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Alzheimer's Drugs Alternative Payment Models Should Get CMS Support – Duke Margolis

by Cathy Kelly

Some US Medicare Advantage plans are exploring alternatives to Medicare's average sales price plus 6% payment formula for Biogen/Eisai's Aduhelm. Other MA plan sponsors urge the Medicare agency not to allow coverage for Aduhelm and similar drugs without an evidence development requirement.

Some private insurance plans, including Medicare Advantage sponsors, are considering alternatives to Medicare's traditional average sales price plus 6% reimbursement model for *Biogen, Inc.*'s and *Eisai Co., Ltd.*'s Aduhelm for Alzheimer's disease and the Centers for Medicare and Medicaid Services should help advance those efforts, the Duke Margolis Center for Health Policy told CMS in 11 August *comments*.

Such private sector innovation could contribute valuable insights into CMS' ongoing Medicare national coverage analysis for Aduhelm (aducanumab) and other amyloid-directed monoclonal antibody drugs for Alzheimer's disease, the organization pointed out.

The comments were submitted as part of the Medicare NCA, which is expected to produce a draft national coverage policy for such drugs by 12 January 2022, followed by a final decision in April. (Also see "*Medicare Coverage Analysis Of Alzheimer's Drugs Begins With Focus On Outcomes, Patient Eligibility*" - Pink Sheet, 13 Jul, 2021.) Duke Margolis has been an active participant in efforts to sort out the policy disconnect between the US Food and Drug Administration's approval of Aduhelm and Medicare's "reasonable and necessary" reimbursement standard. (Also see "*Medicare Coverage For Aduhelm Conditioned On Randomized Trial Would Be 'Unusual' – McClellan*" - Pink Sheet, 16 Jul, 2021.)

A number of private payers sponsoring Medicare Advantage plans have concluded so far that the

current data on the mAB therapy does not support unrestricted coverage, Duke Margolis noted. However, some Medicare Advantage sponsors are also exploring alternatives to Medicare's standard ASP plus 6% payment model. For example, "payment might be based on continuation (e.g., no or lesser payments for patients who terminate treatment early due to safety issues or progression) or partial capitation (e.g., drug payments reduced or capped above some level of spending in the population)," the comments explain.

> ***"We … encourage CMS to consider the long-term impact of the potential approval for this drug, and whether it could undermine the 'reasonable and necessary' Medicare coverage standard, which can have ramifications for future opportunities to develop effective treatments and for patient safety," the Blue Cross and Blue Shield Association said.***

Payers have also proposed "an 'accelerated approval' payment rate that could be increased after evidence improves and/or full approval occurs, which would be difficult to implement under current Part B payment rules," the organization observed. Advisors to the Medicaid program have recommended such an approach for that program. (Also see "*Higher Medicaid Rebates For Expedited Approvals Offer Modest Savings But Target Growing Concern*" - Pink Sheet, 8 Apr, 2021.)

Duke Margolis advised that CMS "should explore ways in which it can support private plans in implementing innovative contracting alternatives to traditional Part B payment, or potentially even pilot such models."

Such payment reforms "are not easy to implement quickly, but they could improve access to mAB therapies as well as other available or emerging [Alzheimer's disease] therapies. … Now is the time to advance these models, both to inform the current NCA and to provide a stronger foundation for efficient access to effective therapies in the future."

Biogen and Eisai have expressed interest in developing value-based payment arrangements for Aduhelm but so far none that tie payment to outcomes or other milestones have been announced. That likely reflects payer disappointment that the companies have chosen an aggressive $56,000 per year price for the drug despite its limited evidence base.

Large Payers Skeptical About Medicare Coverage

In separate comments to CMS, private payers sponsoring Medicare Advantage plans seek restrictions on coverage for Aduhelm until more data on its safety and effectiveness has been developed. AHIP, Kaiser Permanente and the Blue Cross and Blue Shield Association all counseled against routine Medicare coverage for Aduhelm and urged that if CMS decides to cover the drug, it do so only in the context of evidence development requirements.

"It does not appear that CMS can conclude that [Aduhelm] is 'reasonable and necessary' as required by the statute based on currently available evidence," AHIP *said*. But "if CMS determines under the statutory framework that aducanumab qualifies for Medicare coverage in some circumstances, we urge the agency to narrowly target coverage within the context of an evidence development process."

Similarly, "our clinical specialists believe that the risks to our patients exceed the benefit of reducing amyloid burden without significant clinical improvement," Kaiser Permanente, which is a major Medicare Advantage sponsor, said in its *comments*. "Therefore, our specialists believe the drug should only be administered in the context of a randomized clinical trial. The data do not support its routine use for the treatment of Alzheimer's disease."

Finally, "we feel strongly that aducanumab does not meet the statutory coverage standard of 'reasonable and necessary' as the current evidence highlights numerous safety risks and uncertain clinical benefits," the Blue Cross and Blue Shield Association *echoed*.

> ***"States are simply not equipped to be the primary source of coverage for an Alzheimer's therapy of enormous cost and questionable benefit, particularly in light of Medicaid's existing role as the largest payer of long-term services and supports for the same population." – National Association of Medicaid Directors***

"We also encourage CMS to consider the long-term impact of the potential approval for this drug, and whether it could undermine the 'reasonable and necessary' Medicare coverage standard, which can have ramifications for future opportunities to develop effective treatments and for patient safety," the association added.

However, "if CMS decides to cover aducanumab, it is critical that it be covered under 'coverage with evidence development' and should target the appropriate patient population based on clinical trials."

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Stakes Are High For Medicaid Programs

Among payers, state Medicaid directors are also concerned with the Medicare coverage decision because Medicaid bears responsibility for some costs incurred by seniors who are dually eligible for both programs. Cost sharing would amount to 20% of the cost of the drug under the Medicare Part B program.

But a decision not to cover the drug in Medicare would create a worse scenario for Medicaid programs, the National Association of Medicaid Directors pointed out in *comments* to CMS. If Medicare doesn't cover Aduhelm, the burden for dually eligible beneficiaries will fall on Medicaid, which could increase total state and federal Medicaid spending on the drug by roughly 250% nationally, the group estimated.

"States are simply not equipped to be the primary source of coverage for an Alzheimer's therapy of enormous cost and questionable benefit, particularly in light of Medicaid's existing role as the largest payer of long-term services and supports for the same population," NAMD maintained.

If Medicare covers Aduhelm with evidence development requirements, CMS "should allow states the flexibility to apply the same coverage in their Medicaid programs," the group suggested. The agency could also add Aduhelm to the list of drugs subject to restricted coverage under the Medicaid Drug Rebate Program, NAMD pointed out. "This would give states the same flexibility available to other payers to scale back or pause coverage until more reliable evidence of efficacy emerges."