HPR57

Evidence Demonstration Framework for Medicare Part B and D Products Subject to Inflation Reduction Act (IRA) Price Regulations

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Background

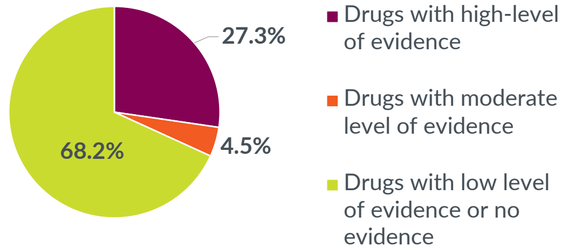
- The Inflation Reduction Act (IRA) of 2022 enacts a drug price provision that allows Medicare to negotiate prices of drugs covered under Medicare Parts B and D directly with manufactures.
- Center for Medicare & Medicaid Services (CMS) will adjust price offers based on an internal analysis of clinical benefit assessment vs. alternatives, and the extent to which the drug and therapeutic alternatives address unmet medical needs. Manufacturers will then have an opportunity to negotiate prices with CMS.
- The objective of this study was to build on ICER's Unsupported Price Increase (UPI) Framework and develop the best evidence-based approach that manufacturers can leverage to potentially negotiate prices of drugs subjected to IRA regulations.

Methods

- Using the CMS Medicare Part D and B Spending by Drug database, the top-selling drugs in Medicare parts B and D (2022) likely to be subjected to IRA regulations were identified.
- Using ICER's UPI framework from 2020 and 2021, the type, level, credibility, and quality of evidence needed to inform pricing negotiation between manufacturers and payers were derived.
- A total of 22 drugs across two years were assessed using ICER's framework to determine if these drugs reported a price increase (≥2% in WAC within the last year) that was supported by new clinical evidence (provided by manufacturers).

Results and Discussion

Figure 1: Level of evidence across drugs with increased prices (2020-2021) (N=22)



Only **27.3% of drugs that increased their price** were deemed by ICER to have **high quality supporting evidence**

- Price increases were justified solely based on high quality of evidence developed for post-launch drugs. In contrast, drugs assessed to have low- to moderate- post-launch evidence were viewed unfavorably suggesting that negotiating a price increase was not justified.

ICER's designations for level of evidence of post-launched drugs (2020-2021)

No or low level of post-launch evidence

- Small sample size of the registry
- Short follow-up
- Lack of proper control
- Allocation bias
- Potentially selective outcome reporting
- Treatment emergent adverse events
- Voluntary nature of participants
- No post-launch evidence

Moderate level post-launch evidence

- Susceptibility to bias from open-label trial design
- Irrelevance to the dosing/preparation of interest

High level post-launch evidence

- Longer overall survival rates
- Lower rates of rehospitalization compared to control arms
- Post-launch evidence for a new indication and/or patient populations

Conclusions

- Assessment of ICER's approach suggests that as IRA empowers CMS to negotiate prices with drug manufactures, it is likely to scrutinize their evidence critically, possibly resulting in much evidence deemed irrelevant or low quality.
- While this study is based on ICER's UPI reports and may not be directly applicable to price negotiations with CMS, it provides a framework to help establish a post-launch evidence strategy that can be deemed of high quality.
- To optimally drive price negotiations with CMS and commercial payers, drugs likely subject to IRA regulations will need to provide meaningful evidence beyond the product label that is of appropriate type (both economic and clinical data), quality, as well as have a high level of credibility.
- For new therapies, manufacturers will need to optimize trial designs and demonstrate the level of clinical and economic benefits (e.g., lower rates of rehospitalization, new evidence for new indication, and/or longer overall survival rates) required to minimize their risk of not attaining a favorable price or preferred formulary placement.

REFERENCES – ICER_UPI_2021_Assessment_031522.pdf; UPI_2022_National_Report_120622.pdf (icer.org)
ABBREVIATIONS – CMS: Centers for Medicare & Medicaid Services; ICER: Institute of Clinical and Economic Review; IRA: Inflation Reduction Act; UPI: Unsupported price increase; WAC: Wholesale acquisition cost

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