Accelerated Approval of Highly Expensive Disease-Modifying Agents: Lessons to Learn from the Aducanumab Approval.

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Abstract

There were many previous examples of disease-modifying expensive agents accelerated approval by The US Food and Drug Administration (FDA), which have been failed to show any clinical effectiveness in confirmatory trials in patients, subsequently withdrawn from the market. Recently on June 7th 2021, The FDA has issued an accelerated approval to a highly expensive disease-modifying agent aducanumab. In the present study, we will explore the challenges to address and lessons to learn from the approval of aducanumab another highly expensive only disease-modifying agent for Alzheimer's disease.

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Aducanumab.docx available at https://authorea.com/users/569488/articles/711717-accelerated-approval-of-highly-expensive-disease-modifying-agents-lessons-to-learn-from-the-aducanumab-approval