



January 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

The Epilepsy Leadership Council (hereinafter “ELC”) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS)’s proposed rule entitled Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P). The ELC is a coalition of more than 30 professional societies, patient advocacy organizations, and governmental agencies working together to improve the lives of people living with epilepsy, seizures and related disorders. An important element of the ELC’s policy agenda is to ensure that Medicare beneficiaries living with epilepsy continue to have access to the full range of anticonvulsants through the Six Protected Classes policy. The proposed rule significantly reduces the protections afforded to patients in the current classes of special clinical concern and would allow plans to impose additional barriers that will impede people with epilepsy from accessing their anticonvulsants, as well as exclude anticonvulsants from the formulary in certain instances. For this reason, the ELC finds the proposal contrary to our principles and respectfully asks that it be rescinded.

Epilepsy is a condition of the brain causing seizures—which are disruptions of the electrical communications between neurons. According to the Centers for Disease Control and Prevention, at least 3.4 million people in the U.S. live with seizures, including 470,000 children. Treatments are available that can stop or control seizures for most people with seizures and epilepsy. However, despite available treatments, about one third of people with epilepsy—many of whom have rare forms of epilepsy—live with uncontrolled seizures or intractable epilepsy.

Mortality rates among people with epilepsy are three times higher and sudden death rates are twenty times higher than rates for the general population. Studies suggest that each year there are about 1.16 cases of SUDEP for every 1,000 people with epilepsy.¹ Most cases of SUDEP occur during or immediately after a seizure. For people with frequent generalized tonic-clonic seizures the relative risk increases to an absolute risk of up to 18 deaths per 1,000 patients annually.

The Six Protected Classes policy was specifically designed, according to CMS, to “mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.” Of utmost concern is that the proposed rule would give plans more flexibility to force people relying on medications in the protected classes to go through prior authorization and step therapy, putting them at risk of delayed access to the most effective treatments. While these tactics are already utilized by Part D plans, they are challenging and potentially dangerous to people living with a chronic, complex condition like epilepsy and increased application of these tactics creates greater risk. Epilepsy is a spectrum condition that impacts each individual differently. Depending on factors like seizure type and side effects that come with anticonvulsants, it can take time for each person—with guidance from their healthcare provider—to find an anticonvulsant that works for him/her and allows him/her to achieve seizure control. Timely access to the full range of anticonvulsants is of critical importance. The delays that step therapy and prior authorization bring can be life-altering and even life-threatening for someone with epilepsy. They face the very real possibility of breakthrough seizures, which can lead to injury, disability or even death. The policy changes related to step therapy and other prior authorization allowances proposed by the rule are particularly dangerous for individuals who have been stable on an anticonvulsant and are first joining a Part D plan or are switching from one Part D plan to another. The proposed rule ignores clinical advice, progress that has been made to find an anticonvulsant that’s effective and, ultimately, places the individual’s health and life in jeopardy.

The second two components of the protected classes proposal could also have significant negative effects on the epilepsy community. Being able to exclude anticonvulsants from the formulary—either because there is a new formulation, or the price of the medication has increased above a specified threshold—essentially equates to instituting step therapy. If a person with epilepsy was stable on the medication that is now excluded, s/he may be forced to try other anticonvulsants that may or may not work for him/her. Therapeutic equivalence cannot be assumed across products within the same class, and this is increasingly the case as new targeted therapies are identified. In addition, the new formulation exclusion could stifle access to innovative therapies that have less debilitating side effects for some people.

Finally, eliminating portions of the existing protections could increase Part A or Part B costs. People with epilepsy who are unable to access the most medically appropriate treatments may experience poor outcomes and life-threatening occurrences, which could require increased utilization of health care provider services and increased utilization of emergency room facilities.

While we understand and support the need to control costs, Medicare’s Six Protected Classes were established for a reason. The populations that rely on protected class medications—including people with epilepsy—need access to the full range of approved treatments so that the most appropriate medication can be identified and be provided in the most effective manner. Barriers or delays in access to anticonvulsants are literally life-threatening. The ELC urges the Administration to rescind all proposed revisions to the Six Protected Classes of medications in this proposed rule.

If you have any questions, please contact Chair of the ELC’s Advocacy Committee Kari Rosbeck at krosbeck@tsalliance.org or (301) 562-9890, ext. 210.

Sincerely,

Aicardi Syndrome Foundation

American Clinical Neurophysiology Society
American Epilepsy Society
Batten Disease Support and Research Association
The Bow Foundation
The Brain Recovery Project
Chelsea's Hope Lafora Children Research Fund
Child Neurology Foundation
Citizens United for Research in Epilepsy
CSWS Epilepsy & Landau Kleffner Syndrome Foundation
Danny Did Foundation
Dravet Syndrome Foundation
Dup15q Alliance
Epilepsy Foundation
FamilieSCN2A Foundation
Finding a Cure for Epilepsy and Seizures
Hope4Harper
Hope for Hypothalamic Hamartomas
International Foundation for CDKL5 Research
International League Against Epilepsy
Jack Pribaz Foundation
KCNQ2 Cure Alliance
Lennox-Gastaut Syndrome Foundation
My Epilepsy Story
National Association of Epilepsy Centers
NORSE Institute
PCDH19 Alliance
Ring14 USA Outreach
Seizure Tracker
TESS Research Foundation
Tuberous Sclerosis Alliance
Wishes for Elliott

¹ Thurman DJ, Hesdorffer DC, French JA. Sudden unexpected death in epilepsy: Assessing the public health burden. *Epilepsia*. 2014;55(10):1479-85.