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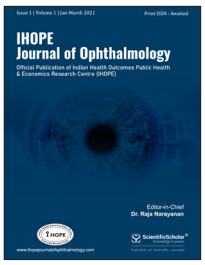

Editorial

Inflation reduction act: Would it impact Medicare's spending on anti-VEGF drugs in ophthalmology?

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Ophthalmic medications account for a significant portion of drug spending by United States public health-care agencies, with aflibercept (Eylea®), ranibizumab (Lucentis®), and bevacizumab (Avastin®), ranked 2nd ($3,013,081,886), 6th ($1,113,026,180), and 10th ($680,539,026), respectively, among the top 10 drugs purchased by Medicare Part B in 2020.[1] These drugs inhibit the actions of vascular endothelial growth factor (VEGF) in conditions that are characterized by angiogenesis (neovascular age-related macular degeneration, diabetic retinopathy, and retinal vein occlusions).[2] Aging of the U.S. population combined with a growing prevalence of metabolic syndrome promises to increase the number of elderly patients requiring intraocular anti-VEGF therapy,[3-6] and since Medicare is the primary medical insurance provider for the majority of these patients, the burgeoning cost of ophthalmic anti-VEGF therapy becomes a matter of significant public interest.

Two factors contribute significantly to the total public cost of these drugs – the inability of Medicare to negotiate drug prices and monopoly patents. Competition between drugs within the same therapeutic class should drive down prices, but evidence shows that the approval of new drugs within a class does not consistently lower prices in the United States pharmaceutical market.[7] Medicare does not currently negotiate the price of branded drugs and is prevented by law from doing so for Medicare Part D drugs,[8] thereby allowing manufacturers to set high prices for newly approved brand-name competitors without fear of any downward price pressure that might result from competition.[9] Eylea (approved in the U.S. in 2011) was priced at $1850 per dose (vs. $1950/dose for Lucentis), but neither price has changed during the subsequent 11 years.[10] Brand name drug producers may apply for multiple overlapping monopoly patents related to a single molecule, a practice known as "patent thickets,"[9] making it more difficult for competitors to introduce generic versions or biosimilars that may have lower prices. Regeneron, the developer of Eylea, has faced at least 10 legal challenges in the U.S. over its thicket of patents, all of which serve to limit the entry of competitive drugs into the market.[11] These two factors contribute to the higher prices that U.S. consumers – compared to those in other countries around the world – pay for anti-VEGF drugs.

The Inflation Reduction Act (H.R. 5376), which was signed into law on August 16, 2022, includes provisions related to tax reform, budgetary deficit reform, energy, climate change, healthcare subsidies, and prescription drug price reform. To address the high public cost attributed to pharmaceuticals, the United States Congress included a statute within the Inflation Reduction Act that allows Medicare to negotiate drug prices.[12] This requires the federal government to

negotiate the prices of selected Medicare Part B and Part D drugs beginning in 2026. The Secretary of the Department of Health and Human Services (HHS) will select drugs from among the 50 Medicare Part B drugs and the 50 Medicare Part D drugs with highest total spending for price negotiation. The Inflation Reduction Act instructs the HHS Secretary to select the "highest" ranking drugs among this subset of 100 drugs, but it remains to be seen whether the order of selection will exactly match the rank order of total spending. Additional criteria for price negotiation include (1) brand name drugs or biologics without approved generics or biosimilars and with only one seller, (2) small molecule drugs that have been approved for at least nine years, and (3) biological drugs that have been licensed for at least 13 years. The HHS Secretary may exclude drugs from price negotiation if there is a "high likelihood" that a biosimilar will be licensed prior to the time that a newly negotiated price would take effect.

In September of 2021, the U.S. Food and Drug Administration (US FDA) approved a ranibizumab biosimilar (a second biosimilar has since been approved),[13] thereby exempting Lucentis from the future price negotiation under the Inflation Reduction Act, and three biosimilars to Avastin have already been approved. Thus, of the three anti-VEGF drugs originally mentioned, only Eylea might qualify for price negotiation by Medicare. Only Medicare Part D drugs will be eligible for price negotiation in 2026 and 2027; the 15 drugs with the highest spending totals will be selected from the Part B and Part D schedules in 2028; and 20 additional Part B or Part D drugs per year will be eligible for negotiation beginning in 2029. If a biosimilar competitor to Eylea is approved before 2028, the HHS Secretary may choose to exclude Eylea from price negotiation. Several companies have already signaled their intent to seek biosimilar approval from the US FDA in 2023.

Drugs that are selected for price negotiation under the Inflation Reduction Act will have their prices to Medicare capped at a "Maximum Fair Price" (MFP), which will be defined as the lowest of: (1) A discounted version of the drug's Non-Federal Manufacturer Price (non-FAMP) in 2021, adjusted for inflation, (2) a discounted version of the drug's non-FAMP 3 years before its negotiated price is due to take effect, only applicable for 2027 onward, or (3) the Part B or Part D drug price in the year before its negotiated price is due to take effect. The non-FAMP is defined as the average drug price paid by non-federal wholesalers who distribute drugs to nonfederal purchasers.[14] Drugs that have been approved for fewer than 12 years will be discounted 25% off non-FAMP; drugs approved from 12 to 15 years will be discounted 35% off non-FAMP; and drugs approved for at least 16 years will be discounted 60% off non-FAMP. Drugs selected for price negotiation will be subject to these discounted MFPs until a generic or biosimilar is approved. The determination of MFP requires knowledge of non-FAMP but non-FAMP is proprietary market data that is not publicly available.

The Congressional Budget Office estimates that $101 billion could be saved over 10 years after implementation of the Inflation Reduction Act's Medicare drug price negotiation policy.[15] The pharmaceutical industry argues that negotiating public drug prices would reduce the incentive for innovation and slow the creation of new drugs because expected revenue would be insufficient to offset the high cost of drug development. The Congressional Budget Office, however, estimates that this new price negotiation policy would prevent development of only 15 (1.2%) of the 1300 drugs projected to be approved over the next 30 years.[15]

What does all this mean for ophthalmic pharmaceuticals? To the best of our knowledge, projected cost savings for ophthalmic drugs under this new policy have not been published, but since the top selling ophthalmic drugs either already have approved biosimilars (Lucentis) or are likely to have approved biosimilars within the next 2 years (Eylea), the Inflation Reduction Act may have minimal impact on overall Medicare spending for ophthalmic drugs within the foreseeable future.

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