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 National Association of Epilepsy Centers (NAEC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS)'s proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P). NAEC's comments focus on the rule's proposed exceptions to the requirement that all Part D plans include in their formularies all drugs in the six protected classes of drugs, one of which is anticonvulsants. Full access to these medications is critical to individuals living with epilepsy and we are concerned that the proposed changes could place our patients' health and safety in jeopardy.

Epilepsy is a disorder of the brain characterized by repeated seizures. The Centers for Disease Control and Prevention estimates that 3.4 million people in the U.S. live with epilepsy, including approximately 3 million adults and 470,000 children. Epilepsy is typically diagnosed after a person has had at least two seizures on two separate occasions that were not caused by a known medical condition. The goal of treating people with epilepsy is to eliminate seizures without causing side effects. Many individuals with epilepsy are treated effectively with a single medication, but it often requires trying several options before determining the most effective treatment. Additionally, about one third of people with the disorder live with uncontrolled seizures or intractable epilepsy, who may require a complex set of medications to treat their condition. Mortality rates among people with epilepsy are three times higher and sudden death rates are up to twenty times higher than rates for the general population.

NAEC is an organization of 250 specialized centers in the U.S. that diagnose and treat patients with complex and intractable epilepsy and seizures. NAEC supports epilepsy centers in delivering quality comprehensive care to people with epilepsy, by setting standards of care, accrediting level 3 and 4 epilepsy centers and advocating for access to high quality epilepsy center services.

Medicare Part D Protected Classes of Drugs Policy

Congress identified six categories or classes of drugs of clinical concern when establishing the Medicare Part D program (the "six protected classes") – anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants – and required Part D plans to cover "all or substantially all" of the drugs within these classes. This policy was put in place to ensure that vulnerable

Medicare beneficiaries would have access to needed medications and to ensure that Part D plans would not discourage these individuals from enrolling in their plans.

It is critically important that the current protected classes policies are maintained for anticonvulsants for multiple reasons. One out of three individuals with epilepsy will not respond to a single drug, so developing an effective treatment plan that controls seizures without side effects involves multiple trials of one drug at a time and/or trials of multiple drugs taken together. An unrestricted formulary providing multiple medication options with novel mechanisms of action and side effect profiles is essential. In addition, both elderly and disabled Medicare beneficiaries typically live with multiple co-morbidities and are prone to medication side effects[1], making the need for access to a full formulary for these patients even more critical.

While the proposed rule would not eliminate the six protected classes, it does seek to make significant changes to the program that could harm beneficiary access to medically-appropriate therapies provided in a timely manner. We strongly urge CMS to proceed cautiously when considering any potential changes to the six protected classes.

Allowing Part D Plans to Use Prior Authorization, Step Therapy, and Utilization Management

NAEC strongly opposes CMS' plan to allow Part D plans to impose utilization management tools for anticonvulsant treatments, as these measures will cause delays or prevent access to effective therapy, which could be fatal for people whose seizures are no longer controlled when these medications are not available to them. The proposals related to step therapy and prior authorization 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. People with epilepsy are exquisitely sensitive to changes in anticonvulsants. Half of people with epilepsy require the use of multiple drugs before finding the right drug that renders them seizure free; since no tests can predict which drug will control seizures in any one person, several drugs might be tried. Once a patient finds a drug that works, it is medically contraindicated to stop that drug or switch to another drug, since it is not known whether a new drug will be effective. If patients are forced off their medications while the provider is seeking prior authorization or if step therapy is required (or being overturned), then they may start having seizures, which can be life threatening.

Because epilepsy is a very heterogeneous disorder, a single medication or single mechanism of action will not be effective in all cases.[2] Therefore, step therapy or "fail first" policies are not rational means to treat patients and could be clinically dangerous. While the purpose of these types of utilization management tools is to drive prescribers to lower cost drugs, such as generics, not all brand anticonvulsants have generic alternatives and the formulations of generics can vary substantially. While prescribers utilize generic drugs they do so cautiously, since one brand of generics can be substituted for another brand without notification of patient or provider. These treatment differences can be so significant that they lead to the need for emergency treatment or hospitalization.

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[1] Institute of Medicine (US) Committee on the Public Health Dimensions of the Epilepsies; England MJ, Liverman CT, Schultz AM, et al., editors. Epilepsy Across the Spectrum: Promoting Health and Understanding. Washington (DC): National Academies Press (US); 2012. Available from: https://www.ncbi.nlm.nih.gov/books/NBK91506/ doi: 10.17226/13379

[2] Labiner DM, Drake KW. Formularies, costs, and quality of care: Formulary restrictions are not the answer, especially for epilepsy. Neurol Clin Pract. 2013;3(1):71-74.

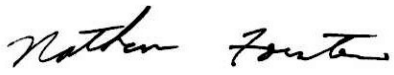
Allowing Part D Plans to Exclude New Formulations of Drugs or Drugs with Price Increases Greater Than Inflation

We appreciate CMS' interest in pursuing measures to allow Part D plans to reduce drug costs, but do not support as drafted the two additional exceptions to the protected classes of drugs policy proposed in the rule. The two exceptions are: 1. Excluding from a formulary a new formulation of a single source protected class drug, regardless of whether the older formulation remains on the market and 2. Excluding from a formulary a protected class drug if the price of the drug increases beyond the rate of inflation. These two exclusions would provide plans with broad discretion to not include needed drugs in their formularies. There is data showing that the older formulations of anti-epileptic medications cause more side-effects and greater interactions with other medications. This is especially problematic for Medicare's elderly and disabled beneficiaries with epilepsy, who are on multiple medications for other health conditions. For this reason, we would ask that CMS not make a blanket exclusion of new formulations.

In addition, we are concerned that the proposed exclusion for drugs that increase in price above inflation will impact access to needed therapies for some patients. This is especially concerning for patients whose seizures are well-controlled, who may be forced to switch to an ineffective medication due to these exclusions. Therapeutic equivalence cannot be assumed across products within the same class, and this is increasingly the case as new targeted therapies are identified. We would suggest that CMS explore other means to reduce the cost of drugs under Medicare, whether it be through value-based assessments or a rebate program similar to that used under Medicaid.

We would be happy to answer any questions related to our comments. Please contact Ellen Riker, NAEC Executive Director, at eriker@dc-crd.com or 202-524-6767 for additional information.

Sincerely,



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