

March 5, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Administrator Verma:

Thank you for the opportunity to comment on the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 Medicare Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter.

Avanir Pharmaceuticals, Inc., founded in 1988, is a biopharmaceutical company focused on acquiring, developing, and making available innovative therapeutic products for the treatment of central nervous system (CNS) disorders. One of our currently approved products, NUEDEXTA, is indicated for the treatment of pseudobulbar affect (PBA), a neurologic condition characterized by involuntary outbursts of laughing and/or crying that are incongruous or disproportionate to the patient's emotional state. The condition is a sequela of CNS disorders including Alzheimer's disease, ALS, Parkinson's disease, multiple sclerosis, stroke, and traumatic brain injury (TBI). PBA is associated with impaired social and occupational function, embarrassment, social phobia, withdrawal, and isolation for both patients and their caregivers, which can result in increased disability in patients. People with PBA experience high rates of comorbidities, health care resource utilization, and institutionalization.<sup>1,2,3,4</sup>

Avanir would like to raise three issues in our comment letter:

1. While Avanir appreciates the Centers for Medicare and Medicaid Services' (CMS) action in 2017 to increase the specialty tier threshold in Part D, we recommend that CMS provide annual adjustments to this threshold to reflect ongoing changes in the marketplace for specialty drugs.
2. Avanir continues to be concerned with the level of coinsurance or copay allowed under both the "non-preferred brand" and "non-preferred drug" tiers that can lead to excessive

---

<sup>1</sup> Colamonic J, Formella A, Bradley W. Pseudobulbar affect: burden of illness in the USA. *Adv Ther.* 2012;29:775-798.

<sup>2</sup> Choi DH, Jeong BO, Kang HJ, et al. Psychiatry comorbidity and quality of life in patients with post-stroke emotional incontinence. *Psychiatry Investig.* 2013;10:382-387.

<sup>3</sup> Chen YK, Wong KS, Mok V, Ungvari GS, Tang WK. Health-related quality of life in patients with poststroke emotional incontinence. *Arch Phys Med Rehabil.* 2011;92(10):1659-1662.

<sup>4</sup> Rudolph JL, Fonda JR, Hunt PR, et al. Association of pseudobulbar affect symptoms with quality of life and healthcare costs in veterans with traumatic brain injury. *J Affect Disord.* 2016;190:150-155.

costs for beneficiaries who rely on a drug that is the only FDA-approved drug to treat a condition, due, at least in part to the ability of plans to meet CMS actuarial standard by “blending” brand and generics on the same tier. We recommend that CMS exclude any such drug from non-preferred tiers.

3. Related to the second issue, though not directly addressed in this year’s Advance Notice, Avanir urges CMS to address the current gap in the tiering exceptions process for patient access to lower copays or coinsurance where there is no similar, clinically appropriate alternative in a lower-cost tier because there is no other FDA-approved drug.

### **Specialty Tier Threshold**

CMS’s adjustment to the specialty drug threshold in 2017 was an important, and welcome change. As we commented then, and again last year, we believe that the specialty tier threshold should be subject to annual review and adjustments, rather than ad hoc adjustments, as was the case twice before. We believe that CMS should adopt a policy of indexing the specialty tier threshold to the same indices used to adjust other key portions of the program, such as the deductible. In this way, the program’s overall structure will remain balanced over time. We believe that this would be an important step in keeping growth in the specialty tier requirements in line with other key program parameters. More importantly, an annual adjustment would help protect beneficiaries from excessive coinsurance resulting from medicines that are priced at levels near the threshold and are eventually forced by cost growth into the specialty tier. It would also protect beneficiary access to needed drugs since the tiering exception process is not available for drugs on the specialty tier.

As a related matter, in the past (2014 and 2015), CMS provided a detailed analysis of the specialty tier in a memo accompanying the Advance Notice. This analysis was not provided by CMS in 2016, 2017, and again in 2018, though CMS refers to such an analysis again in this year’s Advance Notice and Call Letter. We urge CMS to resume its practice of publishing its analysis of the specialty tier threshold along with the Advance Notice and Call Letter *each* year. We found the agency’s past analyses critical in understanding CMS’ position in setting the specialty tier threshold as well as its view of developments in the Part D program. It would be a great help to us in understanding proposals if this data were available concurrently with the Advance Notice and Call Letter.

### **Coinsurance in Non-Preferred Tiers**

For many years, CMS favored a copay rather than coinsurance structure. One reason is that a flat-dollar copay is easier for beneficiaries to understand their out-of-pocket costs and allows them to make comparisons across different plans. However, with changes in the pharmaceutical marketplace over the past few years, cost-sharing arrangements have been changing. As a result, CMS and some stakeholders expressed concern that copays do not always work to a beneficiary’s advantage. For example, CMS noted that among some plans, copays have actually resulted in higher out-of-pocket costs for beneficiaries, particularly for generic drugs, than coinsurance. In the 2017 Advance Notice and Call Letter, in a review of 2015 prescription drug event data, CMS found that some beneficiaries paid less in non-preferred drug tiers that utilize coinsurance than they would have in tiers that use copays.

A corollary concern, which CMS has also discussed, is that tier labeling has been increasingly confusing for beneficiaries and providers, particularly as both generic and brand drugs are included in non-preferred drug and non-preferred brand tiers. For the 2017 plan year, CMS provided for a non-preferred tier to encompass both brand and generic, and in the 2018 Advance Notice, CMS provides for greater clarity between non-preferred *drug* and non-preferred *brand* tiers, and what may be placed in each, so that beneficiaries can better understand their choices and the cost-sharing implications.

Equally concerning has been the impact on calculation of actuarial value of mixing generic and non-preferred brand drugs on the non-preferred brand tier. We agree with CMS' proposal to limit generic composition on the non-preferred brand tier to 25 percent and support CMS' intent to conduct outlier analysis and require additional justification of plans.

Over the past several years, the Kaiser Family Foundation (KFF) has tracked the evolving Part D landscape and found:

- In 2018, most PDPs have five cost-sharing tiers, with copayment and coinsurance rates varying widely across Part D plans. Of particular note, they report that “Nearly all PDPs charge coinsurance for higher-cost specialty and non-preferred drugs, which usually results in higher out-of-pocket costs for enrollees than when plans charge copayments.”
- As of 2016, for drugs on the non-preferred brand tier, the median *coinsurance* rate had risen to 40 percent, a substantial share of the drug's cost and more than the median *copay* for that tier.

KFF also noted that in 2015, 132 PDPs required beneficiaries to pay half the cost of drugs on the non-preferred tier, the maximum allowed, up from only 29 PDPs in 2014. In effect, in a growing number of plans, beneficiaries now pay more for a drug on the non-preferred tier than if it were on the specialty tier.

As burdensome as a 50 percent coinsurance can be, the concept behind multiple tiers with preferred and non-preferred drugs is that a clinically similar drug is available on a preferred tier with lower cost-sharing. However, when there is no clinically similar drug (in other words, there is only one drug approved for a particular indication), placement on a non-preferred tier with high cost-sharing is not just burdensome or financially prohibitive, but also potentially discriminatory and contrary to CMS's own policies. In its Prescription Drug Manual, CMS states:

CMS will review tier placement to ensure that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, sponsors should utilize industry best practices. . . . Best practices in existing formularies and preferred drug lists generally place drugs in a less preferred position only when drugs that are therapeutically similar (i.e. drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.<sup>5</sup>

---

<sup>5</sup> Medicare Prescription Drug Benefit Manual, Chapter 6, Sec. 30.2.7

While only 1 percent of prescriptions are in the specialty tier and the goal is to encourage patients to use less costly alternatives, in the case of treating PBA, there are no other FDA approved alternatives. Herein lies the problem for beneficiaries affected by PBA. While most plans place NUEDEXTA on their preferred brand tier, some place it on their non-preferred tier *with higher coinsurance than if it were on the specialty tier*. Such a formulary design can be discriminatory and, when viewed on CMS and plan websites, lead a beneficiary with a condition that is treated by a unique drug to restrict their choice of plans. Consistent with its statement in the Manual, we urge CMS to closely scrutinize where drugs with no clinical alternative exists are placed on plan formularies.

### **Tiering Exception Requests**

In theory, beneficiaries or physicians might resort to a tiering exception request, which is not an easy process but at least a pathway that may offer recourse. However, the current regulations and guidance for a tiering exception request are premised on the notion that there is a clinically equivalent drug on one or more lower tiers such that the prescriber “must indicate that the preferred drug(s) would not be as effective as the requested drug for treating the enrollee’s condition.” Where no such equivalent therapy exists, a plan can issue a denial notice by simply asserting that the requested drug “does not qualify for lower copay.” In effect, the current policy creates a “Catch-22” for beneficiaries and a higher risk of discriminatory practice. A plan can place a drug on a non-preferred tier with a 50 percent coinsurance or excessive copay, leaving beneficiaries with no practical alternative. Or, by placing a drug on the specialty tier, preclude use of the tiering exception process entirely.

### **Recommendations**

In order to reduce the risk that a plan design may be discriminatory and to further CMS’s effort to simplify the cost-sharing requirements for beneficiaries across tiers, we recommend that CMS consider two policy changes:

- Exclude drugs with no FDA approved therapeutic indication from any non-preferred tier.
- For those drugs that have an FDA approved therapeutic indication, limit coinsurance so that, at a minimum, it does not exceed that which would apply in the specialty tier.

### **Conclusion**

Avanir appreciates the opportunity to review and comment on these important issues and remains optimistic that policy changes in the Part D program will continue to improve affordable access to critical therapies for beneficiaries with PBA. We are willing to make ourselves available as a resource to you and your staff at any time, and we look forward to working with you to help provide critical access to medicines for Medicare beneficiaries.

Sincerely,



Molly Ryan  
Head of Government Affairs  
Avanir Pharmaceuticals Inc.