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Price Controls and Competition

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The Inflation Reduction Act of 2022 (IRA), which was signed into law by President Biden on August 16, 2022, represents one of the most significant pieces of healthcare legislation passed since the Patient Protection and Affordable Care Act (ACA). The law introduces a number of sweeping changes with impact to Medicare Part D benefit design and price control mechanisms for drugs on the Medicare benefit. While these legislative changes will have ramifications across the healthcare ecosystem, they are likely to have a significant impact on manufacturers.1 The IRA includes a provision that requires the Secretary of the US Department of Health and Human Services (HHS) to negotiate prices with drug companies for a limited number of drugs covered under the Medicare Part D and Part B benefits. The Drug Price Negotiation program will only apply to single-source brand-name drugs or biologics without generic or biosimilar competition that have been on the market for more than 9 years for small-molecule drugs or more than 13 years for biologics. The program will also roll out over time, initially applying to 10 Part D drugs in 2026, another 15 Part D drugs in 2027, an additional 15 Part D and Part B drugs in 2028, and 20 more Part D and Part B drugs in 2029 and beyond. Selection of drugs for negotiation will be based on ranking in terms of Medicare Part D and Part B spending, respectively.[1,2]

This approach to select drugs for price negotiation is based primarily on the amount of Medicare spending associated with a given product. As a result, it is likely that we will have scenarios where one drug within a therapeutic area is selected for price negotiation, leading to a lower price in Medicare, while other drugs in the class are not impacted by this process. This issue could be compounded if the price negotiated for Medicare becomes the benchmark for Commercial plans as well. For Medicare, drugs selected in the formulary negotiation process are also likely to enjoy strong formulary placement.

As the formulary development and contracting dynamics for Medicare and beyond will almost certainly change, it is important for all manufacturers to have a clear and persuasive clinical and economic value story for their products or portfolios. For products impacted by the HHS Drug Price Negotiation, strong data may support the negotiation process. For products that will compete against negotiated drugs on the Part D and Part B Medicare plans, the value story must resonate to maintain or achieve optimal payer access, given the lower cost of the negotiated drug. Manufacturers should assess the risk of negotiation for direct competitors and therapeutic alternatives to their products or portfolios. Payers are facing Medicare benefit design changes that increase their cost liability as part of the IRA; thus, they are expected to seek opportunities for cost savings across benefits and may disadvantage higher-cost alternatives.

Payers can be expected to push to extract additional value through new or existing rebate contracts to achieve or maintain formulary access. Having clinical data that can provide meaningful differentiation from competing products can help manufacturers gain more leverage in negotiations and support continued patient and provider demand. Manufacturers should assess the potential to generate clinical data to support additional indications, real-world evidence to support generalizability and durability, and/or cost-effectiveness data to demonstrate value.

References:

1. Cubanski J, Neuman T, Freed M. Explaining the prescription drug provisions in the Inflation Reduction Act. KFF (Kaiser Family Foundation). January 24, 2023. Accessed February 9, 2023. https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/

2. Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: next steps in implementation for initial price applicability year 2026. January 11, 2023. Accessed February 9, 2023. https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf

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