TRINITY

WHITE PAPER

What Is Keeping Community Oncology Providers Up at Night?

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The State of U.S. Community Oncology and Opportunity for Pharma

Community oncology practices are critical to the delivery of cancer care in the United States, treating about 80%[1,2] of patients. (~40% in community clinics and ~40% in community hospitals).

Providing top-quality care in the community setting has unique challenges, including keeping pace with the accelerating innovation in cancer care (13 novel drugs and additional 67 indication expansions approvals in 2023 alone[3]) while treating a widely diverse patient population, navigating increasingly complex non-clinical prescribing decision influencing factors (e.g., U.S. managed care organization (MCO) medical benefit management, pathways, protocols) and ensuring sustainable financial models for these mostly independent practices throughout dynamic changes.

To aid in elevating the voice of community oncology in the United States, Trinity Life Sciences recently engaged with ~50 leaders of diverse U.S. community oncology practices during the national meeting of Cornerstone Specialty Network, an organization that provides long-term, sustainable value through a collaborative network of community-based oncology practices.

This whitepaper highlights key insights from that engagement with the intent of amplifying community oncology perspectives on addressing key opportunities and the challenges and concerns they face for 2024 and beyond.

[1] Bringing Research to the Community to Reduce Cancer Disparities, https://www.cancer.gov/research/areas/disparities/chanita-hughes-halbert-clinical-trials-community-access. Accessed March 10, 2024.

[2] A Wave of New Cancer Treatments Challenges Community Oncologists to Keep Up, https://www.scientificamerican.com/article/a-wave-of-new-cancer-treatments-challenges-community-oncologists-to-keep-up/. Accessed Marck 10, 2024.

[3] Oncology Regulatory Review 2023, https://www.fda.gov/about-fda/2023-oce-annual-report/oncology-regulatory-review-2023. Accessed March 10, 2024.

Executive Summary

- **Community oncology is in the driver's seat for continuing to deliver an outsized impact on improving outcomes** for the ~80% of patients with cancer in the United States treated in community clinics and hospitals. Realizing that impact will take investment from practices themselves and support from life sciences manufacturers.
- The **top five most concerning issues** for community oncology are related to access, medical benefit management, reimbursement and practice finances according to the ~50 community practice leaders we met with.
- **Cancer care continues to become increasingly complex,** notably in ways that **community oncology practices are at various degrees of embracing,** including multi-disciplinary management in earlier settings of care, treating increasingly niche patient populations while providing care to a broad set of patients, adopting therapies requiring specific expertise/training/accreditation/infrastructure, and navigating a reimbursement landscape which puts treatment choice at risk.
- The **magnitude of benefit from novel therapies will require community practices to find opportunities** to offer these options. Adoption can be accelerated through academic partnerships, broadening the "community" knit to include surgical specialties and local hospitals, and appropriate life sciences manufacturer education and product access support.
- By primarily implementing the standard pharmacy benefit management playbook rooted in a "Stick"-based approach and hard steerage as the backbone of their medical benefit management strategy, U.S. MCOs can inappropriately and unnecessarily reduce oncologists' therapeutic options and interject unnecessary delays into patient onboarding to critical and life extending therapies.
- While rebating to U.S. MCOs has become a fairly common approach for manufacturers to manage access and achieve appropriate formulary positioning for pharmacy benefit products, paying MCO rebates on medical benefit products is significantly detrimental—not only to manufacturers but also to oncology providers. This has and will continue to disproportionally impact community oncology practices relative to integrated delivery networks (IDNs) and Health Systems, which have significantly more reimbursement influence and rates with U.S. MCOs.
- The reason behind this negative reimbursement impact is due to average selling price (ASP)+X based reimbursement established under Medicare Fee-for Service (FFS) and adopted widely by both commercial and Managed Medicare MCOs. Since all price concessions are considered in the ASP formula, all rebates paid to U.S. MCOs will drive a reduction in ASP. Accordingly, to ensure providers are not underwater on the drug reimbursement, manufacturers must incorporate additional provider discounts, further eroding ASP and reducing the MCOs ASP+X reimbursement costs even further. This pattern over time will result in the feared ASP "downward spiral" and will very likely result in shorter periods to effectively market medical benefit products. Net unit prices will erode at much faster rates than would be expected under prior pricing, reimbursement and market access structures for physician administered products with only provider contracting. This aspect of reimbursement and practice economics results in impacts that the Centers for Medicare & Medicaid Services (CMS) never intended and will further erode patient care.

2024 Community Oncology Priorities

With the backdrop of cancer care continuing to evolve rapidly, including 13 novel drugs (new medical entities or biologics) and an additional 67 approval decisions (indication expansions) approvals in 2023 alone,[4] community oncology practices are managing complex, interrelated priorities:

- Delivering top-quality patient care on-par with best-in-class institutions
- Keeping pace with the proliferation of innovation in cancer care, including new modalities and the role of systemic pharmacotherapy evolving
- Navigating non-clinical factors which increasingly influence or limit treatment options and oncologist decisions
- Ensuring sustainability of practice finances

Approximately 50 community oncology practices individually ranked each of the following 15 life sciences manufacturer-oriented priority options reflecting key 2024 issues and opportunities:

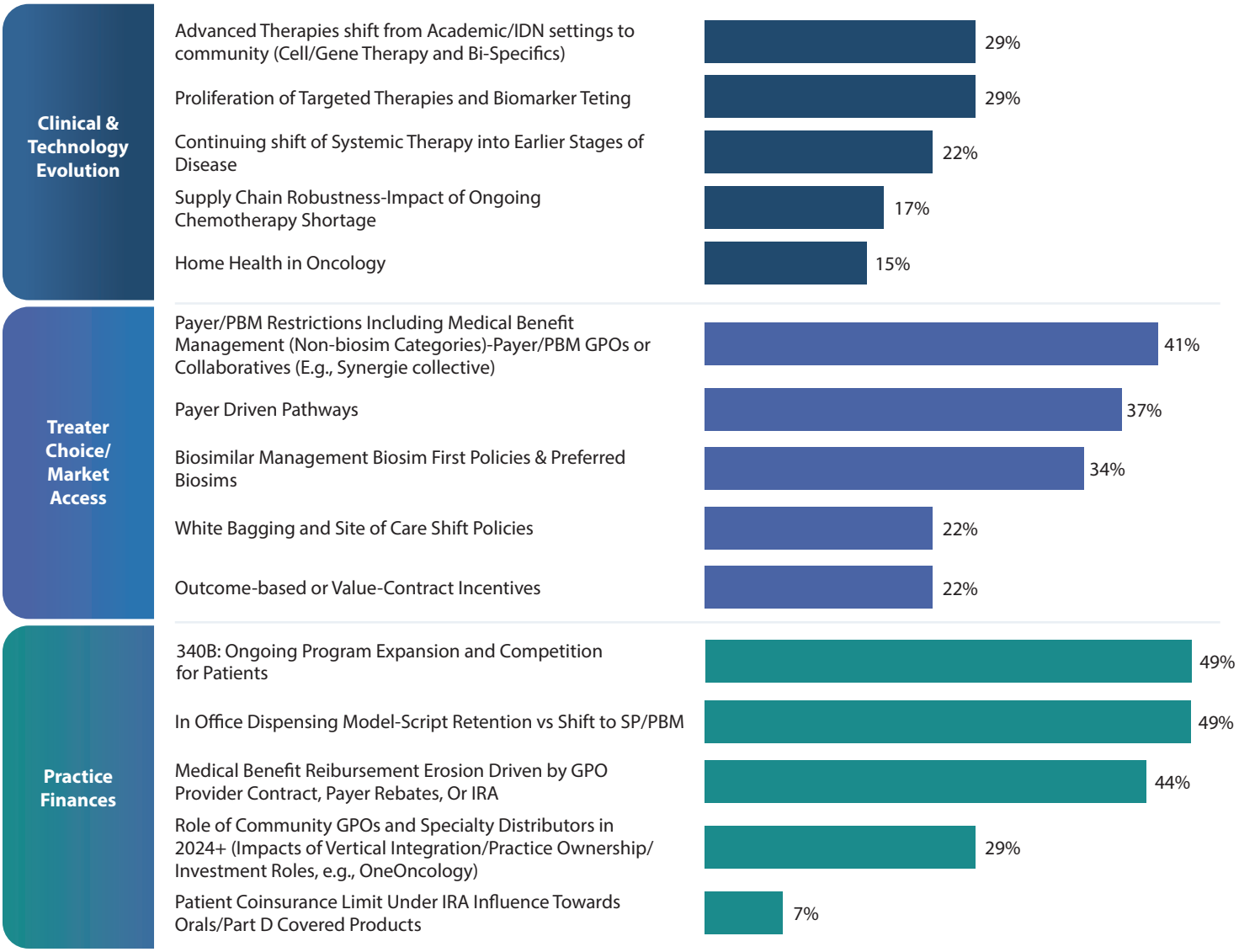

FIGURE 1 | Top U.S. Community Oncology Priorities for 2024

[4] Oncology Regulatory Review 2023, https://www.fda.gov/about-fda/2023-oce-annual-report/oncology-regulatory-review-2023. Accessed March 10, 2024.

Clinical and Technology Evolution

As the ongoing pharmacotherapy innovation in oncology is multi-faceted and complex, we focus this paper on three key themes that are tangibly impacting patient care today. These themes are actively, or soon, becoming realities for community oncology practices. Each practice will need to decide if and how to evolve given the changing paradigms in care.

Shift of Systemic Therapy to Earlier Stages of Disease

The shift towards administering systemic therapy, including more combination regimens such as chemotherapies ± PD-(L)1 immunotherapies, to earlier stages of disease in solid tumors has been shown to improve outcomes in a growing number of tumor types (e.g., non-small cell lung, triple negative breast, melanoma, urothelial, renal cell, cervical).

This treatment paradigm is considered a standard of care option in many of these tumors already (e.g., non-small cell lung, triple negative breast, renal cell), a comparatively new approach in others (e.g., cervical) and experimental in many more (e.g., endometrial, head and neck).

The impact to community oncology practices will be nuanced based on their unique current ways of working with surgeons.

> ~55% of practices expect to work with surgeons earlier in the treatment paradigm (either in a multidisciplinary team (MDT) or 1:1 setting)
>
> ~40% of practices already work closely with a surgeon and expect no change
>
> The remaining ~5% rely on surgeons to be primarily responsible for treatment decisions in early stage disease.

For the ~40% of practices expecting their working relationship with surgeons to evolve, multi-specialty practices and partnerships with surgical-focused practices and/or community hospitals are likely to continue to become more commonplace. As the standard of care for treating earlier stage disease continues to evolve to include systemic treatment earlier, community oncology will play an increasingly important role in realizing improved outcomes.

Proliferation of Targeted Therapies

Shifting focus to later stages of disease, we expect the trend of "precision oncology" and increasingly specific targeted therapies to continue showing improved outcomes. While the theme of precision oncology is not novel, it continues to manifest, including:

- **Antibody drug conjugates (ADCs)** – which are commonly approved for biomarker-specific indications or show improved efficacy in patients who more highly express the target protein
- **Biomarker-specific, tumor agnostic therapies** – including RET mutations, NTRK mutations, Microsatellite Instability Biomarker (MSI-H), Tumor Mutational Burden (TMB), and potentially HER2 if trastuzumab deruxtecan's indication expansion is successful

The challenge for community oncology practices is two-fold: [1] Logistically, what is the best approach to getting test results back in a timely and sustainable way, and [2] Clinically, how to balance the tradeoff of identifying increasing small patient populations while delivering care to a broad set of patients across many tumor types.

Logistically

To ensure both informed decision making and timely access to care, for biomarkers identified via tissue-based testing, next generation sequencing (NGS) will continue to play an important role and will be expected to continue to be facilitated through major providers (e.g., FoundationOne, Claris).

For biomarkers identified via immunohistochemistry (IHC), there is a decision for community oncology practices who do not have in-house testing facilities today: Invest an in-house laboratory (space, equipment, staff) to accelerate answers and potentially develop another revenue stream, or alternatively, continue to partner with third-party providers.

Clinically

Community oncologists are juggling the balance of increased caseload while delivering patient-specific, quality care in a complex environment with more therapeutic options available, which are optimized for smaller prevalence and more nuanced patient populations.

> "Newer targeted agents bring promising efficacy outcomes. However, this is balanced by unique safety profiles, including from ADCs (e.g., ocular toxicity and interstitial lung disease). Minimal practical experience with small molecules targeting patient populations with single digit prevalence also presents challenges, with limited opportunity for real-world adverse event management."

While we expect uptake for targeted therapies including ADCs and small molecules within the community, adoption is likely to be paced compared to academic counterparts and potentially used in later lines of therapy allowing for time for off-site biomarker testing results.

"Democratization" of Novel Therapeutic Classes

Incremental to targeted therapies, the entry and "democratization" (defined as classes being administered outside of the academic setting) of novel therapeutic classes including cell therapy, gene therapy and bi-specific antibodies is expected to be another frontier for community oncology.

The uptake of these therapies in the community will take a more measured approach given the unique preparation, administration, monitoring and adverse event profile needs. Notable highlights are summarized as follows:

- **Cell Therapy:** Practice infrastructure for sample collection (apheresis) and administration, process accreditation, ongoing manufacturer capacity questions, in-patient monitoring needs & associated adverse event management, as well as costs and navigating insurance coverage
- **Gene Therapy:** Similar challenges to cell therapy, with even more challenging accreditation and need for nuanced patient identification and selection
- **Bi-specific Antibodies:** Relatively more accessible than cell or gene therapies, although the need for monitoring (often requiring in-patient stay) and relatively novel adverse event experiences

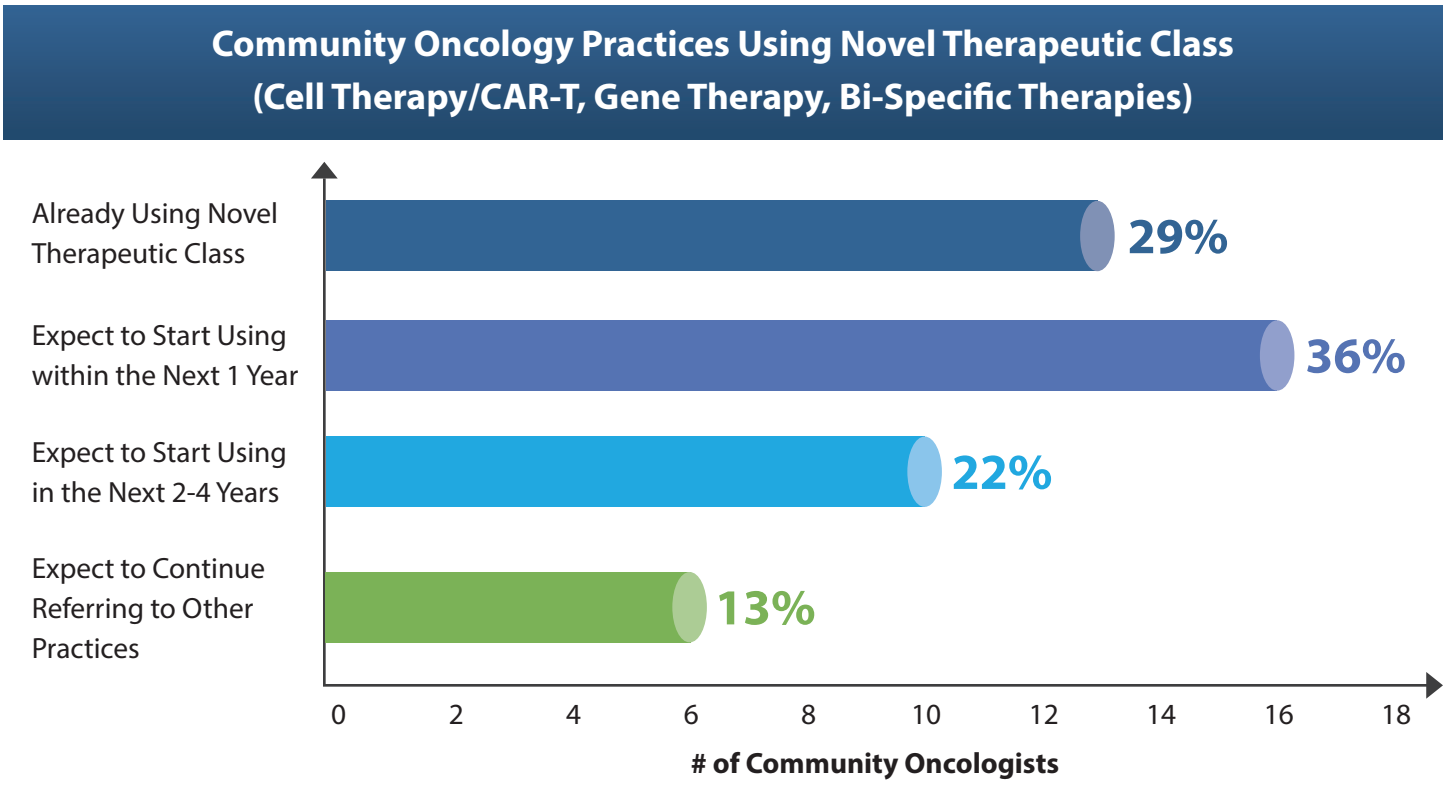

FIGURE 2 | U.S. Community Oncology Practices' Utilization of Novel Therapeutic Classes

The improved outcomes offered by novel classes is expected to carry enough importance that community practices will find it imperative to find a successful path to adoption. Adoption has the potential to be accelerated if support is provided to the community, including specific opportunities from life sciences manufacturers:

- Community collaboration with academic/IDN settings for training, adverse event management
- In-patient admission and monitoring privileges with local hospitals
- **Hands-on training and support from life sciences manufacturers** including associated help with accreditation
- **Life sciences manufacturer partnership on therapeutic accessibility**—both perspectives of therapeutic **manufacturing availability** and cost **'risk-sharing' to buffer potential payer risks** (e.g., payment delay, lack of coverage)

Treater Choice/Market Access

Future of Managed Oncology

In the historical context, U.S. Managed Care Organizations (for purposes of this paper, defined broadly as U.S. insurers, pharmacy/medical benefit managers, and "Payer group purchasing organizations (GPOs)" and "Rebate Aggregation Collectives") have had a limited role in proactive oncology treatment management. However, the future of oncology care is marked by a clearly growing intent and observable trends of MCO stratgies and tactics to extract oncology care cost savings through the control "playbook" MCOs used for many years. The playbook is intended to accomplish therapeutic preference and control as well as rebate "revenue generation"' and cost reductions in pharmacy benefit management.

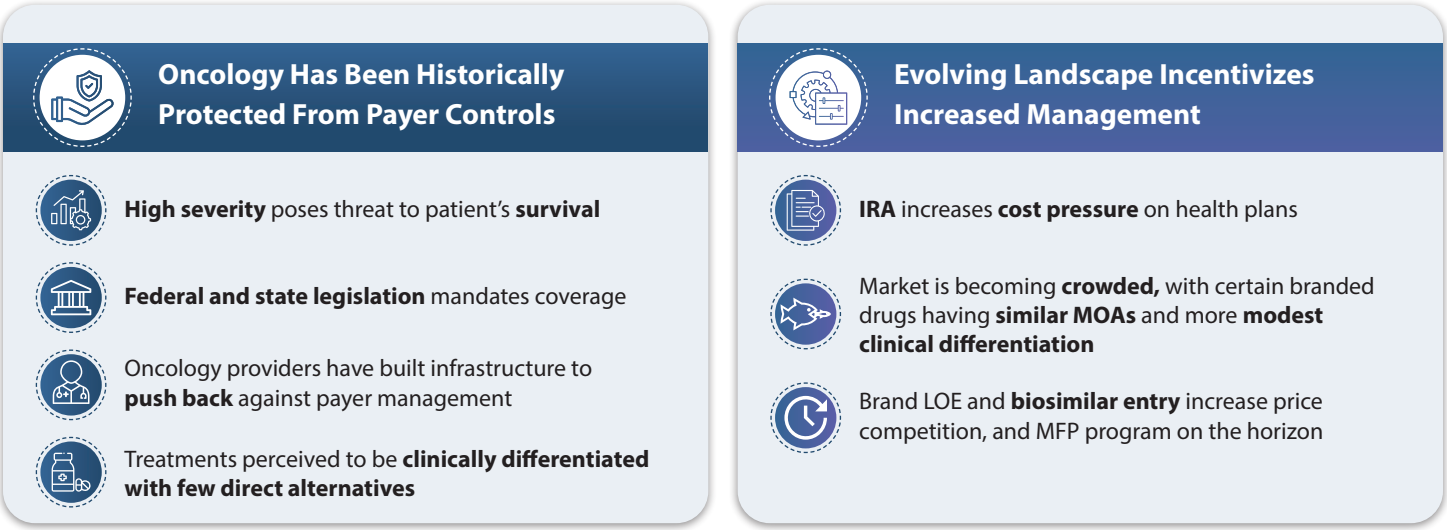

FIGURE 4 | Shifting Landscape and Increasing Payer Management in Oncology

These trends reflects a shift towards a more rigorous approach to managing oncology care, where MCOs actively seek to control costs and improve healthcare system efficiency. To be clear, these are certainly objectives the collective industry partners should strive to achieve. Healthcare cost controls and more efficient treatment paradigms are not problems in and of themselves. Further, there are certainly some product categories, indications and MOAs where product choice among a range of "clinically proximate" options, in particular biosimiars and numerous categories with "me too" approvals, should be shaped towards the more cost-effective options. That said, the key challenges, issues and concerns with respect to the accomplishment of these objectives are generally rooted less on the objective at hand, and more on the "How", the specific mechanisms and tactics deployed by the U.S. managed care environment. The vast majority of oncology management thus far has been implemented through the "Stick" model rather than the more preferred, provider friendly and flexible "Carrot" model.

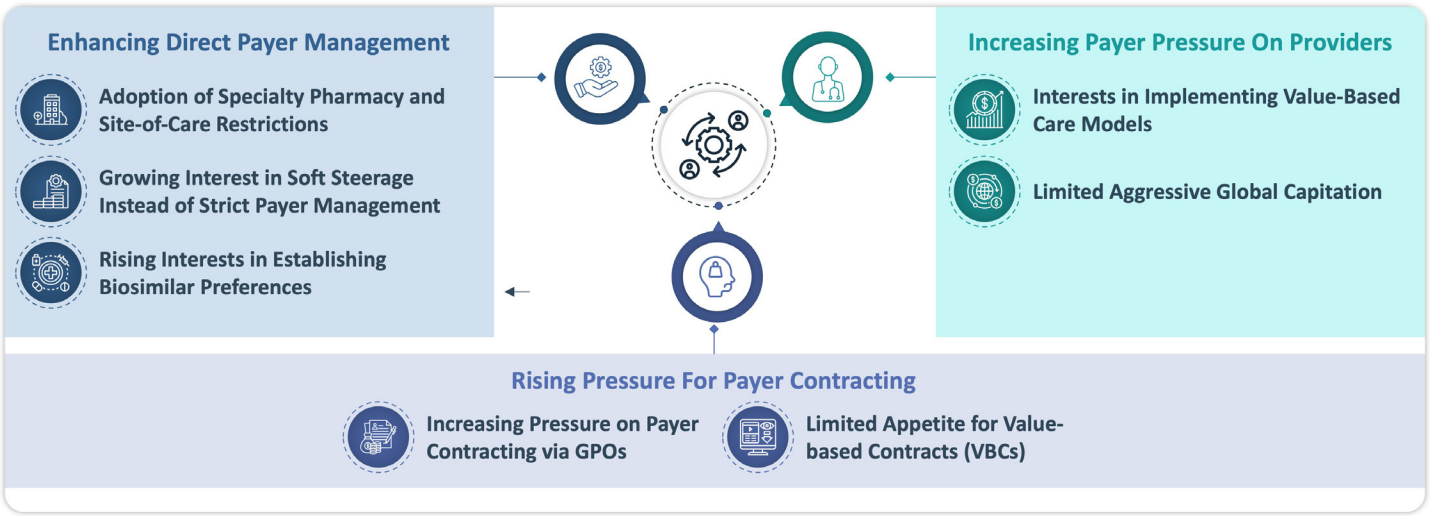

FIGURE 5 | Growing Payer Interest in Restrictions, Coupled with Pressure for Provider Contracting

Stick Model	Carrot Model
» "Mandatory rebates" to acheive formulary preference/avoid disadvantagement or blocking » Utilization management and restrictions inclusive of step edits, site of care restrictions, and specialty pharmacy shift/white-bagging/to shift physician administered products to the pharmacy benefit » Pharmacy Rx redirection to shift oral product dispensing from the practice's local or onsite pharmacy to an MCO's specialty pharmacy » "Value Based" Structures based on strict MCO Pathways, Formulary Adherence, or reduced reimbursement models	» Soft Steerage models based on enhanced Reimbursement based modeled » "Value Based" Models based on enhanced reimbursement/value benefit sharing with providers based on cost of care management across patient and time-period cohorts

While these approaches have existed for years under the pharmacy benefit, it was more uncommon under medical benefit/physician administered drugs until the last several years. Further, in oncology care where patients regularly progress through multiple lines of therapy throughout cancer treatment, the red tape and rules (which vary from MCO to MCO), can have life-impacting effects by delaying treatment or even taking certain preferred therapies off the table as oncologists work through their armementarium and protocols based on NCCN guidelines and personal/ practice experience.

The evolving landscape emphasizes the need for a clear vision of the future. Manufacturers and oncologists alike must proactively develop robust points of view on how the oncology landscape is transforming and formulate strategies and become active participants with MCOs to collectively and effectively navigate evolving market dynamics. This entails recognizing the shifting trends and challenges in payer management and HCP reimbursement for physician administered products, which are generally covered under the medical benefit ("buy and bill"), as well as for oral pharmacy benefit products dispensed through community practice dispensing pharmacies. Collectively, community practices and pharmaceutical manufacturers must engage with MCOs to actively build strategies ensuring continued emphasis for oncology patient outcomes remains the number one priority for treaters, manufacturers and managed care organizations..

As a result, this shift towards enhanced direct payer management increases MCO pressure on providers to implement value-based care models and limited aggressive global capitation, and a rising pressure for payer contracting via group purchasing organizations (GPOs) with limited interest in value-based contracts (VBCs). Ultimately, stakeholders must proactively adapt to these changes to ensure optimal patient care within managed oncology settings.

The anticipated impact of clinical and technological evolution in 2024, particularly for community oncology providers and patients, is likely to be shaped by a range of emerging payer trends. In addition to implementing direct control over products, payers are actively exploring strategies to shift risk and cost pressures onto other stakeholders, including healthcare providers and drug manufacturers. This shift suggests a broader reconfiguration of healthcare delivery, where providers and manufacturers may encounter heightened financial and operational challenges.

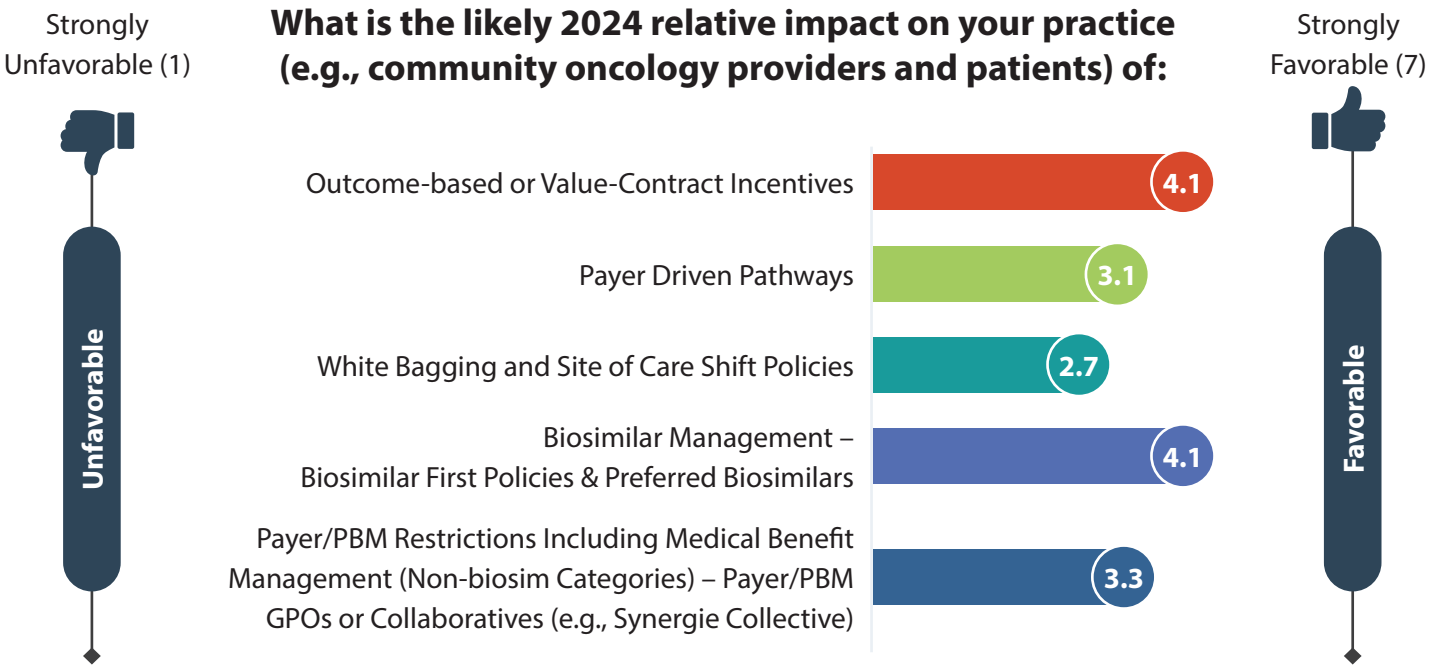

FIGURE 6 | Relative 2024 Impact of Emerging Payer Trends on Community Oncology Providers and Patients

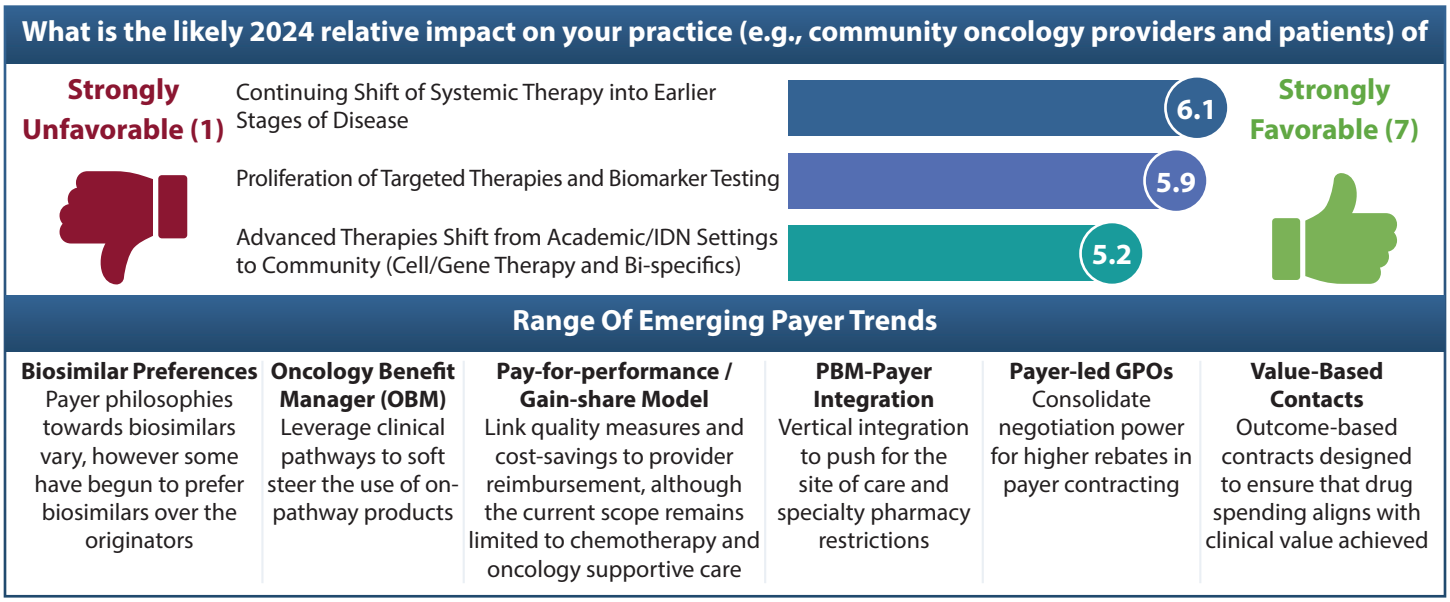

FIGURE 7 | Impact of Emerging Trends on Community Oncology Providers and Patients

Community Oncology Practice Finances

Over the past 15 years, significant transformations have reshaped the landscape of healthcare contracting. While provider-driven contracting has persisted, its scope has expanded beyond oncology supportive care environments to encompass various therapeutic classes, particularly those with emerging biosimilar competition and advancements in areas such as Immuno Oncology, Immunology, Ophthalmology, and Neurology. Furthermore, numerous therapeutic areas now confront increasing pressures from U.S. Managed Care entities, including Payers, Pharmacy Benefit Managers (PBMs), and offshore rebate aggregator organizations such as Zinc, Ascent, Emisar, and the newly launched Synergie Medication Collective by Blues/Elevance Health (formerly Anthem). These rebate pressures extend across both Medical and Pharmacy Benefit products where heightened MCO rebate demands on commercial sales are also likely to trigger Best Price and drive down Average Manufacturer Price (AMP) impacting the Medicaid program unit rebate amount (URA) and lowering the 340B pricing program unit ceiling price. In this case, the new managed care concessions have a compounding effect by also reducing realized revenues on 340B sales, which in recent years have contributed up to 50 percent of units sold for some oncology products. These shifts highlight the evolving dynamics of contracting strategies and the multifaceted challenges encountered across different segments of the healthcare system.

The evolution of medical benefit management in categories with payer engagement requires manufacturers to integrate financial and strategic considerations to optimize long-term value and opportunities effectively. This involves a delicate balance, often referred to as "threading the needle," wherein manufacturers must strategically trade-off between leveraging managed care and provider financial value to enhance product access and capture potential and realized market share.

In developing a robust contract strategy, it is crucial to base decisions on market and channel-specific insights, coupled with a deep understanding of customer preferences and behaviors. Rather than solely focusing on numerical metrics, the strategy should aim to optimize outcomes within the context of the competitive and clinical landscape. This optimization entails a nuanced approach, distinguishing between broad versus targeted strategies and tailoring contractual structures to align with customer needs and preferences. One such consideration revolves around the potential repercussions of pharmaceutical companies exclusively directing contracting efforts towards providers, potentially leading to ASP erosion and subsequent reductions in payer costs.

Key Model Assumptions (across scenarios)	
WAC Price	$1,000
Price Increases	0%
Demand Forecast	2% each quarter
Provider Assumptions	
% of Demand Sale	**Mid-Large Providers:** 60%
	340B Ceiling: 38%
	WAC Sales: 2%
Managed Care Assumptions	
% of Demand Sale	**Large MCOs:** 40%

Table 1 | Model Assumptions Across Scenarios

Contracting Scenarios Overview		
Scenario	**Mid-Large Provider Contracting**	**Payer Contracting**
Scenario 1: No Contracting	0%	0%
Scenario 2: Provider Contracting Only	4% OID	0%
Scenario 3: Provider & Payer Contracting	4% OID	8% Rebate (% off WAC)
Scenario 4: Provider & Payer Contracting w/ Escalating Provider Rebate	OID Range: 4% - 18% (Variable Provider OID to Maintain NCR above water)	0%
Scenario 5: Payer Contracting	0%	8% Rebate (% off WAC)

Table 2 | Contracting Scenarios Overview

Looking ahead, we have modeled various levels of contracting with payers and/or providers to gain insights into the potential impact on ASP, provider incentives and overall cost dynamics. The scenarios suggest that contracting with providers could naturally reduce payer costs, leading to ASP erosion. Furthermore, scenarios involving non-contracted products and payer concessions to providers shed light on the importance of provider incentives and negotiation dynamics.

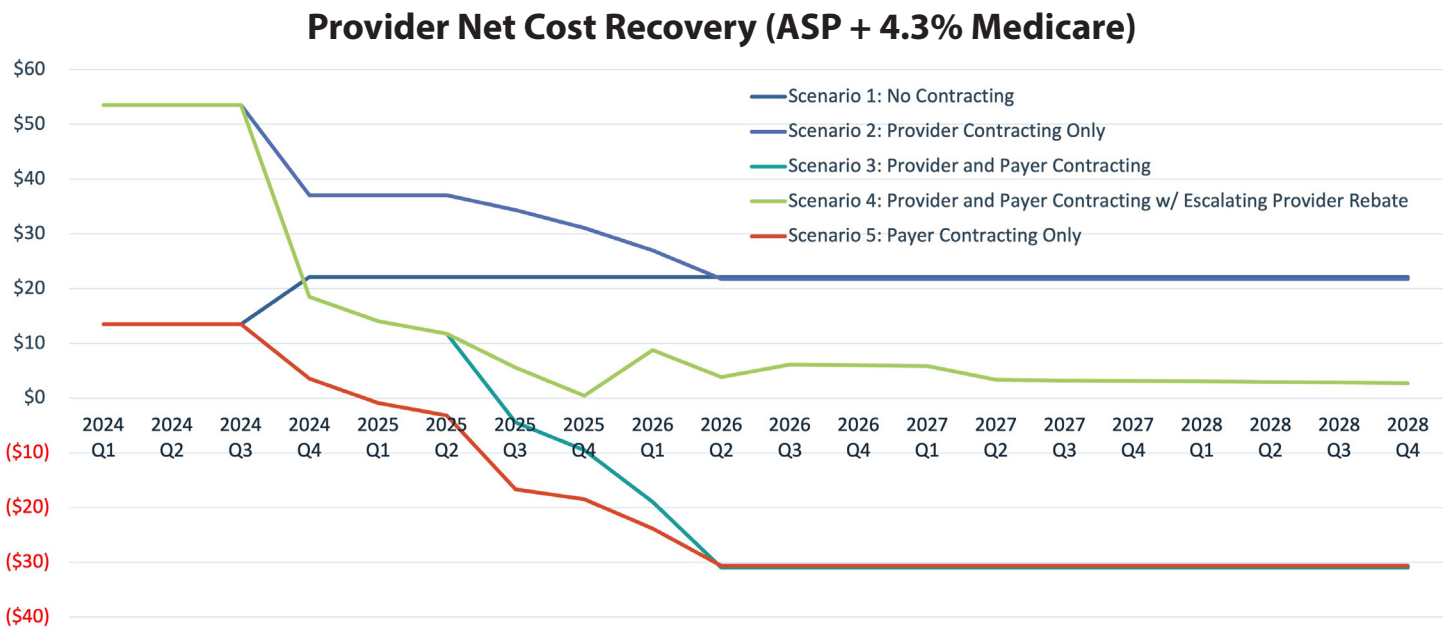

FIGURE 9 | Provider Net Cost Recovery (ASP + 4.3% Medicare)

Despite the differences in contractual arrangements and pricing structures, payers realize cost savings across all scenarios even in instances where there is no formal contracting in place. The graphical representation highlights the financial implications for payers and the cost-saving opportunities within various payer engagement strategies. By visualizing these trends, stakeholders can gain valuable insights into the evolving dynamics of reimbursement costs and the potential for optimizing payer-provider relationships to achieve mutually beneficial outcomes.

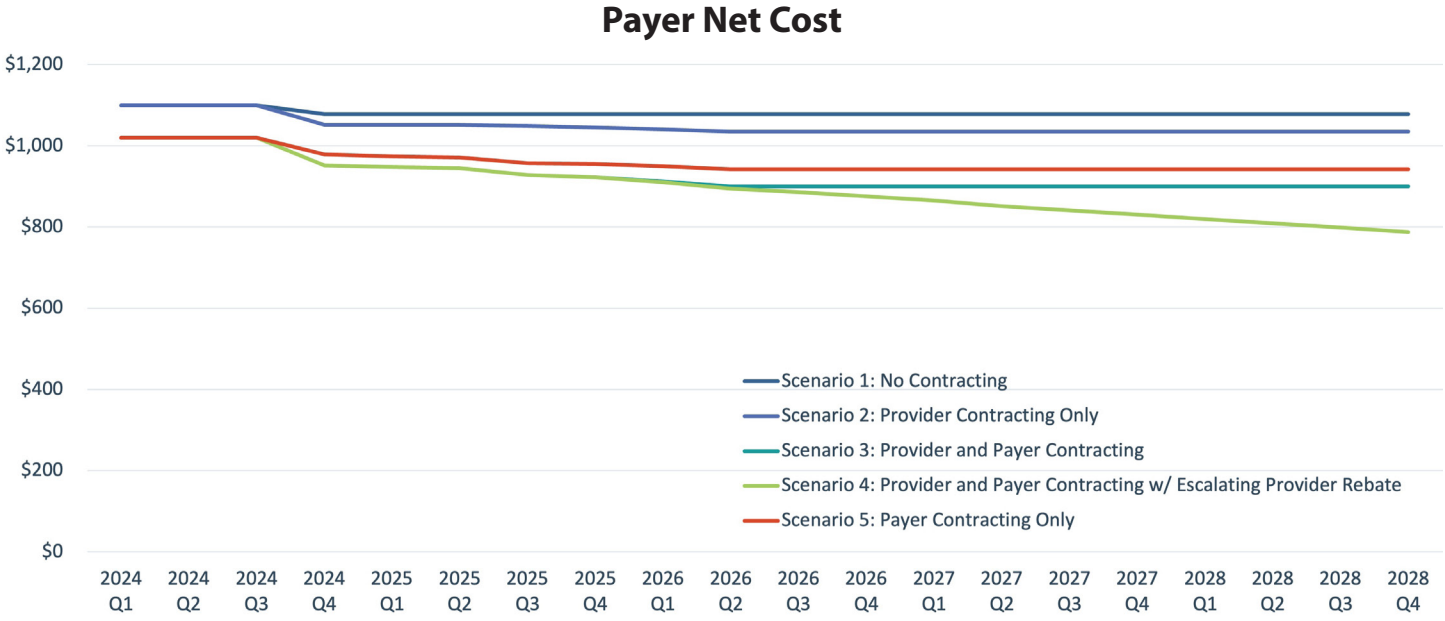

FIGURE 10 | Payer Net Cost

In analyzing the Blended Net Price Per Unit across all five scenarios, it becomes evident that erosion of ASP also impacts the 340B price. Despite the fact that the 340B pricing is excluded from ASP calculations, there are consequential effects on the net margin for commercial providers. This illustrates the complex dynamics at play within pricing structures and the interplay between payer and provider negotiations, emphasizing the importance of strategic decision-making to maintain optimal financial outcomes.

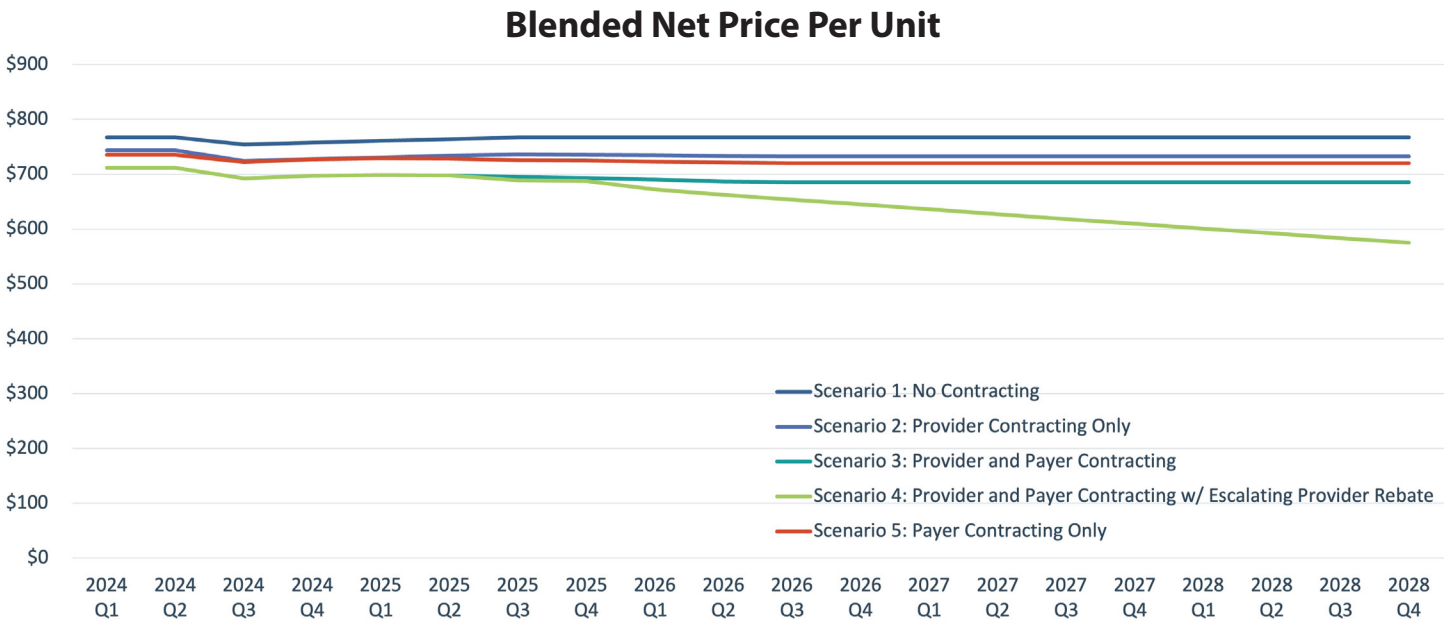

FIGURE 11 | Blended Net Price Per Unit

Ultimately, the convergence of payer and provider contracting represents a critical point where manufacturers must navigate complex trade-offs to optimize market access, value proposition and financial outcomes. By leveraging insights from modeled scenarios and adopting a strategic, customer-tailored contracting approach, manufacturers can position themselves for sustainable success in an increasingly dynamic healthcare landscape.

Conclusion

Community oncology – who treat ~80%[1,2] of patients today – will continue to play a critical role in the delivery of cancer care in the United States. Delivering that care with consistent quality, at scale, will require navigating an increasingly complex environment, of which **approximately 50 community practice leaders highlighted access, medical benefit management, reimbursement and practice finances as the top areas of concern in 2024.**

- **Access, Treater Choice & Practice Finances:** The concerning themes of 2024 include "stick"-based pharmacy benefit management strategies utilized by U.S. managed care organizations (MCOs), rebating practices to MCOs for medical benefit products, and the ASP+X reimbursement model, which threaten patient care by restricting treatment options and risking delay to therapeutic delivery
- **Clinical:** Incremental to access-related challenges, therapeutic approaches are continuing to become more complex, including multi-disciplinary care in earlier stages of disease, proliferation of targeted therapies with specific testing & logistical needs, and novel therapies with unique safety profiles and administration requirements

Ultimately, addressing these challenges will need to be through a collaborative effort across community oncology practices themselves, life sciences manufacturers, policy makers and patients. We believe that life sciences manufacturers have the opportunity to make an outsized impact by providing training & resources, certification and thoughtful product accessibility choices.

Trinity and Cornerstone Partnership, Methodology and Disclosures

- Insights in this document are sourced from Trinity Life Sciences' expertise, augmented and quantified through engagement with Cornerstone Specialty Network (CSN), an organization that provides long-term, sustainable value through an aggregated network of community-based oncology practices. Primary market research survey results are sourced from a November 2023 meeting with Cornerstone Specialty Network, of which 59 participants are represented in this paper.
- Given the nature of in-person conference data collection, total sample sizes in each question ranged from 37-46 (of the 59 total practices who provided input to any question) depending on the number of practices who were available to respond to each question.
- All content, discussion topics and interpretation are the opinion of Trinity Life Sciences and not intended to be reflective of the perspective of Cornerstone Specialty Network in part or whole.

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John has over 25 years of consulting experience and is a member of Trinity's Evidence, Value, Access, and Pricing (EVAP) practice leadership team where he focuses on US Reimbursement and Contracting. He is an expert in Provider and Payer Contracting and Access Strategy, U.S. Government Pricing, Access Analytics, Practice Economics analytics, and Scenario Planning to guide data-driven pricing and contracting decision support.

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Parker has 10+ years of experience, partnering with pharmaceutical manufacturers from emerging biotech through the largest life sciences firms. Parker is a cancer survivor, bringing a unique patient-focused lens to his work, with a personal and professional passion for Oncology. Parker's work spans across new and in-line product strategy, implementation, and operations, leveraging primary and secondary data to maximize insights & impact.

Parker holds an M.S. in Technology Management and B.A. in Economics from the University of Illinois Urbana-Champaign.

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Work has centered around U.S. reimbursement and contracting, pricing strategies, and value demonstration engagements across a broad array of therapeutic areas. Experience has spanned across commercial and HEOR roles, involving extensive engagement in primary and secondary research, real-world evidence analysis, and market access in support of strategic planning efforts.

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