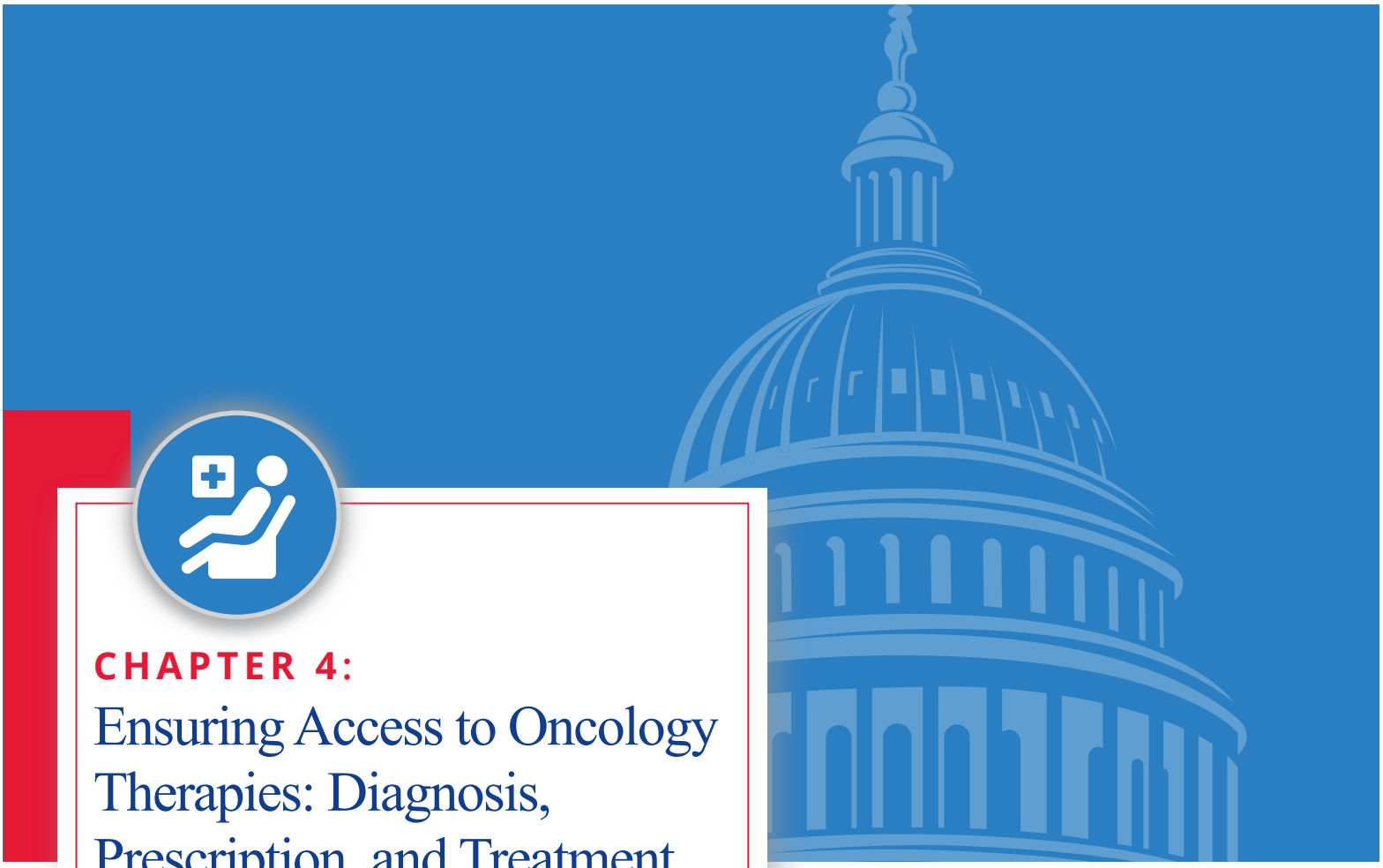

CHAPTER 4:
Ensuring Access to Oncology Therapies: Diagnosis, Prescription, and Treatment

ENSURING ACCESS TO ONCOLOGY THERAPIES: DIAGNOSIS

Trend: The oncology drug market is under immense pressure due to rising costs of innovative therapies, chronic shortages of essential GSIs, and the increasing influence of consolidated insurers/PBMs.[45] Market distortions, such as 340B and growing mandatory government rebates and discounts, contribute to higher launch prices for new products, exacerbate drug shortages, and threaten the viability of the biosimilar market intended to reduce costs. The oncology drug market is a harbinger of what other specialty drug markets now face or will face shortly.

For physician-administered therapies, the Medicare six percent add-on payment (i.e., ASP plus six percent) is essential to covering overhead, infrastructure and staff costs required to procure, store, handle, and safely administer complex oncology drugs.[46] This system has been under attack for years by policymakers. Due to sequestration, the add-on payment, in reality, is 4.3 percent and practices are not paid the full ASP plus six percent because the Medicare portion of the payment is cut by the two percent sequester. Practices rely on the add-on payment to offset otherwise unreimbursed costs that have increased significantly over time, especially since the pandemic-fueled increase in inflation of staff salaries and costs for materials.[47] [48] [49]

As noted in the physician reimbursement section above, physician payment for chemotherapy administration has essentially unchanged since 2014. Furthermore, codes for chemotherapy infusion services were established in 2005 and have not been updated since, despite significant increases in practice expense relating to these codes (e.g., electronic medical records, USP 800 compliant pharmacies, and increasing physician practice expense), payment has decreased with the other codes from the MPFS.[50] Net cost recovery from the drug reimbursement itself is no longer adequate to cover the increasing cost of administration and this will be made worse with the implementation of the IRA.[51]

Unfortunately, the IRA exacerbates these challenges and threatens the ability of independent practices to continue treating Medicare patients. This is because it ties reimbursement to the negotiated maximum fair price (MFP) plus six percent, rather than ASP plus six percent. This shift will drastically cut reimbursement to practices for Part B drugs, disproportionately impacting independent community oncology practices that do not have the drug profits from 340B and higher services payments that are available to hospitals. Furthermore, practices with in-house medically integrated dispensing pharmacies will face additional challenges from IRA Part D price negotiation due to administrative burdens and financial risk associated with retrospective MFP effectuation.[52]

There was a fundamental lack of understanding in developing the IRA that all indications of a drug, especially in cancer treatment, are not developed all at once on initial drug approval. Typically, an indication for a particular cancer is tied to a drug's initial launch, with additional indications developed and launched over time, with pediatric cancer indications developed later in a drug's lifecycle. The practical impact of this market reality is that as a drug without competition approaches the IRA negotiation point, pharmaceutical manufacturers may well stop any further research investments in the drug for additional indications. Given that pediatric indications are typically late in the drug lifecycle, the IRA could have an alarming adverse impact on the development of pediatric cancer drugs.

Independent community oncology practices are also contending with persistent shortages of essential GSIs, critical to many standard cancer treatment regimens and clinical trial protocols.[53] Persistent, unanticipated shortages compromise patient care and increase costs.[54]

In addition, the future of the biosimilar market is threatened by aggressive payer controls, restrictive formularies that favor more profitable products, and ongoing ASP price erosion.[55] Without policy adjustments to protect biosimilar pricing and ensure adequate coverage, this vital market segment risks destabilization, undermining the cost savings it was meant to deliver to patients and payers.[56]

Patient Impact: Rising drug costs, restrictive payer controls, and opaque PBM rebate practices lead to delayed treatments and higher out-of-pocket expenses for patients, forcing many to choose less effective, costlier alternatives.[57] Broader challenges, including chronic shortages of critical GSIs and the uncertain future of the biosimilars market further hinder efforts to lower costs and ensure access to high-quality cancer care.[58] Adding to these pressures is the prospect of Medicare price negotiation changes under the IRA, which will significantly reduce drug reimbursement and lead to more independent practice closures.

The Facts: Access to Cancer Care is Threatened by Medicare Drug Negotiation Under the IRA

IRA Medicare Drug Negotiation Will Slash Oncology Reimbursement

As an unintended consequence of the IRA, the erosion in ASP for negotiated drugs will lead to billions of dollars decrease in physician reimbursement for physician-administered oncology drugs, threatening the viability of independent community oncology practices.

Currently, Medicare reimburses physician-administered Part B drugs at ASP plus six percent, which is adjusted down to ASP plus 4.3 percent by sequestration. The add-on payment above the drug acquisition cost covers essential overhead costs for administering complex treatments. Because of the way that the IRA is operationalized, the add-on payment will be based on the new MFP negotiated by CMS, which will be significantly lower than the ASP, leading to steep cuts to provider reimbursements. As Medicare ASP is also tied to commercial market reimbursements, the spillover impact will compound the financial burden on providers.

An analysis by Avalere that analyzed the impact of negotiation on 10 drugs that are likely to be negotiated shows that physicians could lose at least $25 billion in add-on payments across both Medicare and the commercial market through the end of 2032 for the first 10 Part B drugs that may be negotiated under the IRA. The greatest impact will be felt by independent oncology practices that administer the four oncology/hematology drugs on the list. They are projected to see $12-19 billion in losses, which is a 39-64 percent decrease in Medicare add-on payments and a 13-21 percent reduction in commercial and MA add-on payments.[i]

Source:

i. *Sullivan, Milena, et al. "Commercial Spillover Impact of Part B Negotiations on Physicians." Avalere. 16 September 2024.* https://avalere.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

The Facts: Access to New Pediatric and Rare Cancer Drugs is Threatened by Medicare Drug Negotiation Under the IRA

IRA Implications on Treatments for Pediatric and Rare Cancers

The IRA includes two provisions that raise serious concerns for patients with pediatric and rare cancers:

1. Under the IRA, small-molecule drugs are subject to government price negotiations nine years after their Food and Drug Administration (FDA) approval date. In contrast, biologics have a 13-year window.

   At a high level, the IRA sets up a framework that reduces the period during which manufacturers of small-molecule drugs can recoup their substantial research and development (R&D) investments at market-driven prices, compressing it from what was traditionally closer to the overall length of patent exclusivity to a shorter negotiation window. For any drug developer, this shortened exclusivity period can decrease the long-term expected return on investment, influencing which drugs get researched and ultimately brought to market. For pediatric cancers—a small, specialized segment of the oncology space—this chilling effect can be pronounced.

   Pediatric cancer therapies often require additional, specialized clinical trials, which take more time and entail higher costs relative to adult trials. Drug sponsors must meet additional regulatory requirements (e.g., pediatric study plans), further extending the R&D timeline. If a company perceives that it will only have a short window to recoup investments before an MFP is established, it may deprioritize research in small-population diseases, such as rare pediatric cancers, where commercial returns are already modest relative to larger, adult indications.[i] In summary, when you shrink the time frame for return on investment, you create a disincentive to pursue smaller, riskier patient populations that urgently need new cancer and other treatments.

2. The IRA exempts certain orphan drugs used to treat only one rare disease or condition for which the only approved indication (or indications) is for such disease or condition.

   The IRA exempts certain orphan drugs used to treat only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition from the drug price negotiation program.[i] In addition, drugs with an annual Medicare cost of less than $200 million are exempt from negotiation, a provision that could shield some orphan products from negotiation. As a result, researchers may be disincentivized to pursue follow-on indications for orphan drugs, harming innovation and setting back patients.

Source:

i. Congressional Research Service. "Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects." 8 December 2023. https://crsreports.congress.gov/product/pdf/R/R47872

ENSURING ACCESS TO ONCOLOGY THERAPIES: PRESCRIPTION AND TREATMENT

The 119th Congress must address GSI drug shortages, ensure the stability of the biosimilars market, and mitigate the negative impacts of the IRA.

Address GSI Drug Shortages

- Exempt low-cost GSI drugs that are prone to be in short supply from 340B discounts, Medicaid rebates, and IRA inflation rebates.
- Change the basis of reimbursement for GSI drugs from ASP to Average Wholesale Price (AWP) as a more appropriate and stable pricing for low-cost GSIs.
- Create market incentives for manufacturers for GSIs with three or fewer active manufacturers.

Stabilize the Biosimilar Market

- Implement policies to address biosimilar pricing and coverage issues to stabilize and ensure a robust, healthy biosimilar market.
- Prohibit insurers and PBMs from restricting coverage to select biosimilars by banning the use of rebates on these products in Medicare.

Fix IRA's Unintended Consequences

- Legislate a technical fix to the IRA that removes providers and patients from the middle of price negotiations and is budget neutral by having drug manufacturers rebate the negotiated price difference directly to Medicare.
- Legislate a technical fix to the IRA to remove the MFP from ASP calculations to prevent spillover effects of MFP on non-Medicare populations.
- Address the IRA small molecule development disadvantage by extending the start time of negotiations to the same time frame as biologics.
- Incentivize pediatric cancer drug development by exempting pediatric cancer drugs from the Medicare drug price negotiations under the IRA.

Sources:

i. *Assistant Secretary for Planning and Evaluation. "ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs." 22 May 2023.* https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs

ii. *American Society of Health-System Pharmacists. "Severity and Impact of Current Drug Shortages." June/July 2023.* https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf

iii. *Bond, Amelia M, et al. "The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence from the 340B Program." Health Affairs. 1 May 2023.* https://pubmed.ncbi.nlm.nih.gov/37126754/

Preserving and Safeguarding the Role of Generics and Biosimilars in Cancer Treatment

Generic Drugs

Prescription drug shortages lead to increased costs for patients and the health care system. Drug shortages force patients to stop treatments, face delays, or receive potentially inferior treatments.[i] Generic drugs comprise most medications in shortage at any given time. A 2023 American Society of Health System Pharmacists (ASHP) analysis found that 56 percent of drugs in shortage in 2023 cost less than $1 per unit. GSIs, of particular importance in cancer treatment, represent an estimated 67 percent of shortages overall.[ii]

A fundamental challenge for generic drug manufacturers is the Medicare Part B drug reimbursement system, which is based on ASP, and also used by commercial payers. Additionally, 340B drug pricing discounts and Medicaid rebates erode drug prices, and the IRA's inflation penalty further puts downward pressure on GSI drug prices. These pressures mean, at best, there is little to no margin to invest in manufacturing upgrades, and at worst, there is no manufacturing redundancy as manufacturers leave the market, leading to shortages.

Biosimilars

Biosimilars can improve patient access to affordable cancer treatments and help prevent drug shortages. It is imperative that biosimilars are reimbursed at a fair rate to oncology practices to encourage their uptake.

Biosimilars can be a mechanism to lower drug spending in the U.S. Trastuzumab exemplifies the cost savings that biosimilars can produce. In less than three years, the prices of some of the versions of the drug declined by over 50 percent. However, due to financial incentives that make them less profitable than reference drugs, a Health Affairs study found that 340B hospital utilization of biosimilars dropped by 22.9 percent compared to other hospitals.[iii] With almost one-third of hospitals in the U.S. being 340B program participants, this has alarming implications for biosimilar uptake.

ENSURING ACCESS TO ONCOLOGY THERAPIES: ONGOING TREATMENT

The 120th Congress and beyond must incentivize domestic drug supply, address GSI drug shortages, establish payment parity for radiopharmaceuticals, and ensure diversity in clinical trials.

Incentivize Domestic Drug Supply

- Establish a quality program for manufacturers of GSI drugs that financially rewards quality and continuous drug supply by increasing payments. Conversely, penalize poor quality and gaps in drug availability.
- Provide direct financial incentives (e.g., tax incentives, incentive bonus payments) for manufacturers to produce quality GSI drugs domestically, with continuous supply.
- Use tax incentives to encourage the development of manufacturing plants in the U.S. to ensure a stable supply of GSI drugs, not dependent on other countries. ***This should be considered a national security priority.***

Address GSI Drug Shortages

- Ensure that policy solutions to address drug shortages do not put an undue burden on independent oncology practices and allow additional flexibilities for independent practices where appropriate (e.g., core standard requirements for drug purchasing).

Establish Payment Parity for Radiopharmaceuticals

- Mandate Medicare site-neutral payments for therapeutic radiopharmaceuticals. Under the HOPPS, therapeutic radiopharmaceuticals are considered a "drug" and are paid at ASP plus six percent when ASP data is available. The additional six percent is meant to reimburse for the complexity of the drugs, many of which are used to treat various types of cancer. However, radiopharmaceuticals furnished in the physician office are not paid at ASP and are instead paid by Medicare Administrative Contractors (MACs) under a variety of payment limits that vary geographically and, in the majority of MACs, are invoice-based pricing. As a result, freestanding radiation centers are most frequently paid significantly less than a HOPD and may not be able to justify offering radiopharmaceutical therapy because of the low reimbursement. This discrepancy is limiting access to care for patients with cancer in many communities.[59]

Ensure Clinical Trial Diversity

- Ensure that diverse patient groups are represented in clinical trials.
- Allow foundations to assist patients with the expenses associated with participating in clinical trials.