September 27, 2019

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Re: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1717-P)

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma:

On behalf of the more than 20 stakeholder members of The Headache and Migraine Policy Forum (HMPF), thank you for the opportunity to provide input as CMS proposes changes to hospital outpatient prospective payment and ambulatory surgical center payment systems. HMPF is a group of diverse stakeholder advocates who seek to advance public policies and practices that promote accelerated innovation and improved treatments for persons living with headache disorders and migraine disease. We appreciate the opportunity to comment on the proposed rule and to express specific concerns regarding the proposed use of prior authorization for botulinum toxin injections for chronic migraine patients.

While HMPF shares CMS's concerns that the Medicare program be protected from abusive billing practices and therefore must value those services which are reasonable and necessary, we believe the increases in botulinum toxin injections are explained by the medically appropriate usages as described below.

As CMS continues its rulemaking process, HMPF hopes you will consider the impact to the migraine community and that your final assessment will soundly reflect upon the following:

Increased Utilization of Prior Authorization for Botulinum Toxin Injections Will Cause Extended Suffering and Lead to Unintended Health Outcomes for Persons Living with Migraine Disease.

First, to understand the scope of migraine disease and the impact of this proposed rule on chronic migraine patients, it is important to understand that migraine is a hereditary neurological and chronic disease that affects both the mind and the body. It is more than "just a headache" – there

exists a substantial systemic impact, both in severity and duration, to the patient. The pain of a migraine attack, especially compared to other medical conditions, can be debilitating.

In addition, we know that patients already endure a series of challenges when they seek treatment. Poorly managed migraine disease leads to excessive opioid use, adverse outcomes including frequent doctor visits, ER visits, necessary medical treatment for co-morbid conditions, and more. Patients often experience misdiagnosis and disease stigma. Timeliness and consistency of access to treatment is therefore crucial in ensuring patients do not experience increased "chronification" due to needless delays.

It is also troubling that CMS does not specify whether proposed prior authorization would extend for a period of time - perhaps one year - or become an ongoing burden every 90 days for the same patient. For a patient population that experiences continual uncertainty of when an attack may occur, such a disparity and imbalance in care would be devastating and create a costly rippling effect on patient quality of life – affecting workforce absenteeism / presenteeism, family life, and increasing known co-morbidities of migraine disease such as anxiety and depression.

Migraine Disease is Now More Accurately Diagnosed and Treated Than in Years Past, Leading to a Reasonable and Necessary Increase in Botulinum Toxin Injections for Medicare and Medicaid Patients.

CMS fails to acknowledge that much progress has been made in the diagnosis and treatment of migraine disease over the past decade. Enhanced diagnostic protocols have allowed clinicians to better and more accurately diagnosis migraine attacks and – most importantly - neurotoxin therapy was approved for treatment of migraine disease. CMS must therefore recognize that the vast majority of the utilization growth for code 64615 has been for medically appropriate and clinically supported indications resulting from improved diagnostic and treatment options.

Requiring Prior Authorization for Botulinum Toxin Injections Will Exacerbate Costly Opioid Abuse and Misuse by Persons Living with Migraine Disease.

HMPF understands that there is no one-size-fits-all for this chronic disease. Individualized, multidisciplinary, multimodal, coordinated, and comprehensive care is vitally important to effective treatment. The migraine patient community welcomes treatment options – including botulinum toxin injections - that are more effective and pose fewer side effects than opioids. However, despite evidence-based guidelines not recommending opioids as a first-line treatment of migraine attacks,[1] opioids account for nearly 10 percent of total medications prescribed to treat chronic migraine.[2] Providing treatment options that reduce the number of headache days or migraine attacks per patient would therefore decrease the dependence upon opioids for pain management.

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[1] Silberstein SD (2000) Practice Parameter: Evidence-based Guidelines for Migraine Headache Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 55:754–762

[2] Thorpe, K. Prevalence, Health Care Spending and Comorbidities Associated with Chronic Migraine Patients. Feb 2017. Retrieved at: http://allianceforpatientaccess.org/why-impact-cost-of-chronic-migraine-comorbidities-justify-whole-person-care/

To wit, a 2017 study in *Cephalgia* looked at 2,860 ambulatory care visits for migraine and found that opioids were prescribed to 15.2 percent of patients.[3] Another 2017 study in *The American Journal of Emergency Medicine* reviewed 1,222 visits to emergency departments for migraine attacks and found that opioids were ordered in 35.8% of these visits. By facility, opioids were ordered in 12.3% of academic medical center visits, 40.9% of urban emergency department visits, and 68.6% of community emergency department visits.[4] Should CMS require burdensome prior authorization for botulinum toxin injections and such utilization leads to delays in treatment, the economic and personal cost of such a policy would likely grossly outweigh any intended cost savings. Non-opioid migraine treatments such as neurotoxins must therefore be made more accessible to patients who need them, not less.

The Proposed Rule May Inadvertently Discriminate Against Certain Patient Populations – Including Women and Veterans – Disproportionately Affected by Migraine Disease.

Migraine disease is two to three times more common in women than men, with the highest prevalence between the ages of 18 and 49,[5] during a time when many women are in the middle of their careers. Women are more likely than men to experience longer and more intense migraine attacks, report more migraine-associated symptoms such as nausea and visual aura, and have higher levels of headache-related disability.[6,7] Seeking and receiving care for migraine also varies by gender.[8]

Veterans receiving Medicare benefits would also be affected. Between 2001-2007 migraine diagnoses across the Armed Services increased by 27%. Of service members who deployed to Iraq for a year or longer, 36% experienced migraine.[9] Therefore, CMS should consider the fact that requiring burdensome prior authorization utilization for botulinum neurotoxin injections may adversely affect some veterans living with migraine disease.

We urge CMS to continue to keep the patient perspective at the center of your rulemaking process. If you would like additional information regarding migraine disease, please do not hesitate to contact Lindsay Videnieks with HMPF at (202) 299-4310 or Lindsay@headachemigraineforum.org

On Behalf of:

The Alliance for Balanced Pain Management
The Alliance for Patient Access
Association of Migraine Disorders

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[3] Charleston Iv L, Burke JF (2017) Do racial/ethnic disparities exist in recommended migraine treatments in US ambulatory care? *Cephalalgia*. 2017 Jan 1:333102417716933
[4] Young, Neil, et al, Multicenter prevalence of opioid medication use as abortive therapy in the ED treatment of migraine headaches. The American Journal of Emergency Medicine, Vol. 35, Issue 12, 1845-1849; available at: http://www.ajemjournal.com/article/S0735-6757(17)30454-0/abstract
[5] Buse et al. Headache. 2013 Sep;53(8):1278-99. doi: 10.1111/head.12150. Epub 2013 Jun 28.
[6] Ibid.
[7] Bolay et al. Cephalalgia. 2015 Aug;35(9):792-800. doi: 10.1177/0333102414559735. Epub 2014 Nov 25.
[8] Lipton et al. Headache. 2013 Jan;53(1):81-92. doi: 10.1111/j.1526-4610.2012.02265.x. Epub 2012 Oct 18.
[9] Veterans who deployed are more likely to develop migraine. VA.gov. Available at: https://www.blogs.va.gov/VAntage/38022/veterans-who-deployed-are-more-likely-to-develop-migraines-or-headache-disorders/

The Coalition For Headache And Migraine Patients (CHAMP)
The Danielle Byron Henry Foundation
Global Healthy Living Foundation
GoldenGraine.com
Healthy Women
The Migraine Diva
Miles for Migraine