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Financing and Reimbursement
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RESEARCH BRIEF

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Model Contracts for Innovative Oncology Therapies

When there is substantial uncertainty about a new product's expected value, stakeholders may have strong reasons to consider performance-based contracts. One of the hardest tasks in crafting such contracts is measuring the added value – the measurement needs to be clear but also simple to operationalize. A multi-stakeholder working group defined appropriate considerations when creating a value-based contract for new cancer therapies.

The NEWDIGS/FoCUS Oncology Multi-stakeholder working group focused on designing financial solutions to link clinical value to financial results, and drafting strategies for addressing which parties to include and which payer types to address.

While the patient is the ultimate beneficiary, we considered three main stakeholders involved in direct contracting: drug developers/manufacturers; providers, including physician organizations and hospital systems; and payers, including private insurers, government agencies and government contractors. Contracts for new cancer therapies could engage any pair or all three types at once.

There is widespread performance-based contracting between providers and payers, and some groundbreaking experience with developer-provider contracts. The multi-stakeholder working group decided to draft model contracts for developer-payer agreements, believing that the very high costs for these products would inhibit providers from taking on the financial risk, and that the larger scale offered to a payer agreement could help

KEY TAKEAWAYS

- The NEWDIGS/FoCUS Oncology Team drafted model contracts for performance-based agreements.
- Choosing the right clinical performance measures is important and can be challenging. While the specific metrics will vary across disease states and products, a few general principles hold. Metrics should be meaningful, measurable, timely, robust, accessible, forecastable and scalable.

ensure that patient numbers adequate to assess overall performance were covered by the contract. Commercial insurers acting under Medicare Advantage or managed Medicaid may also be able to engage with developers under similar agreements.

Direct government payers – Medicare and Medicaid – face significant regulatory and legislative barriers to innovative performance contracting. For example, state Medicaid budgets are set annually by legislators, so that multi-year cost accounting may require enabling legislation. Medicare is forbidden to negotiate directly with developers on price, and is legally required to cover most cancer treatments, leaving little motivation for developers to make concessions and little flexibility for Centers for Medicare and Medicaid Services.

Significant barriers also face agreements between manufacturers and commercial insurers: performance contracts could impact Average Sales Price (ASP) or lead to establishment of new and lower Best Price

determinations; third-party distributors such as PBM's could also complicate financial adjudication and data acquisition. Since these barriers may also affect government payers, the multi-stakeholder working group chose to develop models for the commercial market.

Choosing clinical performance measures is important and difficult. The multi-stakeholder working group drafted selection criteria for outcome measurement to help guide stakeholders. The criteria apply across disease states and products, and should be generally useful.

Meaningful

- Matter to patients, or strongly correlate to outcomes that matter to patients
- Strongly related to treatment effectiveness

Measurable

- Part of routine care (to avoid added cost, and ensure consistently availability)
- Clear and unambiguous results
- Outcomes relate to the added value of the product

Timely

- Outcomes likely to happen during a reasonable contract duration
- Viewed within the context of how well the endpoint can measure uncertainty

Robust

- Insensitive to potential biases, such as patient selection, interpretation of test results, availability of test results, and other confounding variables

Accessible

- Results should be accessible to both parties at no cost or a low cost
- If EMR data is required, the metric should be in structured data rather than free text

Forecastable

- Evidence supports an estimate of expected success rates and expected variation in success rates
- All parties should be able to make informed decisions about risks and rewards

Scalable

- Organizations should be able to manage multiple agreements and multiple products at once

For example, in Diffuse Large B-Cell Lymphoma (DLBCL) and Acute Lymphocytic Leukemia (ALL) treated with CAR-T cell therapies: Overall Survival at 6, 12 and 24 months would be unambiguous, meaningful, and measurable, while expected outcomes could be based on survival rates from clinical trials. Quality of life, on the other hand, though important, is not routinely measured; bone marrow transplant after CAR-T, though costly, may represent treatment failure in some patients but a deliberate therapeutic strategy in others. The multi-stakeholder working group proposed use of overall survival at 6 and 12 months as the simplest solution.

We aimed for simple and transparent metrics, because any ambiguity or disagreement could lead to disputes involving large sums between partners, and put important, long-term relationships at risk.

Even that simpler option creates challenges. About a quarter of commercial plan members change health plans each year, and even with the 6- and 12-month timeline, many patients will no longer be members of their original health plan when the outcome can be measured. Data on those ex-enrollees will no longer be available to the contracting payer. We therefore designed a model that relied only on data related to continuing members and was calibrated to have a neutral outcome if the product performed as expected. Better survival could lead to bonus payments to the developer, while lower-than-expected survival could lead to money return to the payer. Neither party would be systematically disadvantaged by lost-to-follow-up patients.

As products mature and become validated, consistent data on real world use accumulates and the expected outcomes in contracts should transition from clinical trial data to real world data. We hope performance contracts expand data collection and sharing; by enriching the available data over time, outcomes measurement and adjustments for risk factors will become more accurate and transparent.

The multi-stakeholder working group consulted experts in the regulatory environment and believes that such contracts would fall within the known Warranty Safe Harbor and/or Discounts Safe Harbor, and thus be allowable. Many regulatory and financial issues remain, of course, among them the potential for impact on 340b pricing and reimbursement, questions about whether New Technology Add-on Payment reimbursement would be applied, what settings these therapies will be administered in, and the effect of a potentially competitive market.

A FoCUS multi-stakeholder working group is working to assess the regulatory and financing barriers for government payers and ways to overcome them.

ABOUT FOCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and potentially curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement.

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