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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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December 10, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra,

I write to express my concern about the scheduled increase in Medicare Part B premiums in 2022 and urge you to work to limit these premium increases associated with uncertainty about anticipated Medicare spending on new Alzheimer's disease drugs, such as Aduhelm (Aducanumab). Medicare beneficiaries cannot afford to be saddled with a record increase in monthly premium costs—especially when those premium costs are being driven up by uncertain expectations of sky high Medicare costs for an outrageously expensive drug like Aduhelm that has presented limited clinical evidence of its effectiveness.

On June 7, 2021, the Food and Drug Administration (FDA) granted accelerated approval for Aduhelm for treatment of Alzheimer's disease. This accelerated approval came despite the fact that the FDA's Advisory Committee recommended that FDA not approve the drug, after studies failed to show strong evidence of the drug's effectiveness. Despite the lack of evidence, Biogen, the manufacturer of Aduhelm, has set an astronomical \$56,000 per year list price for this drug. Immediately following FDA's approval of Aduhelm, during the Finance Committee's hearing with you regarding the 2022 Health and Human Services (HHS) budget, I raised concerns about the impact of this high-priced drug on Medicare's finances and questioned whether Medicare should cover the drug, given the lack of thorough clinical evidence on the drug's efficacy.

On November 12, 2021, the Centers for Medicare and Medicaid Services (CMS) announced the Medicare Part B premium rates for 2022, which established a \$21.60 per month increase in the standard Part B premium, from \$148.50 in 2021 to \$170.10 in 2022. This 14.5 percent hike in premiums amounts to the largest Part B premium increase in the history of the Medicare program. CMS officials have indicated that about half of the Part B premium increase for 2022 is due to contingency planning for the costs associated with possible Medicare coverage of Aduhelm and other new Alzheimer's disease drugs. Specifically, CMS is adding approximately \$11 per month to the Part B premium to fund an increase in Medicare's contingency reserve within the Supplementary Medical Insurance (SMI) Trust Fund to cover future Medicare Part B spending on Aduhelm and other Alzheimer's disease drugs that are not currently covered.

Critically, this \$11 per month addition to the Medicare Part B premium for Aduhelm-related contingency reserve funding is not based solely on expected Medicare Part B spending on these Alzheimer's disease drugs in 2022, as this premium increase also accounts for *uncertainty* around the anticipated costs of Aduhelm and other Alzheimer's disease drugs for the Medicare program. On July 12, 2021, CMS opened a National Coverage Determination (NCD) analysis to determine whether Medicare will establish a national coverage policy for Alzheimer's disease drugs, including Aduhelm.

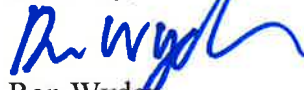
Given that Aduhelm has been approved via FDA's accelerated approval process, which requires additional post-approval trials "to verify that the drug provides the expected clinical benefit," it is possible that any near term Medicare coverage for Aduhelm under the NCD could have a limited and narrow scope of coverage, pending further evidence. In fact, Medicare often provides "coverage with evidence development" in these types of scenarios. Following the results of this NCD process, there will be less uncertainty about Medicare spending on Aduhelm and other Alzheimer's disease drugs, which is currently built into the Part B premium collection for the contingency reserve.

The Social Security Act gives the Secretary of HHS broad authority in determining the appropriate contingency margin to include in monthly actuarial rate calculations. Medicare should allow the current coverage determination process to unfold—and reduce uncertainty—before adding Aduhelm-related contingency reserve costs to Medicare beneficiaries' premiums.

Rather than assessing the current \$21.60 per month Part B premium increase in full, I urge you to reduce the amount of premiums collected for the contingency reserve related to uncertainty around new Alzheimer's disease drugs and allow for more time to project expected Medicare costs for these drugs with a higher level of certainty. Taking this type of approach would reduce near-term expenses for seniors on fixed incomes and ensure that the Part B premium accurately reflects Medicare's expenditures for Aduhelm and other Alzheimer's disease drugs that are not currently covered by Medicare.

Thank you for your attention to this critical issue. I stand ready to work with you to help ensure that seniors are not burdened with excessive premium increases.

Sincerely,



Ron Wyden
Chairman
Committee on Finance