Life Sciences | eBook

Making outcome-based **pricing initiatives add up** in the healthcare industry

info@vistex.com | www.vistex.com

Vistex®
Now it all adds up®

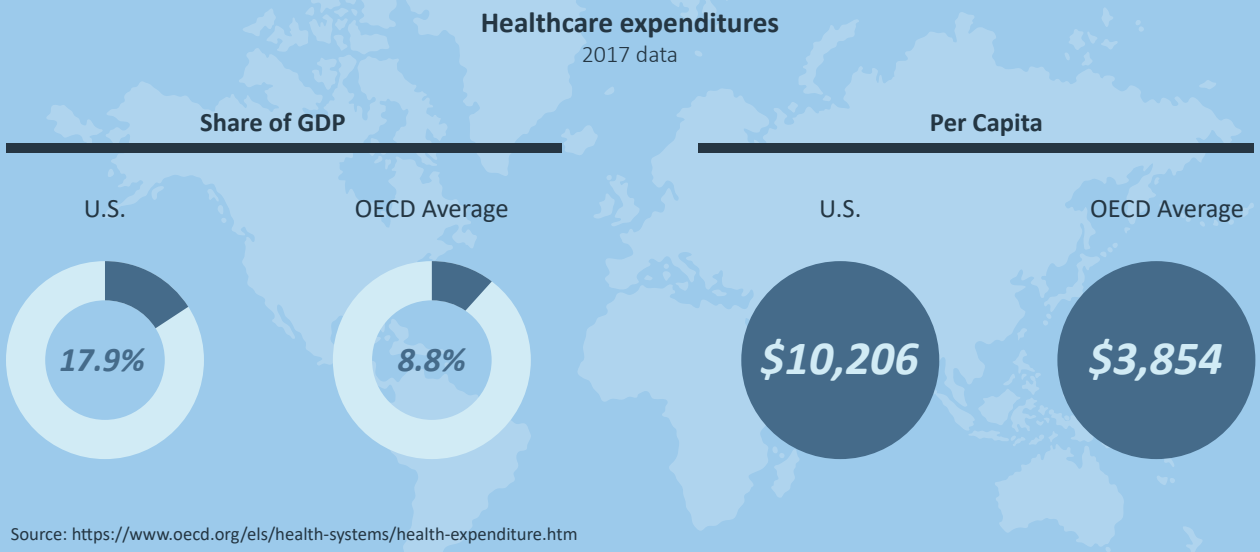
Does outcome-based pricing add up to a cure for an ailing healthcare industry?

A distorted reimbursement model has driven healthcare costs ever higher, and elevated healthcare spending to the top budget item for many governments across the globe. But several major industry players have begun to experiment with outcome-based pricing models as an innovative approach to aligning reimbursements more closely with positive outcomes, while simultaneously bringing greater stability and predictability to pricing in the Life Sciences industry.

This eBook evaluates the current state of reimbursement models, the adjustments that need to be considered, and methods for reform. This eBook also offers practical alternatives for both outcome-based pricing and payment methods, for all stakeholders in the value chain.

Contents

Vistex®



Source: https://www.oecd.org/els/health-systems/health-expenditure.htm

Global healthcare spending has risen steadily over the last decade. The U.S. government dedicated close to 18% of GDP to healthcare in 2017; unfortunately, increased spending has not had a significant impact on outcomes. The U.S. was ranked 35th in the Bloomberg 2017 Healthiest Country Index.

The rising cost of healthcare is placing increasing pressure on the entire healthcare delivery chain, including providers, payers, producers, and patients. In a recent Biopharma poll, more than 80% of healthcare executives identified pricing as the industry's most pressing issue.

Healthcare Players: Drug Makers, Healthcare Providers, Insurance

Drug manufacturers seek to provide drugs and products with the highest level of efficacy, while maximizing shareholder value, despite R&D investment of billions of dollars over many years. The primary goal of the drug manufacturer is clear: to ensure that their drugs provide the highest value at a price that is representative of the benefit to the patient, provider, and payer. This is not an easy process, but by aligning therapeutic outcomes with reimbursements, manufacturers may have found a way to ensure patients get access to new therapies.

Providers work with patients to identify their respective disease states and ascertain treatment protocols to improve patient health as quickly and cost effectively as possible. They administer treatments and are held accountable for patient care, but are also potentially liable for ineffective or poor-quality treatments that lead to readmissions. Plus, they leverage effective treatment protocols to help control or reduce their costs by reducing the length of the hospital stay.

Payers dispense vast sums of money for drugs and care coverage, which are designed to improve patients' quality of life and return them to their productive selves. However, payers have little or no visibility into the true effectiveness of the treatment. They finance treatments based on submitted data that, historically, has shown about a 50-60% chance of a positive health outcome.

When your drug prices don't add up to favorable results, it's time to consider outcome-based pricing

By linking drug prices with desired results, outcome-based pricing puts the focus on the patient, while aligning all the players around the consequences for patients. This alignment is not always obvious and can vary from therapy to therapy. For example, many of the newer, large-molecule products leverage biomarkers to identify patients likely to have a positive predisposition to a therapy based on research that was proven in a clinical trial.

The drug company essentially establishes a risk-sharing model that allows for higher reimbursements for better outcomes and lower reimbursements for reduced outcomes, such as failing to achieve the outcome documented in a clinical study. This relationship between pricing and outcomes ensures that payers receive the full value of the drugs or products, resulting in the form of a healthy patient. And providers benefit from improved outcomes that typically reduce the cost of care, while minimizing readmissions.

Additionally, outcome-based pricing strategies may take on a variety of forms for various drugs and devices. Pricing should be reflective of the type of product and the therapy utilized. For example, many oncology-related therapies will most likely include a genomically-defined patient population sharing a common biomarker, which demonstrates a higher likelihood of a positive outcome. Conversely, diabetes patients may not have a biomarker, but may require a more holistic therapy that utilizes drugs, exercise, and diet to enable a higher quality of life. In either case, the therapies are designed to improve the health of the patient, ensure a return to the productive lifestyle enjoyed before diagnosis, and reduce the long-term cost of healthcare.

Cost of medication non-adherence

2018 data

Global Pharma Revenue

Source: Statista

Amount Forfeited to Non-adherence

U.S. Pharma Revenue

Source: HealthPrize Technologies https://adherence564.com

Amount Forfeited to Non-adherence

Source: https://www.uspharmacist.com/article/medication-adherence-the-elephant-in-the-room

Lastly, to ensure that outcomes fairly represent the results that are achievable, all members of the value chain should have an expectation that patients are responsible for some level of adherence to the stated protocol, including an insistence that they take their medication or follow their treatment schedule. By some estimates, up to a third of all prescriptions written are never filled. Since reimbursement is determined based on the outcome, without adherence to the protocol, the results may not meet expectations, causing reimbursement anomalies.[1] Recently, the emergence of inexpensive and highly effective sensors and devices has automated the process and tracked patients' drug-taking or device-using activities to ensure adherence. This will allow for more accurate tracking and validation of outcomes before reimbursement is made.

1. Truven Health Analytics NPR Health Poll, Fall 2017.

> For drugs with predictable outcomes based on clinical trial data, the price could be defined in a contract based on associated biological markers.

When the numbers don't add up, it's time to usher in a new era of outcome-based pricing models

For drugs with predictable outcomes based on clinical trial data, the price could be defined in a contract based on associated biological markers. This would be relatively effective for specialty drugs that are shipped to doctors or clinics for direct use by patients. The contract for this treatment type could include information from treatment submissions and payment records to determine if the treatment had the requisite potential for success. This information would then be used to define different levels of reimbursement for the treatment.

The hospital would submit reimbursement data to the payer and then to the manufacturer, or directly to the manufacturer. The scenarios could be managed in a variety of ways. For example, the manufacturer could pay higher rebates for shorter stays if the outcome was focused on minimizing hospital stays. This would require providers and payers to share outcome data, similar to the way they currently do for standard managed-care prescription rebates. Outcome records would need to include codification to identify the patient, as well as outcome codes and other indicative data, such as age, sex, procedure/treatment, hospital length of stay, etc. This information could then be used to calculate rebate payments.

Other processes will need to be defined, such as pricing methods based on patient dose, like offering a single price to a patient, even if dosage sizes vary. This is consistent with the new approach that focuses on achieving effective outcomes, rather than simply encouraging product use.

If a patient was required to maintain adherence to an ongoing treatment, the reimbursement model would include pricing rules to track script data for the initial script, and then track refills. Reimbursement would be based on a sliding scale, with variations depending on how long the patient stayed on the treatment. This could also be used to determine if a drug treatment is effective. For example, the reimbursement would change if the patient switched drugs during treatment.

> Outcome-based reimbursement agreements require dynamic and flexible solutions that also consider patient factors like test results, biomarkers, age and more.

A new era for outcome-based pricing models

Outcome-based reimbursement agreements will require a more dynamic, flexible, and iterative solution that could create agreements that go well beyond standard pricing calculations linking reimbursements to remission rates, days in hospital, or reduced A1C levels. Such systems would need to consider patient and population prerequisite data, including diagnostic test results, existence of specific biomarkers, disease states, outcome codes, tumor characteristics, age, and more, as part of the calculation matrix.

Systems would leverage a variety of analytics to measure, track, and predict outcomes, while also monitoring patient data for potentially adverse events or side effects that may be emerging from the data. The system would also need to validate the data against data provided, looking for trends or anomalies that may cause payment discrepancies, or lead to further analysis and a potential change to the pricing matrix.

These new pricing strategies will not only be required for pharma and biopharma, but also for the medical devices industry, such as pricing based on procedures performed, rather than simply on equipment purchased. This requirement can also expand to reimburse for outcomes achieved, such as increased mobility for orthopedic implants, as well as reimbursement based on diagnostic tests performed, instead of the actual purchase of equipment test kits and reagents. Regulatory changes will also need to be considered. These pricing model shifts will impact government contract pricing and government rebate programs.

“Regardless of the fate of the Affordable Care Act (ACA), outcome-based reimbursements will continue to increase in frequency and complexity, because this approach has the potential to introduce real value into the healthcare market.”

A practical approach to outcome-based pricing

More of these agreement types are on the horizon, with new and evolving methods to more precisely determine outcomes already in development. Regardless of the fate of the Affordable Care Act (ACA), outcome-based reimbursements will continue to increase in frequency and complexity, because this approach has the potential to introduce real value into the healthcare market.

Below are some of the outcome-based agreements that are already in place across the Life Sciences industry:

- Amgen has negotiated an agreement with Harvard Pilgrim Healthcare on the development of an outcome-based rebate contract for Repatha®, the company’s cardiovascular product. Under the terms, Amgen will receive a higher reimbursement if the patient experiences an outcome that surpasses the outcomes achieved in clinical trials.

- Merck has used clinical data to determine the potential outcome of one of its drugs, and has used this to ensure that the payer network is more likely to include the drug on their approved formularies. Merck and UnitedHealth Groups have undertaken a multi-year project to use patient data to develop and test pay-for-performance models.

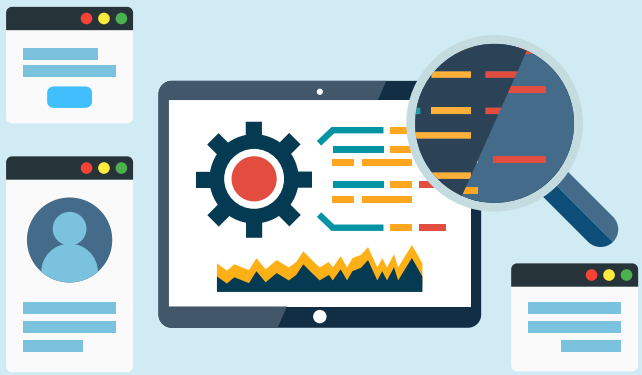
- Eli Lilly and Anthem have agreed to a framework for developing value-based contracts. They are working on the policy environment that would allow this process to work most effectively. This includes potentially necessary changes to government regulations regarding pricing.

- At Merck MSD, KEYTRUDA® patients are required to undergo a diagnostic test to determine their PD-L1 protein levels, in order to qualify for a particular treatment. If the level is sufficiently high, the patient may become a candidate for the treatment. This is an example of a patient population that would be predisposed to a better outcome, provided they pass the diagnostic test.

- Medtronic announced a new outcomes-based agreement with Aetna for type 1 and type 2 diabetes patients currently on multiple daily insulin injections for their diabetes management. The agreement will measure health outcomes for patients that choose to transition to pump therapy using a Medtronic insulin pump. Reimbursement will be tied to lower overall long-term blood glucose levels achieved through better monitoring and insulin delivery using Medtronic’s insulin pump technology.

An increase in such reimbursement scenarios would benefit the entire healthcare system and more clearly align all the players with patient outcomes. Manufacturers would require a greater stake in the outcomes in order to justify the high costs for their products. Providers would benefit with higher patient success rates, and payers would get patients back to a healthy state, while reducing costly hospital stays or readmissions.

> The increasing need for internal and external data sets, both structured and unstructured, will require systems capable of ingesting multiple data sources and rationalizing what reimbursement data is required in real time.



The emerging and critical role of software

Next-generation systems and software will be required to support these processes, and will need to provide both operational and therapeutic analytics that offer improved insights into the patient experience and therapeutic protocol.

The increasing need for internal and external data sets, both structured and unstructured, will require systems capable of ingesting multiple data sources and rationalizing what reimbursement data is required in real time. To achieve this, more data will need to be digitized and stored to propose the rebate amount or reimbursement, and be capable of documenting the outcome, or ancillary diagnostics that are required to determine treatments or outcomes.

Such systems would also require more information types and formats, such as direct and indirect sales data. Treatment data would be needed to define which treatment was provided and associated outcomes, as well as detailed length of stay, follow-up, and any readmission information. Payer information would define the reimbursement provided and be used to define adherence or ineffective treatment due to drug switch, among other attributes. This data will take multiple forms, including EDI, NCPDP, flat files, spreadsheets, CSV, and more. The data will most likely require some level of scrubbing to rationalize and cross-reference the patient and identify the product and treatment used, as well as the payer and provider. This will generate a large pool of associated data that will be used to create the full view of the patient's treatments and outcomes, while allowing for the definition and calculation of reimbursement to the proper parties.

Real-time analytics will be required to monitor and ensure that reimbursement and pricing structures meet expectations and provide input to ever-changing models. Integrated data models will greatly simplify and ensure data lineage, transparency and auditability across the myriad of data points. A comprehensive solution coupled with robust pricing engines will be needed. This will deliver real-time pricing metrics the moment they are needed, while providing complete business context relative to a specific business process.

Subtract inefficiency. Add revenue.

Most of the initial forays in this area have involved manufacturers and payers working together. Over time, the Life Sciences industry will see providers entering this process and becoming key stakeholders. After all, they are the ones prescribing, purchasing, and administering the product, treatment, or procedure, and having the most impact on patient outcomes. They will also be the ones that provide the relevant outcome data.

For now, the outcome-based pricing initiative has been centered on the U.S. marketplace, but other regions are beginning to follow suit. For example, the National Institute for Health and Care Excellence (NICE) in the UK determines if a new product provides greater benefits than others currently available at an acceptable cost. If they believe the benefits do not outweigh the costs, they can require price concessions to increase the benefit-to-cost ratio.

Other countries are keeping a close tab on the outcome-based pricing and payment matrix, evaluating its impact on costs and outcomes, acutely aware that achieving accurate, real-time data is the best approach to achieving a sustainable business model across the entire value chain.

How Vistex Adds Value to Life Sciences

Today's Life Sciences market is impacted by scrutiny over rising costs, tighter innovation funding, proving therapy and product value, and complying with shifting regulatory mandates. Vistex helps Life Sciences companies manage the complexities of pricing, commissions, chargebacks, rebates, royalties, contract authoring, loyalty programs, and regulatory compliance. Vistex provides value to Life Sciences through revenue management, utilizing real-world evidence and outcomes by dismantling silos, validating and exploiting data, and identifying the most profitable plans for satisfying stakeholders.

About Vistex

Vistex solutions help businesses take control of their mission-critical processes. With a multitude of programs covering pricing, trade, royalties and incentives, it can be complicated to see where all the money is flowing, let alone how much difference it makes to the topline and the bottomline. With Vistex, business stakeholders can see the numbers, see what really works, and see what to do next – so they can make sure every dollar spent or earned is really driving growth, and not just additional costs. The world's leading enterprises across a spectrum of industries rely on Vistex every day to propel their businesses.

About the Authors

Joe Miles
SVP, Global Industry Business Development at SAP
Joe Miles brings more than 25 years of software and Life Sciences industry experience, including more than 15 years as an executive driving business strategy with a focus on building strong, sustainable relationships with customers, partners, financial analysts, and industry experts. Joe's experience includes all aspects of the software solution lifecycle, from development and product management to solution marketing.

Bob Steller
Industry Principal, Life Sciences (Vistex)
Bob Steller is an expert in Life Sciences revenue management, operational improvement, and information systems. With 28 years of experience, including 21 years with pharmaceutical companies, Bob leverages his deep knowledge of the industry's unique requirements to help clients with the industry's unique requirements to streamline financial processes and boost overall program performance.

Vistex®, Go-to-Market Suite®, and other Vistex, Inc. graphics, logos, and service names are trademarks, registered trademarks or trade dress of Vistex, Inc. in the United States and/or other countries. No part of this publication may be reproduced or transmitted in any form or for any purpose without the expressed written permission of Vistex, Inc. The information contained herein may be changed without prior notice.

© Copyright 2020 Vistex, Inc. All rights reserved.