letter

• 22 signers of letter to House Appropriations Committee
• Led by AHDA Champions, Reps Peter Welch (D-VT) & David McKinley (R-WV)
NIH
FY20 Appropriations Committee Report Language

Senate

Headache Disorders.—The Committee recognizes: (1) that migraine is the second leading cause of global disability, but that NIH funding for migraine research is strongly incommensurate with this burden; and (2) that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, NIH has recently issued a FOA for research relevant to all types of pain, including migraine and headache disorders, and a few specific announcements that focus specifically on increasing research on back pain and hemodialysis-related pain. The Committee strongly urges the Director of NIH to issue a similar focused group of Requests for Applications to fund fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension.

Helping to End Addiction Long-Term [HEAL] Initiative.—The Committee supports the development of the HEAL initiative, a multi-Institute and multi-agency effort to bolster research to improve treatments for opioid misuse and addiction, and enhance pain management. In addition, the Committee recognizes that migraine is the second leading cause of global disability and that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, the Committee strongly urges NIH to consider funding opportunities for fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension.

House

Headache Disorders.—The Committee recognizes that migraine is the second leading cause of global disability, and that migraine and other headache disorders are poorly responsive to opioids, but that these drugs are often inappropriately prescribed for these diseases. Under the HEAL Initiative, the NIH has recently issued Funding Opportunity Announcements for research relevant to all types of pain, including migraine and headache disorders, and a few specific announcements that focus specifically on increasing research on back pain and hemodialysis-related pain. The Committee strongly urges the Director of NIH to consider a similar focused group of HEAL Initiative Requests for Applications to fund fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension.

Headache Disorders.—The Committee strongly urges NINDS to fund fundamental, translational, and clinical research on headache disorders, including migraine, post-traumatic headache, the trigeminal autonomic cephalalgias, and intracranial hypo/hypertension through the HEAL study.
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Walter Koroshetz</td>
<td>NINDS Director</td>
</tr>
<tr>
<td>Jackie Ward</td>
<td>Chief of Staff</td>
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<tr>
<td>Linda Porter</td>
<td>Director, Office of Pain Policy</td>
</tr>
<tr>
<td>Michael Oshinsky</td>
<td>Program Director, Pain and Migraine</td>
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<tr>
<td>Amy Adams</td>
<td>Director, Office of Scientific Liaison</td>
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<tr>
<td>Alex Tuttle</td>
<td>Health Programs Specialist</td>
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<tr>
<td>Sophia Jeon</td>
<td>Health Science Policy Analyst</td>
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<tr>
<td>D.P. Mohapatra</td>
<td>Program Director, Pain Itch and Somatosensation</td>
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<tr>
<td>Robert Shapiro</td>
<td>Founding President, AHDA</td>
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<tr>
<td>Katie MacDonald</td>
<td>Executive Director, AHDA</td>
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<tr>
<td>Kathleen Digre</td>
<td>President, American Headache Society</td>
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<tr>
<td>Vince Martin</td>
<td>President, National Headache Foundation</td>
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<tr>
<td>Stephanie Nahas</td>
<td>Acting President, AHDA</td>
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<tr>
<td>David Dodick</td>
<td>Chair, American Migraine Foundation</td>
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<td>Peter Goadsby</td>
<td>President-Elect, American Headache Society</td>
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<tr>
<td>Andrew Charles</td>
<td>Treasurer, American Headache Society</td>
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</table>
FDA agrees that migraine is a serious condition, and is aware of the public health impact of migraine-related disability.

In your letter, you inquired specifically about Priority Review and Breakthrough Therapy status for anti-CGRP/CGRP-R monoclonal antibody (CGRP mAb) compounds under development for the treatment of migraine. As described in the FDA guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics¹ (Expedited Programs Guidance), Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may show substantial improvement over existing therapies on one or more clinically significant endpoints. Priority review designation is intended to direct overall attention and resources to the evaluation of applications for drugs that treat a serious condition and, if approved, would provide a significant improvement in effectiveness or safety. Requirements for Breakthrough Therapy designation and Priority review designation are described in the Expedited Programs Guidance. Please be assured that FDA carefully considers relevant evidence provided by drug companies in making decisions regarding Breakthrough Therapy designation and Priority review designation. The FDA generally cannot, however, discuss the data or information submitted in a pending application.

FDA is dedicated to facilitating development and expediting review of products that, for example, are intended to treat serious conditions. Thank you, again, for contacting us concerning this matter. Please let us know if you have further questions.


U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov
CMS:
Appeal of Medicare coverage of oxygen for cluster headache

Currently under review.

Formal Request for National Coverage Determination Reconsideration

The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,


Home oxygen therapy provides highly significant, relevant, useful, medical benefits to Medicare and Medicaid beneficiaries who experience cluster headache attacks.

On (3/22/18), Representative Andy Harris, MD, wrote to you to strongly urge your prompt reconsideration of CAG-00296R. We refer you to his letter (attached) for details regarding home oxygen for cluster headache attacks, the medical and ethical justifications for CMS coverage for home oxygen use, and the significant risks and hazards of denial of access to this therapy for Medicare and Medicaid beneficiaries.

On (8/31/18), you responded to Representative Harris, and stated (letter attached):

"In order to move forward on this topic, published studies demonstrating that the use of high dose oxygen for CH in the home setting leads to improved health outcomes needs to be provided to CMS... In our previous conversations with relevant stakeholders, we’ve encouraged them to submit any new evidence specific for the home use of oxygen prescribed under the durable medical equipment benefit for the treatment of CH. Your letter mentions not-yet published retrospective survey data. We would gladly review this information either in advance of publication or following publication, as well as any other newly published data available in the public domain."

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SSA: “Sequential Evaluation” for SSDI/SSI

Symptoms cannot be evidence for an MDI

There is no listing for headache disorders
SSDI

Migraine:

0.3% of all SSDI claimants
vs 5.1% of all US Disability

Percent Allowed

23% 46%

170 Diagnostic Categories

13th percentile

Migraine Claimants

All Claimants
SSA:

FY20 Appropriations Committee Report Language

Senate

_Headache Disorders._—The Committee recognizes that migraine is the second leading cause of global disability, and strongly encourages SSA to clarify how best to apply the current Blue Book Listing of Impairments to assess headache disorders-related impairments. The Committee believes this could be useful to claimants, representatives, and adjudicators at all levels of the disability determination process, providing detailed guidance regarding what evidence is useful and ensuring consistent decision-making. Further, the Committee commends SSA for agreeing to comply with SSA’s Inspector General recommendation (A–01–15–50022) to ensure that all listings updates are less than 5 years old by the end of fiscal year 2020. The Committee further urges SSA to ensure that all listings are updated as needed to reflect medical and technological advances.

House

_Headache Disorders._—The Committee supports efforts to ensure consistent decision-making with regard to how to appropriately and correctly apply the current Listing of Impairments to headache disorders-related impairments.
SSA:

- AHDA partnered with National Organization of Social Security Claims Representatives (NOSSCR)
- Social Security Ruling (SSR) (8/26/19)
  - The first significant guidance ever issued by SSA for claimants with headache disorders (migraine, cluster headache, etc.)

SOCIAL SECURITY ADMINISTRATION
[Docket No. SSA-2018-0023]
Social Security Ruling, SSR 19–4p; Titles II and XVI: Evaluating Cases Involving Primary Headache Disorders

AGENCY: Social Security Administration.
ACTION: Notice of Social Security Ruling (SSR).

SUMMARY: We are providing notice of SSR 19–4p. This SSR provides guidance on how we establish that a person has a medically determinable impairment of a primary headache disorder and how we evaluate primary headache disorders in disability claims under titles II and XVI of the Social Security Act.

DATES: We will apply this notice on August 26, 2019.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Medical Policy, Social Security Administration,

AHDA Advocacy Case:
Veterans in Pain – Creating Congressional Solutions

AHDA
Identifies key problem

• >100K
  Afghan/Iraq
  Veterans with
  post-traumatic
  chronic
  headaches

• 3 UCNS certified
  headache doctors
  in the VA – all are
  part-time effort
  for headache
National Shortage of Headache Doctors


Minimum # of doctors needed

Number of UCNS-Certified Headache Doctors per 100K Americans with migraine

Opioid Workforce Act (H.R.3414/S.2892)

- CMS would fund 1000 new training slots per year, over 5 years
  - 500 slots funded initially for existing programs
  - 500 slots funded later for new programs
  - “approved residency training programs”
    - Addiction Medicine
    - Addiction Psychiatry
    - Pain Medicine.

- HOH 2020 Ask – amend bill to fund UCNS Headache Medicine Fellowships

- Unfortunately... we could not find a sponsor for this bill amendment
AHDA: Countering Structural Stigma Towards Headache Disorders

- **Research**
  - NIH – Authorization and appropriations for the HEAL Initiative
  - Department of Defense (CDMRP)
    - Increased funding of post-traumatic and chronic migraine research

- **Therapeutics**
  - FDA - Accelerated new drug reviews based “serious condition” designation
  - CMS – Appealing Medicare coverage of oxygen for cluster headache

- **Disability Recognition**
  - Social Security Administration: SSDI / SSI reform

- **Access to clinical care**
  - Veterans Administration – funded 7 VA Headache Centers of Excellence
  - Academic Medical Centers – Ongoing efforts to fund Headache Medicine Fellowships
Join us for **Headache on the Hill**

February 8<sup>th</sup> and 9<sup>th</sup>, 2021

info@allianceforheadacheadvocacy.org