

January 26, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
RE: Most Favored Nation (MFN) Model [CMS-5528-IFC]

Dear Administrator Verma,

The American Headache Society (AHS) is the national professional society of health care professionals and scientists dedicated to the study and treatment of headache and face pain, including migraine and cluster headache. We thank you for the opportunity to provide feedback on the “Most Favored Nation” (MFN) model that was recently finalized.

As the AHS’ mission is to improve the care and lives of people living with headache disorders, OnabotulinumtoxinA for chronic migraine has been a necessary and critical treatment for many Americans. It is one of only a few FDA recommended preventive treatment specifically for chronic migraine (migraine with headache on 15 or more days per month) and is also endorsed by the American Academy of Neurology (AAN) and American Headache Society in clinical guidelines and position statements.

Migraine is a common and potentially disabling chronic disease.ⁱ The burden and disability associated with migraine can be substantial. Migraine can impact the function of the individual in multiple roles and settings including occupational, academic, social, familial, and personal. The 2016 World Health Organization Global Burden of Disease (GBD) study reported that migraine is the second most disabling disease worldwide, second only to low back pain.ⁱⁱ The GBD also estimated that migraine caused 45.1 million years lived with disability in a single year. Migraine can be costly to individuals, the workforce and society. Direct costs of migraine include costs of healthcare utilization, copays, deductibles, and costs of preventive and acute pharmaceutical and nonpharmaceutical treatments.^{iii,iv,v}

- A real-world study showed that after use of botulinum toxin for chronic migraine, there was a reduction in health care provider visits (96.2% to 76.7%) and headache-related emergency room or urgent care clinic visits (17.9% to 8.4%) by participants treated with OnabotulinumtoxinA for 2 years.^{vi}
- Indirect costs include missed days of school, lost wages due to missed work, and reduction in productivity.

The burden, impact and costs are greatest among people with chronic migraine. Preventive therapies such as OnabotulinumtoxinA can reduce the number of monthly migraine and headache days resulting in lower direct and indirect costs, reduced disease burden and improved quality of life. As published data suggests, OnabotulinumtoxinA decreases costs in migraine.

Consequently, AHS would appreciate an explanation how CMS determined that reduced utilization would lead to a net reduction in healthcare costs. The AHS would also appreciate an understanding how CMS considered the potential impact on the quality of life of patients who would suffer as a result of this rule.

The AHS strongly urges you to rescind the MFN model as finalized November 20, 2020, which was to be implemented beginning January 1, 2021 but temporarily postponed. Furthermore, AHS asks you for the opportunity to provide additional solutions through a mechanism of robust public comment. While we agree that that the high price of drugs must be addressed, it cannot be done at the risk of harming patients who rely on Medicare for their healthcare.

We have also read the comments submitted by our colleagues of the AAN, dated December 17, 2020. We fully agree with their statement. Specifically, and strikingly, as documented by the AAN: “CMS’ Office of the Actuary (OACT) projects that there is a significant likelihood that patients will lose access to medications under the MFN model. The agency is clearly aware of this model’s devastating impact on patient access and writes that, “a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization.” (85 Fed. Reg. at 76237). We wish to be clear that providers treat patients with OnabotulinumtoxinA for chronic migraine not to make money, but to ensure the patients obtain the right care. By CMS’ own admission, CMS is trying to disincentivize providers from doing what is understood as best, evidence-based, FDA-approved, standard of care treatment for their patients. The AHS is very disappointed that CMS appears to feel this way.

In conclusion, the AHS urges you to act immediately to halt implementation of the MFN Model. The devastating effects of this model cannot be understated. CMS, AHS, and all other stakeholders must find better ways to protect our vulnerable Medicare beneficiaries and the providers that care for them.

If you have questions, please do not hesitate to contact Howard Rosen at hrosen@talley.com

Sincerely,

Peter Goadsby MD, PhD, FAHS
President of the American Headache Society

ⁱ Lipton RB, Bigal ME, Diamond M, et al. Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*. 2007;68(5):343-349.

ⁱⁱ Collaborators GBD Study. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016;388(10053):1545-1602.

ⁱⁱⁱ Stokes M, Becker WJ, Lipton RB, et al. Cost of health care among patients with chronic and episodic migraine in Canada and the USA: results from the International Burden of Migraine Study (IBMS). *Headache*. 2011;51(7):1058-1077.

^{iv} Serrano D, Manack AN, Reed ML, Buse DC, Varon SF, Lipton RB. Cost and predictors of lost productive time in chronic migraine and episodic migraine: results from the American Migraine Prevalence and Prevention (AMPP) Study. *Value Health*. 2013;16(1):31-38.

^v Stewart WF, Bruce C, Manack A, Buse DC, Varon SF, Lipton RB. A case study for calculating employer costs for lost productive time in episodic migraine and chronic migraine: results of the American Migraine Prevalence and Prevention Study. *J Occup Environ Med*. 2011;53(10):1161-1171.

^{vi} Boudreau G, et al. Healthcare Utilization and Health-Related Quality of Life in Adult patients with chronic migraine: Results from the PREDICT study. Presented poster American Headache Society 2020.