



Market Access POV: Warranty Contracts



EXECUTIVE SUMMARY

Warranty contracts are an emerging form of value-based agreement that reimburse payers for the cost of failed treatments, reduce data aggregation complexity, and mitigate Medicaid Best Price (MBP) exposure.

Due to administration fees and premium costs, warranty contracts are best suited for products with efficiency uncertainty and high cost, particularly those that have received accelerated approval from the FDA and lack real-world data. Warranty contracts could also be utilized for products with multiple competitors to achieve looser utilization management or better formulary placement.

What is a Warranty Contract?

Warranty contracts are an emerging form of value-based agreement that reimburse payers for the cost of failed treatments. The key distinction between warranty contracts and other types of value-based agreements lies in their **administration by a third party**, which often acts as an insurer and is regulated by state insurance departments.

STRUCTURE

Third-Party Administrator



Sponsored Captive

- Separates the financial risk (capital and premiums) associated with the warranty
- Acts as an administrative entity and provides services such as warranty policy underwriting, claims adjudication, accounting, audit, and actuarial analysis



Incorporated Cell

- One sponsored captive could establish multiple cells with each containing the risk associated with a single manufacturer
- A single cell has no impact on the other cells or the sponsored captive



Manufacturer

- Sets aside risk capital reserves in the incorporated cell to help fund warranty claims
- Pays an administrative fee and a warranty premium to the third-party administrator based on the duration and complexity of the contract as well as the claims, which address the uncertainty of the drug's future performance and the amount to be paid if the medicine underperforms

Why Use a Warranty Contract?

Warranty contracts address efficacy uncertainty, reduce data aggregation complexity, and mitigate Medicaid Best Price exposure.

Address Efficacy Uncertainty

Warranty contracts ensure payers pay for efficacy and return payers' cost if the therapy fails to meet predefined criteria.

Reduce Data Aggregation Complexity

Warranty contracts standardize administrative and operations structure regardless of the type of therapy under the warranty. The third-party administrator performs data aggregation and claim evaluation, alleviating the burden on the manufacturer and the payer.

Mitigates Medicaid Best Price Exposure

Under Medicaid Best Price regulations, manufacturers are obligated to offer the lowest price to Medicaid. Therefore, if a manufacturer enters into an agreement with a payer and provides reimbursement for the failed treatment, that reimbursement, seen as a rebate, must be applied to all Medicaid payers as well.

However, since the warranty contract is administered by a third party, the reimbursement does not qualify as a rebate and avoids triggering the Best Price regulations.



...the benefits paid by the third party in the event the drug did not meet certain clinical, or performance measures are exempt from 'best price' because payments made from the third party to the payer do not represent a price available from the manufacturer to any best price eligible ...

– CMS



Who Uses Warranty Contracts?

Due to administration fees and premium costs, warranty contracts are best suited for **products with efficiency uncertainty and high cost**, particularly those that have received accelerated approval from the FDA and lack real-world data. Warranty contracts could also be utilized for **products with multiple competitors** to achieve looser utilization management or better formulary placement.

Real-World Examples of Warranty Contracts

DRUG	COMPANY	INDICATIONS	WARRANTY PROGRAM DETAILS	THIRD-PARTY ADMINISTRATOR
Xalkori	Pfizer	Metastatic Non-Small Cell Lung Cancer	<ul style="list-style-type: none"> • First product using a warranty contract in 2021 • Refunds the entire cost to any patient and health plan for ineffective treatment within the first three months 	AIG Claims, Inc.
Panzyga	Pfizer	Primary Humoral Immunodeficiency	<ul style="list-style-type: none"> • Refunds patients and commercial health plans for up to four treatments of the drug if it is “discontinued by the patient’s healthcare provider for clinical reasons” 	AIG Claims, Inc.
Cablivi	Sanofi	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)	<ul style="list-style-type: none"> • Refund is triggered based on individual clinical outcomes on platelet count • Refunds the cost of six doses for ineffective treatment and up to 12 for worsening symptoms while receiving treatment • Refunds will consider the cheaper option between wholesale acquisition cost (WAC) and actual acquisition cost 	AIG Claims, Inc.
Zynteglo	Bluebird Bio	Adult and Pediatric Patients with β -Thalassemia who require regular red blood cell (RBC) transfusions	<ul style="list-style-type: none"> • Bluebird will reimburse contracted commercial and government payers up to 80% of the cost of the therapy if a patient fails to achieve and maintain transfusion independence up to two years following infusion 	Real Endpoints
Talicia	Redhill Biopharma	Helicobacter Pylori	<ul style="list-style-type: none"> • Reimburse the patient and commercial health plan if the patient completed a full 14-day treatment course and infection is not eradicated based on post-treatment confirmation testing 	Truveris

Third Party Administrators Offering Warranty Contracts

OutcomeRx	<ul style="list-style-type: none">• Provides first-warranty offerings for biopharmaceuticals including cell and gene therapies• Warranty coverage includes costs for alternative therapies, hospitalizations, and other medical expenses associated with therapy inefficacy
AIG Claims, Inc.	<ul style="list-style-type: none">• Provides claims administration for Pfizer Pledge™ Warranty Program that include Xalkori and Panzyga• Provides claims administration for Sanofi's Cablivi Warranty Contract
Truveris	<ul style="list-style-type: none">• Provides claims administration for Redhill Biopharma's Talicia Warranty Program
Real Endpoints	<ul style="list-style-type: none">• Aggregates mid-sized and smaller health plans and provides them with access to innovative treatment through value-base contracts• Provides claims administration for Bluebird Bio's ZYNTGLO Warranty Program through RE marketplace
Marsh LLC Octaviant Financial Inc. Partnership	<ul style="list-style-type: none">• Launched In May 2023 to offer a warranty program to pharmaceutical manufacturers that develop gene, cell and specialty therapies



Valuate Insight

Competitors from other sectors are entering the warranty contracts market. We expect to see an increasing number of warranty contracts being issued in the next few years.

Warranty Contract Limitations

Warranty contracts face patient mobility challenges and rely on clear definitions of covered claims and efficacy endpoints to reduce adjudication subjectivity.

Patient Mobility	
Challenges	<ul style="list-style-type: none"> • Difficulties in tracking patient mobility • First payer bearing the costs for later payors • Overlooked refunds due to data not reporting back to the original payer
Possible Measures for Third-Party Administrators to Follow Patients and Track Outcomes	<ul style="list-style-type: none"> • Medical and pharmacy claim data • Patient and provider surveys • Self-reported information from both patients and providers • Medical records with pre-acquired consent from the patients <p>Note: These steps may create additional administrative burdens for patients and providers</p>

Efficacy Endpoint Selection	
Challenges	<ul style="list-style-type: none"> • Requires clear definition of covered claims for reimbursement • Relies on clear, easily identifiable and measurable metrics to confirm therapeutic failure • Potential barrier for providers and patients in preparing required documentation to file claims • Potential data privacy concerns to share clinical endpoints
Clinical Measures vs. Claim-Based Measures in Defining Efficacy	<ul style="list-style-type: none"> • Clinical measures can be difficult to track if they require new data infrastructure and pose an additional administrative burden on providers and other stakeholders • Claim-based measures are easier to track because they leverage information that plans and PBMs already gather but do not reflect clinical benefits



Value Insight

The pharmaceutical industry is searching for effective and practical measures to determine value in warranty contracts. They are seeking meaningful and measurable patient outcomes and contracts are easy to execute with low administrative burden.

Work with Valuate Health to Find an Innovative Contracting Solution



Our seasoned team has extensive experience working with payers and all access decision makers



Valuate fosters direct relationships with more than 1,200 market access customers to power market research and insights



We leverage our advanced analytics expertise to enhance your pull-through capabilities, HEOR messaging, and more



Valuate can help you design successful warranty contracts with meaningful patient outcomes that are simple and easy to execute

Thank You



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