

The Drug Warranty and the Rise of Value Based Reimbursement



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The concept of a drug warranty is gaining traction in the marketplace of specialty pharmaceuticals and gene therapies.

In January of this year, Sanofi announced a therapeutic warranty program for Cablivi, a novel treatment for a rare blood-clotting disorder called acquired Thrombotic Thrombocytopenic Purpura (aTTP) in adults. Under the program Sanofi will refund up to six inpatient doses of Cablivi for patients who fail to reach initial clinical response in a hospital, or up to 12 inpatient doses for patients who exacerbate while on treatment. According to OptumRx, Cablivi can cost up to an estimated \$270,000 for treating a typical episode. Similarly, in June, BioMarin announced an outcomes-based warranty that will reimburse payers up to 100% of the cost of its newly approved gene therapy, Roctavian, for the treatment of severe Hemophilia A if a patient does not respond to therapy. The wholesale acquisition cost of Roctavian is approximately \$2.9 million based on the weight of a typical patient.

The emergence of these and other warranty programs reflect the growing reality that, as the cost of therapeutics substantially increase, true payers – self-insured employer groups, traditional health insurance companies, and public plans footing the bill – are no longer willing to fully assume the risk of therapeutic failure. They are demanding that manufacturers share this risk and underwrite the tangible benefits of their pharmaceuticals in the form of a performance-based guarantee. If true payers are going to authorize payment for a multimillion-dollar therapy, they

understandably want to be financially compensated either in part or whole when that therapy does not deliver on the intended outcome in their beneficiary. The days of expecting payers to just absorb the cost of multimillion-dollar therapies are fast coming to an end. As dozens of ultra-high-cost therapies are expected to be approved over the next several years, impacting tens of thousands of patients, pushback from the payer community will only increase and the need for manufacturers to provide recourse is becoming mandatory.

The warranty construct is a simple and efficient mechanism that pharmaceutical manufacturers can utilize to allay payer concerns, share risk, and stand by their products. In simple terms, a drug warranty is an insurance instrument paid for by the manufacturer that spreads risk over the entire treatment population and guarantees a particular clinical or health outcome associated with therapy. If that outcome is not achieved in any patient during a prespecified time, then the instrument compensates the payer for all or a portion of its cost.

Unlike value-based agreements and outcomes-based contracts, warranties do not need to be negotiated individually with payers and their payouts are not held against CMS Best Price, which facilitates their ability to provide payers with real, meaningful payouts, sometimes up to the entire cost of therapy. There is no need to calculate multiple best prices, which reduces logistical complexity, and, because the warranty accompanies each sale, all payers receive the benefit, not just those with the largest scale and greatest bargaining power, enhancing the likelihood that more payers authorize its use, potentially expanding access to more patients.

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Increases Patient Access and Drives Adoption

While pharmaceutical manufacturers will have to pay a fair market premium for their therapeutic warranties, these instruments should not be viewed solely as a cost of commercialization, but rather as a strategic tool that can enhance the overall value proposition of their therapeutic assets. The costs associated with offering a meaningful warranty will be more than offset by an increase in patient access and adoption. In a survey we conducted with our partners at Oliver Wyman, payers told us that they would choose to use a therapy that came with a warranty versus a competing drug that did not, all else being equal in terms of safety, efficacy, ease of administration, etc. Payers will tend to favor a therapy accompanied by a warranty because it provides affirmation to the market that it will deliver on its clinical objective and, even if it does not, provides financial recourse to recapture cost that can be redeployed to their other beneficiaries.

The potential of a warranty to influence consumer perceptions of quality and shift sales is a well-documented phenomenon, particularly for novel products. One need only look to the many business school case studies that have been written about Hyundai's 10-year, 100,000 mile warranty to recognize the strategic use of performance guarantees on impacting buyer behavior and gaining market share. In the world of pharmaceuticals this effect would not only influence uptake and penetration rates, but may also diminish prior authorization times and facilitate more expedient recognition of revenue.

In the world of gene therapies, since current viral vector delivery technologies permit only one chance at receiving such therapy, providers, patients, and their families will be highly discerning when selecting which potentially life altering therapy a patient should receive. A drug warranty may very well be the distinguishing feature that allows one manufacturer to capture the market before the competition. However, in a non-competitive market or even beyond the realm of gene therapy, accelerating the administration of potentially life altering treatment is a better outcome for patients and recognizing revenue sooner is a consequence that no pharmaceutical manufacturer will rebuff. The potential for expanded market share and accelerated sales may even offset the cost of the warranty program itself, which can render the entire proposition of a warranty program cost neutral. The benefits of a drug warranty program also need not be limited to ultra-high cost therapeutics. Any therapeutic – such as one coming off patent where there is a desire to maintain market share and premium pricing in the face of generic competition or a newly approved branded therapeutic looking to break into a highly competitive market – can utilize a therapeutic warranty to influence payer behavior to maintain or enhance market share.

In short, drug warranties are a unique instrument that can be strategically deployed in a number of commercial use cases. While they will become essential for ultra-high cost therapies where payers are increasingly refusing to shoulder the full risk of therapeutic inefficacy, they will also be an invaluable tool to differentiate similar products in competitive markets and establish an overall superior value proposition.

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