# HHS: BIIB Price Cut May Reduce Part B Premium

## Aduhelm NCD Decision Due Jan 12

- **HHS Secretary Becerra notes that the 2022 Part B premium hike will be likely re-assessed by CMS (here).** Given the dramatic price change of Aduhelm by Jan 1 (50% price cut) there is a compelling reason to lower senior's Part B premiums, according to HHS' Becerra. The HHS release popped up on the HHS website as the company presented at the JPMorgan Healthcare Conference (virtual) this morning.

- **As a reminder, CMS increased Medicare Part B premiums (by $21.60; 50% of that due to Adu) and deductibles due to Aduhelm's initial $56K price.** On November 12, CMS issued increases to Part B premiums (+ $21.60 monthly) and deductibles to cover possible costs to the Medicare system posed by Aduhelm. Note ~50% of the $21.60 monthly premium increase is allocated to the Supplementary Medical Insurance Trust Fund (SMI) for contingencies covering Aduhelm and other Alzheimer's treatments. 80% of patients eligible for Aduhelm will be Medicare beneficiaries. Recent reports showed Aduhelm alone could double Part B annual drug spend to $74B; this will now come down.

- **CMS is scheduled to issue a proposed NCD (by Weds Jan 12) and the company hopes a CED will be the case.** We have said that Coverage with Evidence Development (CED) is most likely for BIIB's Aduhelm. BIIB must submit more robust data that includes Black and Hispanic clinical trial participants to maintain Medicare coverage. FDA has given BIIB a 2030 deadline to submit confirmatory trial data. We think that the data will come in a lot sooner. BIIB will initiate further trials in May 2022, and aims to submit data by 2026.

- **NEXT UP: CMS proposed CMS coverage decision will be this week, due Jan 12.** We note that LLY and other competitors may surpass BIIB. LLY has set up a head to head trial comparing its donanemab with BIIB's Aduhelm to test both drugs' abilities to clear amyloid plaques and improve cognition in Alzheimer's patients. Data to date shows LLY's donanemab outperforms Aduhelm. FDA has already granted donanemab Breakthrough Therapy designation, paving the way for timely approval once the company submits comprehensive clinical trial data. LLY may learn from BIIB's hubris and price donanemab more reasonably, sparing itself regulatory headaches. BIIB may announce further cost cutting measures. The company already announced $500M in cost cutting measures by 1Q 2022. The question remains: Can BIIB withstand the reputational damage caused by Aduhelm? All eyes will be on further clinical trial outcomes, but a lot can happen between now and then.


Contact Ipsita Smolinski - 202.250.3741 - Ipsita@capitol-street.com

Background

- **Recall both FDA and BIIB came under fire for the controversial approval for treatment amid a series of questions BIIB's insufficient clinical trial design and Aduhelm's actual safety and efficacy**. The drug was granted accelerated approval by FDA, as it was deemed to be a product addressing unmet need, where benefit outweighs risk. The drug was originally priced at $56K per year. BIIB announced a priced reduction to $28K per year at the end of December 2021.

- **CMS designed the CED mechanism to expedite access to innovative technologies, but how novel is Aduhelm?** An ICER clinical review found that dosing did not impact the results in BIIB's trials, despite the company's claims. BIIB based its efficacy statement on extrapolating dosing from an earlier trial into a later trial. Susan Kremen (Cedars Sinai, and notably a PI for one of Aduhelm's trials) stated that the drug's approval was based on an amyloid pathology, a clinical biomarker that is NOT an indication of efficacy in preventing Alzheimer's.

- **CMS has a precedent of issuing CEDs for amyloid-related diagnostics, but it still may not help BIIB's case.** Several clinical reviews' stated Aduhelm's use of an amyloid biomarker is inadequate in proving its novelty and efficacy. CMS issued CED designations for amyloid PET scans (2013) and PET and other neuroimaging devices for suspected dementia (2004,) but otherwise has no precedent for CEDs for Alzheimer's monoclonal antibodies. See more details here
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- **CMS's decision mandates BIIB share data proving efficacy in under-represented populations.** According to the Alzheimer's Association, Alzheimer's and other dementias cost the US ~$355 B in 2021, disproportionately impacting Asian American, Black, Hispanic and Native American populations, Full report is here. If BIIB's post trial data does not show efficacy in these populations. the FDA has the authority to remove Aduhelm from the market.

- **Aduhelm's approval undermined confidence in FDA's integrity.** In November 2020, FDA statisticians called out BIIB and other FDA officials involved in Aduhelm's approval process for greenlighting the drug's approval based on inconclusive clinical trial results. Specifically, FDA statistician Tristan Massie cited the trials in questions for showing a "lack of substantial evidence, no replication, highly conflicting results in two studies, conflicting subgroup results." See presentation here, slide 3.

- **FDA may reconvene to assess Aduhelm's efficacy in an effort to redeem its reputation.** FDA's accelerated approval of Aduhelm and its relationship with BIIB has called its reputation as the international "gold standard" in setting regulatory protocol into question. Note the Committee for Medicinal Products for Human Use or CHMP (Europe's equivalent of the FDA) rejected BIIB's request to market Aduhelm in the EU. CHMP's refusal to follow FDA's precedent could indicate international speculation re: FDA's integrity.


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