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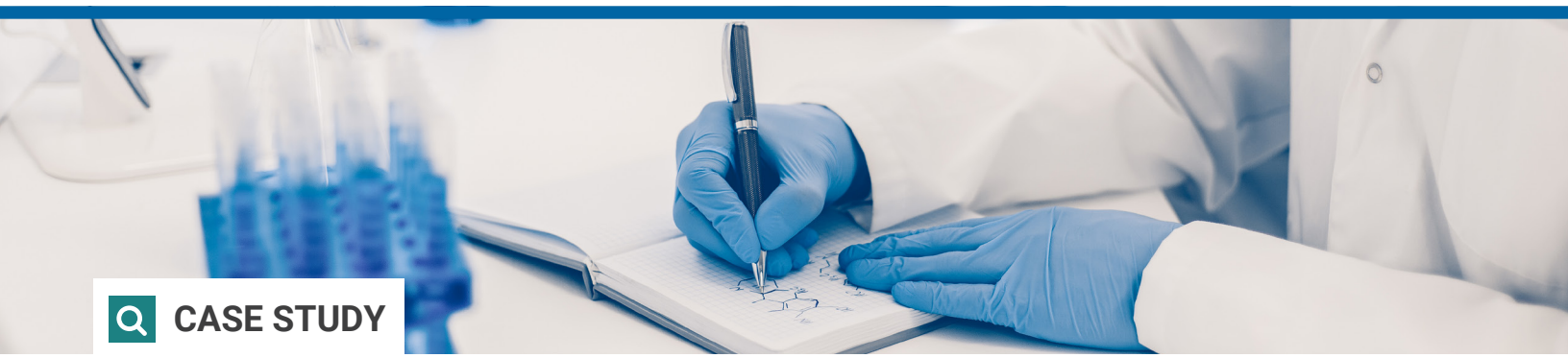

CASE STUDY

Helping life science manufacturers navigate Medicare payment systems

THE CLIENT

A life sciences manufacturer was seeking approval for a new formulation of an existing drug and needed to better understand reimbursement issues facing this new formulation under Part B of the Medicare program.

BACKGROUND

The HMA Medicare team was asked to apply our subject matter expertise—and access to Medicare claims information—to provide a fully formed picture of the reimbursement process for this new drug formulation. Our work involved researching other precedents and the implications of those precedents for the reimbursement of this new formulation, as well as the existing product.

APPROACH

HMA's Medicare team has significant expertise in helping life sciences manufacturers understand and address the policy challenges affecting market access of new drugs and biologics. A key aspect of the Medicare's team's expertise is their ability to understand how various policies interact, causing unexpected outcomes. For this client, we helped educate various internal stakeholders on the pricing implications for their new formulation—and its legal and regulatory issues that could cause the pricing for their new product to be blended with the prior version of the product, potentially creating access problems because of the required higher numbers of units for the new formulation. Our work was aided by research into local coverage documents by Medicare administrative contractors—and analysis of claims data to provide evidence for the hypothesis that coverage for the new formulation could be available under Medicare Part B's coverage of physician services, even though the prior formulation is covered under the pharmacy benefit.

RESULTS

Conventional wisdom in product development teams often paints an incorrect and outdated picture of the policy environment. HMA's expert consultants can provide appropriate context to aid these teams in their planning as new products get closer to market, because of their work to monitor and understand up-to-the-minute changes to the policy landscape. Some reimbursement challenges can be mitigated or eliminated if they are addressed early enough in the development process for new technologies. Once certain approval pathways are set, it may no longer be possible for manufacturers to avoid a link between the prices of different formulations of a drug.

The HMA Medicare team was able to educate the client about Medicare's intricate reimbursement rules, where the same drug, but a different formulation may be reimbursed under different rules. Rather than focusing on the various reimbursement silos, we provided a holistic view of the drug reimbursement landscape, so the client was able to understand that factors such as how many patients are able to self-administer the drug will affect the ultimate reimbursement for both the new and old formulation.

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