EBRI FAST Facts
May 1, 2025, #529

What Employers Should Know About the Inflation Reduction Act and Drug Development

The Inflation Reduction Act of 2022 (IRA) introduced the Medicare Drug Price Negotiation Program (DPNP) with the goal of lowering Medicare spending on medications. The IRA primarily targets Medicare but may have indirect implications for employment-based health plans. One aspect of the drug price negotiation program may lead to reductions in overall pharmaceutical research and development. This, in turn, may decrease the availability of new treatments for employees and their families that might otherwise have improved health outcomes, enhanced worker productivity, and lowered employer spending on health benefits.

Specifically, the IRA allows Medicare to select small-molecule drugs — usually oral medications or pills — for the DPNP as early as seven years after initial Food and Drug Administration (FDA) approval. In contrast, large-molecule drugs (i.e., biologics) — often infusible or injectable — cannot be chosen until 11 years after the first FDA approval. This difference is sometimes referred to as the "Pill Penalty."[1]

A key concern is whether the Pill Penalty disincentivizes drug manufacturers from investing in small-molecule medications. Moreover, the policy may discourage drug manufacturers from pursuing research to find *new uses* (known as follow-on indications) for existing small-molecule drugs. This type of research often occurs years after a drug's initial launch but can significantly expand its clinical value to new diseases or patient groups. For example, one-half of all small-molecule treatment options were developed as follow-on indications.[2] Understanding the real-world importance of these new uses is crucial for evaluating the potential impact of the Pill Penalty on access to drugs among workers and their families.

EBRI Research Snapshot: How Important Are New Uses for Today's Pills?

To investigate the significance of follow-on indications, MarketScan® Commercial Claims from the year 2022 were analyzed. Pharmacy data were examined for eight small-molecule drugs used to treat conditions in oncology, cardiology, and immunology. These therapies were chosen because their follow-on indications target diseases distinct from those originally approved. This allowed us the opportunity to link prescription drug fills to specific conditions using ICD-10 diagnosis codes from the patients' medical claims during the year. For one-half of our initial sample of 142,008 individuals, we were able to confidently associate the member's utilization with the drug's *initial* FDA-approved indication or one or more of its subsequently approved indications.

> ***Key Finding: Workers and their families used medicines prescribed for new uses twice as often than for their initial indication***

Follow-on research often leads to new uses for a medicine to treat different diseases, among other patient populations, or in alternative formulations than listed in the initial FDA approval. For example, post-launch

[1] See Hickey, Kevin J., Hannah-Alise Rogers, and Laura A. Wreschnig. (December 8, 2023). Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects. (CRS Report No. R47872). https://www.congress.gov/crs-product/R47872.

[2] See Partnership for Health Analytic Research. "Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines." 2023. https://advi.com/wp-content/uploads/2024/12/Implications-of-the-IRA-on-Post-Approval-Small-Molecules-2006-2012_Final.pdf.

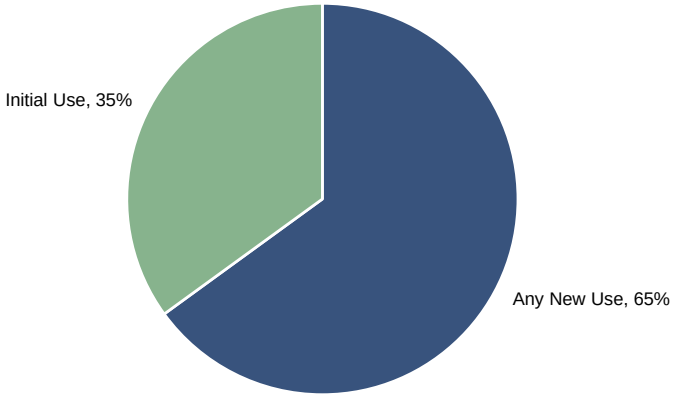
research on Xalkori,® which was initially approved only to treat non-small-cell lung cancer, led to the approval of two new uses to treat two different rare cancers, one of which was the first treatment available to children and young adults.[3]

Our research shows that small-molecule drugs used to treat conditions related to oncology, cardiology, and immunology *were used to treat patients with a follow-on indication about twice as often as for the initial indication.*

- **Initial Use:** 35 percent of utilization was associated with the drug's initially approved indication.
- **Any New Use:** 65 percent of utilization was associated with one of the drug's follow-on indications.

Approval of new uses for the sample of eight drugs in this study took as little as less than one year and as long as 13 years after the initial indication. The number of follow-on uses ranged from two to nine. These findings demonstrate that new uses for small-molecule drugs can become dominant contributors to the overall benefit to patients covered by employment-based health plans.

Figure 1
Share of Drug Utilization by Initial vs. Follow-On Indications, 2022



Source: Merative™ MarketScan® Commercial Claims Database, 2022.

Implications for Employee Health and Employers

While the goal of lowering drug costs in Medicare is important, these findings highlight potential unintended consequences of the IRA's shorter timeline for small-molecule medicines that employers should be aware of:

> ***Value of Continued Research*** **—** The data suggest that follow-on research for small-molecule medicines provides significant, real-world clinical value, expanding treatment options for employees and their families well after a drug's initial market entry.

[3] See PhRMA. "Emerging Value in Oncology: How Ongoing Research Expands the Benefits of Oncology Medicines." 2023. https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_Emerging%20Value%20Report_FIN-web_July2023_v2.pdf.

***Potential Impact on Future Oral Therapies* —** Oral medications are overwhelmingly preferred by patients for their convenience, and they also usually boast higher adherence rates.[4] But the Pill Penalty shortens the period during which drug manufacturers can earn a return on investment for these small-molecule drugs, reducing incentives for manufacturer investment in new uses that can become major shares of utilization for workers.

***Impact on Treatment Landscape* —** There could be fewer future treatment options for conditions prevalent in the work force (e.g., specific cancers, autoimmune diseases, and cardiovascular and obesity disorders). There might also be a shift toward development of specialty medications and biologics (injectables/infusions), which are usually more costly and often require employees to miss work for physician administration.

***Long-Term Benefit Strategy* —** Employers need to consider how the law might inadvertently limit the pipeline of future oral medications available through their health plans — potentially impacting employee well-being and productivity.

Follow-on indications represent a critical area of drug development that leads to FDA approvals and may eventually represent a substantial share of drug utilization among workers and their families covered by employment-based health plans. The IRA's differential timelines for the DPNP, subjecting pills to potential price setting four years sooner than biologics, reduces incentives for this vital follow-on research. Employers should monitor the policy landscape to understand how these dynamics might affect future drug availability, employee treatment options, and overall health care strategy.

This study was conducted through the EBRI Center for Research on Health Benefits Innovation (EBRI CRHBI), with the funding support of the following organizations: Aon, Blue Cross Blue Shield Association, JP Morgan Chase, and PhRMA.

[4] See Eek, Daniel, Meaghan Krohe, Iyar Mazar, Alison Horsfield, Farrah Pompilus, Rachel Friebe, and Alan L Shields. 2016. "Patient-Reported Preferences for Oral versus Intravenous Administration for the Treatment of Cancer: A Review of the Literature." *Patient Preference and Adherence* 10 (August): 1609–21. doi:10.2147/PPA.S106629. https://www.tandfonline.com/doi/full/10.2147/PPA.S106629

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