Controversy One: Headache and Disability

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Southern Headache Society
Orlando, FL, Sept 21, 2013
Disclosures

• Consulting within the past 12 months:

Transcept Pharmaceuticals
Headache Disability

- Migraine and other headache disorders cause >50% of total years of life lost due to disability attributable to neurological diseases globally.

- Migraine is - the 7th ranking cause of disability globally
  - the 14th ranking cause of disability in the US

Steiner et al. *Headache* 2013;53:227
Headache Disability

- ~90% of migraineurs cannot “function normally” during migraine attacks
- ~30% of migraineurs require bedrest during some migraine attacks
- >25% of migraineurs miss ≥1 workday every 3 months due to migraine
- US workers with chronic migraine lose ~14% of their employment productivity

Stewart et al. *JAMA* 2003;290:2443
Stewart et al. *JOEM* 2010;52:8
Headache Disability

- US lost work productivity due to headache disorders is >4 times greater due to presenteeism ($16.4B/year), than due to absenteeism ($3.6B/year).
- ~3M American migraineurs of employment age (18 to 65 years old) report being “occupationally disabled” (10% with EM and 20% with CM).
- ~29% of employed migraineurs have headache ≥11 days / month, but they account for 49% of migraine lost workplace productivity.
- Only ~37% of Americans with CM are employed full-time.

Americans with Disabilities Act (ADA) of 1990
ADA Amendments Act (ADAAA) of 2008

- Prohibits employment discrimination due to impairments that “substantially limit” at least one “major life activity”.
- Disability is assessed in “active state” (i.e. mitigating measures or drugs do not limit disability claims for disorders that are episodic or in remission at times)
- Disability claims must be
  - backed by proof of limitations relative to unimpaired people
  - generalizable (i.e. not specific to one employer or occupation)
Americans with Disabilities Act (ADA) of 1990
ADA Amendments Act (ADAAA) of 2008

• Employers with ≥15 employees must make “reasonable” workplace accommodations:
  ✓ **Required:**
    adjustments of lighting, noise, odors, flex-time, etc.
  ✓ **Not required:**
    changes in essential operations or excessive costs

• Employee complaints may be lodged with the EEOC
Family and Medical Leave Act (FMLA) of 1993

- Employers with ≥50 employees must provide employees having a “serious health condition” (including migraine):
  - Up to 12 weeks job-protected unpaid leave per year
  - May be reduced-schedule, short-term, non-consecutive

- Some employers with <50 employees offer short or long-term disability plans, but these are not required by law

- Some states have statutes that are variations of FMLA
Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI)

- Must have worked long enough & recently enough (work credits)

- **Disability:**
  - “the inability to engage in any substantial gainful activity (SGA) by reason of any medically determinable physical or mental impairment(s) which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.”

- **Medically determinable impairment:**
  - “must be established by medical evidence consisting of signs, symptoms, and laboratory findings - not only by the individual’s statement of symptoms.”

- Problematic: headache disorders which are clinical diagnoses with no diagnostic physical or laboratory findings
Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI)

- SS disability determination - a 5-step process

  - **Are you working?** If your 2013 earnings average >$1,040 / month, you cannot be considered disabled.

  - **Is your condition severe?** The condition must interfere with basic work-related activities.

  - **Is your condition in the Listing of Impairments (Blue Book)?** If not, the condition must be of equal severity to a listed condition. Headache/migraine are not listed.

  - **Can you do the work you did previously?** Must determine if the condition interferes with ability to do the work done previously.

  - **Can you do any other type of work?** Can you adjust to other work based on age, education, experience, skills.
Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI)

- Evidence
  - First - Claimant’s medical sources assessed
  - Then, if necessary, - Consultative Examinations (CE) obtained
    - Formal reports of health professionals
  - Types of evidence considered related to symptoms
    - daily activities
    - location, duration, frequency, & intensity of the pain
    - precipitating and aggravating factors
    - type, dosage, effectiveness, & SEs of any medication
    - Non-drug treatments or measures to relieve pain
    - factors concerning functional limitations due to pain

- Initial determination – made by Disability Determination Services (DDSs)
- If denied – appeal to SSA DAR
- “Sequential evaluation”… repetitive evaluation and denial
Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI)

- SSA “Listing of Impairments” (“Blue Book”)
  - Provides evidentiary criteria – a key advantage for disorders that are solely clinical disorders
- With no headache listing, disability often must be met under an alternative listing – this may be a psychiatric listing, even if it’s marginally appropriate, or compounds stigma.
Design Constraints for a Headache Disorders Blue Book Listing

• Headache disorders are not… headache

• Headache disorders are diverse
  – Primary, secondary, TACs, neuralgias/tics, post-traumatic, etc.

• Headache disorders are often episodic

• Headache disorders often have no exam or biomarker findings

• Headache disorders are often co-morbid
  – Psychiatric disorders, trauma, epilepsy, fibromyalgia, etc.

• Headache disorders may be associated with analgesic overuse
  – Co-morbid pain syndromes
  – Opioid addiction
  – Medication overuse headache (MOH)
“H. Headache Disorders, including migraine, trigeminal autonomic cephalalgias, cranial neuralgias, and related disorders. The degree of impairment due to headache disorders will be determined according to the frequency, duration, severity, and sequelae of symptomatic attacks and their impacts on functional activities. Migraine and other primary headache disorders are not typically associated with clear or reliable diagnostic findings on physical examination, and no validated biomarkers, imaging abnormalities, or laboratory findings are typically diagnostic of the diseases. Whenever appropriate, attributed diagnoses should be consistent with the clinical diagnostic criteria of the current edition of the International Classification of Headache Disorders (ICHD). A detailed description of the individual’s typical or idiosyncratic attack or attack pattern of headache disorder is required. Such descriptions may include, but may not be limited to, the frequency, duration, and presence or absence of (a) premonitory symptoms, (b) ‘aura’ symptoms of disturbances of vision, skin sensation, language, strength, coordination, or vestibular function, (c) location, severity, duration, and qualities of eye, ear, nose, mouth, face, jaw, head, neck, or shoulder pain, (d) amplified, distorted, or pain-inducing sensation to light, sound, touch, movement, smell, or taste, (e) autonomic disturbances including nausea, vomiting, abdominal pain, gastroparesis, diarrhea, constipation, increased lacrimation, ptosis, peri-orbital edema, pupillary abnormalities, rhinorrhea, sweating, or nasal/sinus symptoms, or (f) disturbances of cognition, affect, concentration, language, motivation, attention, agitation, or tolerance of stressful or social environments. To establish a medically determinable impairment due to a headache disorder, an individual must submit supportive documentation of the frequency of impairing symptoms of that disorder. Such documentation may include data from symptom diaries, clinical or functional questionnaire records, medical records, reporting health care provider attestations and documentation, and other sources of ancillary information such as the frequency and nature of evaluations and treatments in emergency departments or other clinical settings. Evaluation of the severity and disability burden of headache disorders may also include, but would not require, consideration of data from validated survey instruments, such as, but not limited to, the Headache Impact Test-6 (HIT-6), the Migraine Disability Assessment Test (MIDAS), the Henry Ford Headache Disability Inventory (HDI), or the Migraine–Specific Quality of Life Questionnaire (MSQ). Where documentation shows that the frequency of use of analgesic medications may have worsened the frequency or severity of migraine or other headache disorder, as in medication adaptation headache or analgesic-overuse headache, this fact should not be considered adversely in the overall assessment of impairment. When a history of physical or other traumatic or abusive experiences, or of co-morbid medical conditions, including psychiatric conditions, is associated with worsened frequency or severity of migraine or headache disorders, this fact may be considered in the overall assessment of impairment. The criteria under 11.20 may be applied only if the impairment persists despite the individual adhering to a prescribed and supervised course of treatments that are consistent with the current standard of medical and surgical care, as supported by submitted documentation.
Proposed Draft Blue Book Listing:

“The Headache Disorders, including migraine, trigeminal autonomic cephalalgias, cranial neuralgias, and related disorders. The degree of impairment due to headache disorders will be determined according to the frequency, duration, severity, and sequelae of symptomatic attacks and their impacts on functional activities. Migraine and other primary headache disorders are not typically associated with clear or reliable diagnostic findings on physical examination, and no validated biomarkers, imaging abnormalities, or laboratory findings are typically diagnostic of the diseases. Whenever appropriate, attributed diagnoses should be consistent with the clinical diagnostic criteria of the current edition of the International Classification of Headache Disorders (ICHD). A detailed description of the individual’s typical or idiosyncratic attack or attack pattern of headache disorder is required. Such descriptions may include, but may not be limited to, the frequency, duration, and presence or absence of (a) premonitory symptoms, (b) ‘aura’ symptoms of disturbances of vision, skin sensation, language, strength, coordination, or vestibular function, (c) location, severity, duration, and qualities of eye, ear, nose, mouth, face, jaw, head, neck, or shoulder pain, (d) amplified, distorted, or pain-inducing sensation to light, sound, touch, movement, smell, or taste, (e) autonomic disturbances including nausea, vomiting, abdominal pain, gastroparesis, diarrhea, constipation, increased lacrimation, ptosis, peri-orbital edema, pupillary abnormalities, rhinorrhea, sweating, or nasal/sinus symptoms, or (f) disturbances of cognition, affect, concentration, language, motivation, attention, agitation, or tolerance of stressful or social environments. To establish a medically determinable impairment due to a headache disorder, an individual must submit supportive documentation of the frequency of impairing symptoms of that disorder. Such documentation may include data from symptom diaries, clinical or functional questionnaire records, medical records, reporting health care provider attestations and documentation, and other sources of ancillary information such as the frequency and nature of evaluations and treatments in emergency departments or other clinical settings. Evaluation of the severity and disability burden of headache disorders may also include, but would not require, consideration of data from validated survey instruments, such as, but not limited to, the Headache Impact Test-6 (HIT-6), the Migraine Disability Assessment Test (MIDAS), the Henry Ford Headache Disability Inventory (HDI), or the Migraine-Specific Quality of Life Questionnaire (MSQ). Where documentation shows that the frequency of use of analgesic medications may have worsened the frequency or severity of migraine, other headache disorders, or in application to post-traumatic headaches, or in any other headache disorder, this fact should be reported.”
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The criteria under 11.20 may be applied only if the impairment persists despite the individual adhering to a prescribed and supervised course of treatments that are consistent with the current standard of medical and surgical care, as supported by submitted documentation.
11.20 Migraine, trigeminal autonomic cephalalgias, cranial neuralgias, or other headache disorders - recurrent, severe symptoms, documented by detailed description of a typical attack or attack pattern, including associated phenomena, with symptoms occurring at least ten days per month in spite of at least 6 consecutive months of prescribed and medically supervised appropriate treatment of the headache disorders and any co-morbid disorders also contributing to impairment.

During symptomatic attacks there are pervasive and significant effects involving two or more of the following domains: interference with activity during the day; alteration of awareness or perception; impaired functioning in social environments; difficulty maintaining sustained concentration, persistence, or pace when completing tasks; inability to tolerate increased mental demands, time constraints, or routine movements; or extreme sensitivity to environmental changes or sensory exposures.
Headache on the Hill 2013
April 16, 2013

The Honorable Carolyn W. Colvin
Acting Commissioner of Social Security
Rayburn Building, Suite 900
6401 Security Blvd.
Baltimore, MD 21235

Dear Acting Commissioner Colvin:

Recently a constituent of mine, John Bebee of Lewistown, Montana, came to Washington, D.C., to raise awareness of severe headache disorders. Along with other advocates from the Alliance for Headache Disorders Advocacy (AHDA), John explained the painful and debilitating symptoms experienced by him, and by the many other chronic migraine and cluster headache sufferers across the country. AHDA is hopeful that increased awareness will lead to better understanding and acknowledgement of those incapacitated by this severe illness.

My understanding is that AHDA has reached out to the Social Security Administration (SSA), providing draft language for inclusion of headache disorders in SSA’s Listing of Impairments. I trust the agency will provide full and careful consideration of this language to facilitate adjudication of legitimate claims of impairment.

Thank you for your attention to this important matter.

Sincerely,

Max Baucus
Chairman
Cases

• 45 year old woman w disabling chronic migraine with fibromyalgia and opioid dependence

• 35 year old man w disabling episodic cluster headache that is active daily for 2 three-month bouts per year