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EVOLVING PROCESSES TO MANAGE VALUE-BASED CONTRACTS

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For the past several years, the pharmaceutical industry has focused on exploring and establishing value-based contracts (VBCs) between manufacturers and their customers. In these arrangements, payments are predicated upon measurements of patient welfare, rather than formulary access, purchase volumes or market share. Yet, despite the appeal of these arrangements, many manufacturers have been reticent to adopt them, given the myriad operational challenges they pose. However, by proactively assessing their proposed contracting strategies, systematic readiness, and any downstream implications, manufacturers can mitigate potential risks while confirming and creating the operational capabilities necessary for success.

Operational Challenges

Appropriate data must be provided to measure rebate qualification successfully. By default, utilization files provided from PBMs may not contain all the necessary information to calculate achievement of value-based criteria. For example, while data files will generally contain the prescription IDs and refill numbers to track adherence, they won't contain the patient information needed to measure outcomes. Addressing this need will entail the addition of new data fields, requiring testing from technical analysts, or providing additional files, increasing strain on business analysts.

VBCs also require more robust functionality from a revenue management system (RMS). As contracting strategies have evolved over the years, so too have the platforms processing them. While most systems support tiered pricing and rebate structures, they're not always able to handle the calculation of associated performance measurements. In these cases, achievement determination happens outside the system and is manually adjusted after calculation. As many VBC strategies involve even more complex performance bases, current generation systems are often not capable of conducting the associated measurements. Exacerbating this is the volume and variability of VBC terms being utilized, making it difficult for software vendors to standardize them. Downstream data requirements for government pricing and discount reallocation can further compound these considerations.

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Recommendations

As the industry inexorably heads toward a value-based market, proactivity becomes increasingly more important. Examination of value-based contract strategies in coordination with organizational readiness, operational capabilities, system capacity, and government pricing requirements will mitigate any potential issues before they occur. Once these have all been adequately assessed, companies need to determine the appropriate steps forward to ensure the best chances of success.

Organizational Readiness

Before engaging in VBCs, manufacturers should first obtain consensus among critical stakeholders after weighing the benefits and costs. Certain types of products and business models are more easily suited to making such a transition, and entry into these arrangements does not occur without growing pains. It is also critical to obtain clinical input and ensure that data can be regularly procured, reliably managed, and that it adequately measures the intended results. Failure to do so will ultimately result in contracts that cannot be operationalized and do not achieve their ambitions. Concurrently, it is important to select an appropriate contract partner who is equally committed to providing and measuring this data. As a result, engaging in a "pilot" contract first is often advisable, prior to extending VBC terms to all contracted entities. This provides an opportunity to test the feasibility of management and potential success of these arrangements with a limited amount of risk.

Operational Capabilities

When performance terms are proposed for earning a rebate, it is critical to ensure that they can be effectively operationalized. A methodology for how the metric is determined should be agreed upon by both parties to prevent any disparities in calculation from occurring. Once this methodology is ascertained, it is imperative to include the data fields and level of detail required for calculation within the contract. By achieving consensus on the performance basis and required formula data, manufacturers and their customers can safeguard against disputes when claims are processed.

System Capacity

Performing an assessment of RMS capabilities will quantify the types of deal structures that can be supported within the current system landscape. This can then guide contract negotiations to determine the arrangements that can be pursued without concern for operational readiness. Having reviews of proposed contract terms with operations and government pricing team members will further help to ensure that agreements are successful. As many systems lack the ability to manage and calculate more complex contracting terms, manual workarounds often need to be established to bridge the gaps. Ensuring that this appraisal occurs proactively will circumvent any system shortcomings in a more effective and sustainable manner.

Government Pricing Requirements

Given the downstream impacts of setting a new best price (BP), taking precautions to prevent it from occurring inadvertently through a VBC is advisable. Since Medicare utilization is excluded from BP calculations, partitioning VBCs to this channel, and precluding them from commercial managed care contracts, will prevent them from setting BP by default. As an additional means of control, avoiding lump sum payments and variable payment ratios on VBCs can reduce the risk of breaching BP. By setting reimbursement rates as a fixed, or tiered, percentage of revenue, the per-unit cost can be determined ahead of time; this can also prevent discounts from needing to be reallocated.

In cases where these measures are not feasible, payment caps can be a reliable method for controlling price points on agreements. In this case, even if the contract theoretically set a new BP, it would not be used in the formula after the cap was exercised. Finally, the usage of "clawback" provisions, wherein reimbursed funds are recouped up to the threshold of BP, can help to mitigate the impact of VBCs when rates vary unexpectedly.

Conclusion

Despite the challenges imposed by existing legislation, the pharmaceutical industry continues to explore more innovative and value-based agreements. Failing to evaluate these terms properly can overburden resources, decrease profitability, and breach compliance with government regulations. Conversely, resisting adoption of these novel contracting strategies can mean losing out on market share in favor of competitors. Manufacturers, therefore, are best served by thoroughly assessing the various strategies, their operational readiness, and legal assumptions, to ensure a seamless, informed, and successful transition into a new contracting landscape.