Internship Training

at

ZS Associates, Gurugram

Value Based Programs of Pharmaceutical Companies in US

by

Priyamvada Pallavi Mishra

PG/19/065

Under the guidance of

Ms. Nikita Sabherwal Associate Professor & Associate Dean -Training

Post Graduate Diploma in Hospital and Health Management

2019-2021

International Institute of Health Management Research
New Delhi

IIHMR DELHI

The certificate is awarded to

Dr. Priyamvada Pallavi Mishra

in recognition of having successfully completed her
Internship in the department of

Knowledge Management

and has successfully completed her Project on

Value Based Programs of Pharmaceutical Companies in US: A Descriptive study

5th March to 30th May 2021

At

ZS Associates, Gurugram

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish her all the best for future endeavors.

Swati Singh

PD Coach
ZS Associates, Gurugram

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Dr. Priyamvada Pallavi Mishra** student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at **ZS Associates Gurugram** from **5th March to 30th May 2021**

The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfilment of the course requirements. We wish her all success in all her future endeavours.

Dean Academics and Student Affairs
Professor and
IIHMR, New Delhi

Assistant

Assistant Dean- Academics &
Student Affairs, IIHMR, New Delhi

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Certificate of Approval

The following dissertation titled

"Value Based Programs of Pharmaceutical Companies in US: A Descriptive study"

at

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is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name	**Signature**
Dr. Arora	
Dr. Manish Priyadarshi	
Ms. Nikita Sabherwal	
Dr. Siddharth Shekhar Mishra	

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Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Priyamvada Pallavi Mishra,** a graduate student of the **Post-Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. She is submitting this dissertation titled "**Value based programs of pharmaceutical companies in US** at "**ZS Associates, Gurugram"** in partial fulfilment of the requirements for the award of the Post- Graduate in partial fulfilment of the requirements for the award of the Post- Graduate Diploma in Health and Hospital Management. This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled

"**Value based Programs of Pharmaceutical companies in US**"

Submitted by **Dr. Priyamvada Pallavi Mishra**
Enrollment no. **PG/19/065**

Under the supervision of **Ms. Nikita Sabherwal**, **Associate Professor and Associate Dean Training, IIHMR Delhi** for award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from 5th March 2021 to 30th May 2021 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Signature-

Priyamvada P. Mishra

FEEDBACK FORM

Name of the Student: **Dr. Priyamvada Pallavi Mishra**

Dissertation Organization: **ZS Associates, Gurugram**

Area of Dissertation: **Value- based programs of pharmaceutical companies in US: A Descriptive study**

Attendance: **Adequate**

Objectives achieved: **Yes**

Deliverables: **Adequate and in depth analysis of programs by top ten pharma companies in US**

Strengths: **A very committed, sincere, diligent, cooperative & positive natured individual with strong drive and zeal for mutual learning.**

Suggestions for Improvement**: Nil**

Swati Singh
PD Coach
ZS Associates, Gurgaon

Date: 11th June 2021
Place: Gurugram, New Delhi

Acknowledgement

First and foremost I would like to thank The Almighty GOD whose grace makes all the things possible the satiation and euphoria that accompany the successful completion of the project would be incomplete without the mention of the people who made it possible.

I would like to take the opportunity to thank and express my deep sense of gratitude to my faculty supervisor **Ms. Nikita Sabherwal**, **Associate Professor and Associate Dean Training, IIHMR Delhi** and mentor my team manager **Ms. Karishma Trikha** , and my consultant **Ms. Nidhi Khatura.** I am greatly indebted to them for providing their valuable guidance and time at all stages of the study, their advice, constructive suggestions, positive and supportive attitude and continuous encouragement, without which it would have not been possible to complete the project.

I owe my whole hearted thanks and appreciation to the entire HES team.

Last but not least I am extremely grateful to my parent for their love, prayers, caring and scarifies for educating and preparing me for my future.

I hope that I can build upon the experience and knowledge that I have gained and make a valuable contribution towards community in coming future.

Table of Contents

List of Abbreviations

VBPCs	Value Based Pharmaceutical Contracts
OBCs	Outcome Based Contracts
LTF	Long Term Financing
VBID	Value Based Insurance Design
SP	Specialty Pharmacy
VBPs	Value Based Programs
AI	Artificial Intelligence
VBP	Value Based Pricing
FDA	Food and Drug Administration
APMs	Alternative Payment Models
OECD	Organization for Economic Co-operation and Development
GDP	Gross Domestic Product
HQ	Head Quarter

Executive Summary

This is an attempt to know that how theories can be applied in a practical situation. This is the report which is based on the 4 weeks' internship program that I had successfully completed in ZS Associates under Knowledge Management team from 1-03-2021 to 31-05-2021 as a requirement of my MBA program. As being completely new to practical, corporate world setting, every hour spent in the consultancy gave me some amount of experience all the time all of which cannot be explained in words. But nevertheless, they were all useful for my career.

In the first part of the project the general information of the consultancy has been collected, information is gathered through primary and secondary sources as well.

In the second part of the subject contains the specialised subject of study or the main project.

The study was started from 1st March 2021, after the submission the project "Value based programs of the pharmaceutical companies in US". The study was based entirely on secondary research.

This report includes some famous Value- based Programs of Pharmaceutical companies in US. There is a comprehensive list of 73 such programs.

My personal views about the Project, my value addition to the Project are also included in the report. With limited knowledge and experience, I tried my best to make this report as much understandable as possible and translated the real-world experience into a document.

Before drawing any conclusion based on this report it may be noted that the report was prepared in a very short term. But still the report may be useful for designing any further study to evaluate the Value based programs in US.

Chapter 1- About the Organization

ZS Associates is a management consulting and professional services firm focusing on consulting and professional services firm focusing on consulting, software, and technology, headquartered in Evanston, Illinois that provides services for clients in private equity, healthcare and technology. The firm was founded in 1983 by two professors at North-western University who developed sales force alignment models using the world's first computer- aided territory mapping system. ZS continues to offer sales force alignment service to this day, in addition to a range of professional services and solutions, many of which are supported by advanced analytics.

Achievements

The company was chosen by Forbes magazine as one of America's best management and consulting firms in 2019 and has been awarded for its company culture by Consulting magazine for several years in a row. The company has been recognized by the Human Rights Campaign Foundation for earning 100 percent on their Annual Corporate Equality Index for LGBTQ workplace equality.

Organization

ZS is a partner owned and led organization, with consulting, analytics and technology employees spanning expertise areas from R&D to commercial. ZS has 24 offices around the world- Boston, Chicago, Evanston (HQ), Los Angeles, New York, Philadelphia, Princeton, San Diego, San Francisco, San Mateo, Sao Paulo and Toronto are in US. Barcelona, Frankfurt, London, Milan, Paris and Zurich are in Europe. In Asia there are 6 offices, out of which three are in India- Bangalore, New Delhi, Pune, Shanghai, Tokyo, Singapore.

Research and Publishing

ZS regularly publishes original blogs, articles, infographics, whitepapers and video content to its website and in external publications including national media such as Forbes and trade magazines such as Pharmaceutical Executive, In Vivo and Medcity news. Topics range from airline revenue management and customer experience to drug pricing and pharma commercial models.

ZS employees have also written and published dozens of books on subjects including sales compensation and sales leadership.

Founders Zoltners and Sinha have written for Harvard Business Review on many occasions over the past decade, contributing more than 40 articles on a range of sales and marketing topics, with particular emphasis on healthcare marketing and healthcare analytics.

ZS employees have been quoted as experts in the field in The Wall Street Journal, The New York Times, Business Insider, NPR and many others.

Industries

ZS operates as a strategic, long-term advisor to its clients, basing its offerings on clients' needs and challenges across the following industries: Pharmaceuticals and Biotech

- Medical Products and Services
- Health Plans and Providers
- Travel and Transportation
- High-Tech and Telecommunications
- Financial Services
- Private Equity
- Energy
- Media
- Consumer Packaged Goods
- Business Services

Chapter 2- Introduction

In the global struggle to manage the cost of health care, practitioners and policymakers are increasingly focusing on value- delivering the best possible health outcomes at the lowest possible cost. The most advanced health systems around the world are documenting broad variations in health outcomes and differences in clinical practice and using these data to identify best practices and using these data to identify best practices and to steer resources toward these interventions that have the highest impact. Such efforts are facilitated by the proliferation of new systems and capabilities in health care informatics that make it possible to collect outcome data and share findings broadly with clinicians and the public. This new paradigm is known as value- based care.

Innovative new technologies are improving how pharmaceuticals are developed, tested, and delivered. Real-time patient data and population health metrics ensure patients are adhering to care regimens and spot health trends before they become widespread issues. Pharmaceutical manufacturers will have to take full advantage of this intelligence to extract the most value from new drugs and therapies and stay ahead of patient health trends.

Some pharmaceutical manufacturers are already using technologies like artificial intelligence (AI) to screen for harmful chemical interactions when creating new drugs, design new medications, and identify biomarkers for illnesses that are traditionally difficult to diagnose. As AI continues to develop, and care providers discover new applications, AI could improve diagnosis accuracy and improve overall care efficiency.

Restricted budgets mean that implementing and properly leveraging this technology can be difficult – enter value-based care. Participation in the VBC model requires hospitals and other care facilities to create and follow comprehensive benchmarking plans. This allows facility leaders to find weak points in financial, clinical, or quality performance and set measurable goals for improvement.

The shift toward value-based care is particularly useful in the proliferation of personalized medicine, with facility and all-payer claims data offering a complete picture of care outcomes by region. This quantity of data can also improve the ways pharmaceutical manufacturers demonstrate the value of new drugs or delivery methods to both payers and healthcare providers, leading to the adoption of more effective and innovative treatments.

One solution for containing costs that has been gaining traction in recent years is value-based pricing (VBP) of pharmaceuticals. Value-based purchasing agreements are created when drug manufacturers and purchasers negotiate costs of a drug based on patient health outcomes or

financial incentives. These alternative payment models, or APMs, have emerged as a possible way to constrain the upfront costs of these new drugs if the manufacturer guarantees their effectiveness. In these agreements, health insurers negotiate with private pharmaceutical companies to receive rebates, discounts or other incentives based on a drug's effectiveness in treating a disease. These agreements can take many forms, such as:

- Insurers requiring clinical results for patients in exchange for an agreed-upon price
- Giving refunds for adverse events caused by the drug
- Lowering the price of a drug for each subsequent prescription refill

Alternative payment models may not directly affect consumer spending but are crafted as a top-down solution to manage insurers' overall health plan costs by adding new and more effective drugs to formularies (the list of approved treatments). The aim of these arrangements is to determine the benefits of specific drug treatments and set prices accordingly. For example, if a blood pressure drug does not perform as expected, the insurer would be entitled to additional rebates.

There are many types of APMs that determine what an insurer ultimately pays for a drug. Pricing can be based on the volume of drugs sold, the amount that the insurer is willing to pay, the clinical benefit in treating patients without negative side effects, or how the drug is being used in a patient's specific treatment plan. In these agreements, insurers have the goal of reducing costs and improving outcomes while manufacturers have the goal of gaining access to formularies and selling more of their product.

Insurance companies and pharmaceutical manufacturers must collaborate for months on these complex agreements because they involve massive amounts of health systems information, data collection and analysis. Since large quantities of patient data must be analysed to successfully negotiate APM contracts, a significant investment by insurance companies is needed to build the necessary data collection infrastructure.

There are also many uncertainties about the legality of creating APMs. These include whether they would affect Medicaid's "best-price" rules for drug rebates by changing the lowest price paid in the market and whether they might count as illegal information sharing between pharmaceutical and insurance companies amounting to collusion. They might even be construed as "kickbacks"—gifts of monetary value from pharmaceutical companies to persuade insurers to use their drugs.

Despite advances in the drug development process, the price of drugs in the United States continues to rise. Total healthcare spending in the US reached $3.6 trillion in 2018 (17.7% of the GDP). The percentage of total US healthcare spending on drugs is about 14%, and this has remained relatively constant in the past decade. Although some argue that healthcare spending on drugs and annual increases in prescription drug prices have been steady and moderate, surveys conducted by Bloomberg, the Commonwealth fund, and the Organization for Economic Co-operation and Development (OECD) suggest that wide gaps in prescription drug pricing and healthcare spending exist in the US when compared to other developed countries. To address the issue of high drug prices in the US, one needs to better understand the challenges involved in the drug development process, the US healthcare financing system and other drivers of rising healthcare costs.

Drug development is a highly regulated, long, and complex process. On average, one in ten drug candidates survives the clinical trials and regulatory process to make it to market. It takes about ten years and $1B to bring a drug to market. These costs can go up to $2B in the case of cancer drugs and specialty drugs. Thus, in order to be sustainable and innovative, drug

companies need to make enough revenue from their marketed drugs to not only cover the costs of manufacturing and distribution of the drugs, but also fuel the research for improving marketed drugs, and developing new drugs. Overall, pharma companies spend 18% of revenue on R&D. These R&D costs are factored in while determining the drug prices.

Steep increases in prices and spending on prescription drugs in the United States have triggered public outrage and questions over their value. Value-based pricing has emerged as a preferred alternative to prices determined by what the market will bear. In response, manufacturers and health plans have begun to publicize their efforts to engage in outcomes-based contracts and long-term financing agreements, which they describe as value-based. Nevertheless, both contracting approaches perpetuate existing distortions in the financial incentives of supply chain and prescribing intermediaries, and fail to realign the prices of drugs to their value to patients, the healthcare system, or society. This commentary describes the challenges of managing drugs according to their value, and describes several alternatives that promise greater impact than contracting strategies.

In an era of rising health care spending and constrained budgets, U.S. policymakers and payers have tried to shift providers' financial incentives from those that pay for greater volume of care to those that pay for high-value care. This move from volume to value is in its early stages, with most payment still based on old fee-for-service models.

Chapter 3- Review of Literature

I have gone through 25 different research papers, selected some papers for literature review.

Value-Based Management of Specialty Drugs: Practical Considerations and Implications for Pharmacy

Objectives	Concerns about high and rising drug prices have prompted a call to manage prescription drugs according to their value. Although not all proposals referred to as "value based" are well suited to advance this mission, health plans must select among them under the influence of competing demands and constraints of their market and nonmarket environments. To understand the implications for health policy, we sought to explore how health plans might select among and implement these approaches for specialty pharmacy (SP) under the incentives and barriers that these conditions create
Methodology	Plans' objectives, operational strategies, and factors influencing their ability to execute on these strategies were elicited in 3 focus groups
Research Design	An experienced research team conducted a qualitative study with Blue Cross Blue Shield health plans interested in implementing value-based SP management
Search Strategy	I have used "Google scholar" to find this article
Keywords	Value based programs; Specialty pharmacy (SP);
Published on	May 13, 2021
Conclusion	Four business objectives were identified, centring on spending levels, spending variability, access to new treatments, and evidence generation for new treatments. Supporting operational strategies included increased utilization management (UM), provider and patient engagement, expanded data analytics, and adjustments to staffing models. Factors that influence their ability to act on these

	strategies include regional and national scale, strength of provider network relationships, disease management capabilities, business and data silos, and potential legislative actions to limit UM

Outcomes-Based Contracting Experience: Research Findings from U.S. and European Stakeholders

Objectives	The objective of this study was to assess the level of recent OBC activity and stakeholder perceptions of these arrangements, as well as the outlook for future OBC activity from a payer and manufacturer perspective in the United States and EU-5 (France, Germany, Italy, Spain, and the United Kingdom)
Methodology	To perform our research, we combined structured interviews with a targeted literature review of publicly available information on specific OBCs in order to provide an assessment of the past and future volume of OBC activity for the United States and the EU-5
Research Design	Using a structured questionnaire, interviews were conducted with 27 experts, including 14 U.S. payers, 5 EU-5 national payers, and 8 manufacturer pricing/market access executives (4 U.S., 4 EU-5). We also used the University of Washington's Performance Based Risk-Sharing (PBRS) database and other targeted publicly available information
Search Strategy	I have found this paper through " PubMed"
Keywords	Outcome- Based contracts; Value- based programs
Published on	June 5, 2018

Conclusion	Using direct input from U.S. and EU-5 payer and pharmaceutical manufacturer decision makers, this research suggests that high OBC growth is expected in the EU-5 and, to a more moderate extent, in the United States, particularly if clear, simpler OBC frameworks can be developed.

Value-Based Pharmaceutical Contracts: Value for Whom?

Objectives	To distinguish between VBPCs and payer–provider value-based agreements; to assess how VBPCs affect costs, clinical outcomes, and access to treatment; and provide suggestions for and examples of how VBPCs can be leveraged to optimize their impact on these key outcomes.
Methodology	To perform our research, we combined structured interviews with a targeted literature review of publicly available information on specific VBPCs in order to provide an assessment of the past and future volume of VBPC activity for the United States
Research Design	An experienced research team conducted a qualitative study
Search Strategy	I have found this paper through "Google scholar"
Keywords	Pharmaceutical contracts; Value-based contracts; Drug pricing
Published on	February 2020

Conclusion	VBPCs may have the capacity to improve the value metric of pharmaceuticals by reducing health expenditures, incentivizing favourable clinical outcomes, and improving access to drugs. Nevertheless, challenges remain with VBPCs including limited real-world evidence on the impact of VBPCs, selection of appropriate surrogate outcomes for evaluating drug efficacy, the lack of evidence that they directly reduce drug costs, and low patient volume affected by VBPCs

Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?

Objectives	To assess the expected benefits and limitations of outcomes-based pharmaceutical contracts in the U.S., including their potential impact on prescription drug spending.
Methodology	Semi structured interviews with payers, manufacturers, and policy experts.
Research Design	An experienced research team conducted a mixed study
Search Strategy	I have searched this article through "Google Scholar"
Keywords	Pharmaceutical contracts; Outcomes-based contracts; Drug pricing
Published on	September 27, 2017
Conclusion	Outcomes-based contracts are intended to shift pharmaceutical spending toward more effective drugs, but their impact is unclear. Voluntary testing and rigorous evaluation of such contracts in the Medicare and Medicaid programs could increase understanding of this new model.

Pharmaceutical Products and Their Value: Lessons Learned and the Path Ahead

Objectives	The objective is to study the value- based pricing of pharmaceutical products
Methodology	The study has been characterized by using rigorous analytic methods
Research Design	An experienced research team conducted a mixed study
Search Strategy	I have searched this article through "Google Scholar"
Keywords	Innovative contracting; Long-term financing; Outcomes-based contracting; Pharmaceutical products; Prescription drugs; Value-based contracting; Value-based pricing
Published on	April 2020
Conclusion	Outcomes-based contracts hide the net price of the treatment, obscuring whether the drug performed to any available value-based price benchmark, and fail to make drugs more affordable to patients. Long-term financing presents another concern in that it establishes a pathway for health plans to offload financial liability after the first payment, passing subsequent payments through to beneficiaries in the form of rising premiums.

Chapter 4- Research Design & Methodology

Relevant studies have been searched by employing mixed method approach

I have used both quantitative and qualitative studies as part of my secondary research, retrieved from online data bases (PubMed, Google Scholar, Lancet)

Data collection: I have collected secondary data from the annual reports of top ten pharma companies as well as research papers based on value- based programs of US

I have gone through 25 research papers, out of them I have selected five papers for literature review

Inclusion criteria: I have included those articles which are published post 2010

Exclusion criteria: I have excluded those articles which are not from US

Chapter 5- Results and Analysis

A unique list of 20 Value- based programs has been found. These programs are from top pharma companies of US- Pfizer, Janssen, BMS, GSK, Eli Lilly, AstraZeneca, AbbVie, Genentech, Roche, Bayer etc.

Tiolto	Highmark and Boehringer Ingelheim today announced a new value-based contract for Boehringer Ingelheim's Stiolto® Respimat® (tiotropium bromide & olodaterol) Inhalation Spray for the treatment of chronic obstructive pulmonary disease (COPD). This marks the second value-based contract between the two companies. It is also the first contract for Highmark to include Medicare plans in addition to commercial health plans
Enbrel	Abarca, a pharmacy benefit manager (PBM) that is disrupting the industry with an entirely new approach to technology and business practices, today announced it has entered into an outcomes-based contract with Amgen (NASDAQ: AMGN) for the drug Enbrel® (etanercept). Under the agreement, Amgen will issue rebates to Abarca's clients for eligible members who discontinue the use of the drug after three months of treatment. This applies to members of commercial health plans who are using the drug for the treatment of moderate to severe rheumatoid arthritis.
Tecfidera	UPMC Health Plan and Biogen Announce Ground Breaking Value-Based Agreement for Multiple Sclerosis Treatments
Avonex	UPMC Health Plan announced today that it has entered into a value-based agreement with Biogen for Avonex® (interferon beta-1a), specialty medication used to treat patients with relapsing forms of multiple sclerosis (MS). In this first-of-its-kind contract, reimbursement provided by the drug manufacturer, Biogen, to UPMC Health Plan will be linked to MS patient-reported measures of disability progression in a real-world population.
Luxturna	Cigna aims to expand affordable access to gene therapies

Epclusa	CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid
Zolgensma	AveXis, a Novartis company, today announced innovative access programs for Zolgensma® (onasemnogene abeparvovec-xioi) for the treatment of paediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (*SMN1*) gene. AveXis is working closely with payers to offer pay-over-time options up to 5 years and outcomes-based agreements up to 5 years, as well as providing a patient program to support affordability and access
Stelara	Prime Therapeutics LLC (Prime), a leading pharmacy benefit manager (PBM) serving more than 27 million members nationally, has signed a value-based contract with the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), for Stelara® (ustekinumab)
Fycompa	Eisai Inc. the U.S. pharmaceutical subsidiary of Eisai Co., Ltd., announced today that they have signed a value-based contract for FYCOMPA® (perampanel) CIII with Oklahoma Health Care Authority (OHCA) premised on reduction of hospitalizations of OHCA patients with epilepsy. The OHCA is the first state Medicaid agency in the country with Centers for Medicare & Medicaid Services (CMS) approval for negotiating value-based or outcomes-based contracts with pharmaceutical companies

Jardiance	The UPMC Health Plan announced today the initiation of a value-based contract with Boehringer Ingelheim effective 1/1/2019 for Jardiance® (empagliflozin), an oral type 2 diabetes medicine also indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. The goal of the contract is to align the incentives of the manufacturer, Boehringer Ingelheim, with the UPMC Health Plan, and will link reimbursement of the drug to costs associated with clinical outcomes in the real-world population
Onpattro	Alnylam Announces Alignment on Value-Based Agreements with Leading Health Insurers and Launches Comprehensive Patient Support Services for Onpattro (patisiran)
Praluent	Sanofi and Regeneron Pharmaceuticals, will lower the net price of Praluent® (alirocumab) Injection in exchange for straightforward, more affordable patient access from Express Scripts. Praluent will become the exclusive PCSK9 inhibitor therapy on the Express Scripts national formulary. The agreement significantly simplifies the documentation necessary to secure insurance coverage and may help reduce out-of-pocket costs for eligible patients
Repatha	Abarca has signed an outcomes-based contract with Amgen for the cholesterol-lowering drug, Repatha® (evolocumab). This agreement is the first of its kind involving Amgen's Repatha and a standalone PBM. This drug will be used to treat multiple sclerosis
Forteo	Harvard Pilgrim Health Care has signed a value-based contract with Eli Lilly & Company for its osteoporosis drug, Forteo, which will measure patients' adherence to the drug. The contract was developed to address the challenge of ensuring that patients keep taking the medication as prescribed by their physician

Bydureon	Harvard Pilgrim Health Care has signed an innovative, outcomes-based contracts with AstraZeneca for Bydureon to treat acute coronary disease and Type II diabetes
Brilinta	Harvard Pilgrim Health Care has signed an innovative, outcomes-based contracts with AstraZeneca for Brilinta to treat acute coronary disease. This medication will be used to lower a patient's chances of having another heart attack or dying from one
Harvoni	Cigna has reached an agreement with Gilead Sciences, Inc. to include Harvoni as the only preferred brand prescription drug treatment for customers with hepatitis C genotype 1, the most common form of the disease in the United States. Cigna clients and customers benefit from obtaining breakthrough clinical cure rates for hepatitis C while significantly lowering the cost of drug treatment
Avastin	Genentech (a drug manufacturer) and Priority Health (a nonprofit health plan) agreed to collaborate on an outcomes-based contract for Avastin ® (bevacizumab) in patients with non–small-cell lung cancer (NSCLC)
Rebif	Prime Therapeutics (Prime), a leading pharmacy benefit manager (PBM), and EMD Serono, Inc., a leader in the U.S. biopharmaceutical market and subsidiary of Merck KGaA, Darmstadt, Germany, have entered into an agreement bringing the first outcomes-based rebate contract for a multiple sclerosis (MS) drug to Prime's CareCentered Contracting program. As an integrated PBM with its health plan clients, Prime is uniquely positioned to ensure members are taking effective prescription medications that truly improve their health by evaluating outcomes data throughout the entire length of the contract

Betaseron	Bayer HealthCare and Health Alliance Medical Plans have entered into an outcomes-based contract for people with relapsing-remitting multiple sclerosis (MS) who are taking Betaseron (interferon beta-1b) to reduce the frequency of clinical exacerbations. The agreement is the first of this type for Bayer HealthCare in the U.S. and is defined by relapses requiring hospitalizations for Betaseron patients covered by Health Alliance

Chapter 6- Conclusion & Recommendation

Policy makers seek to make new treatments available while balancing cost concerns. Although health plans share this aim, they also seek to mitigate spending variability and compensate for the low levels of evidence for new, high-cost SP drugs entering the market. The latter considerations drive preferences toward LTF and OBCs for many plans, which are inferior to VBP and VBID for meeting policy aims to advance innovation. Plans that can expect a positive impact on their business from VBP and VBID are generally those with stronger relationships with provider networks, greater ability to engage patients and manage utilization, and sufficiently large size to absorb short-term spending variations. However, these characteristics also give them the ability to maintain traditional contracting strategies, which have historically perpetuated the delinkage of SP drug prices from their value.

Policy makers who are seeking to advance value-based management of SP drugs should consider reforms that address both limiters and incentives in the market and nonmarket environments in which plans operate. For example, policies and demonstration programs that increase negotiating leverage and encourage management of drugs according to their value could offer a starting point for aligning incentives with VBP and VBID. Others, such as requiring that rebates be passed through at the point of sale, could reduce the appeal of more traditional contracting models while also benefiting patients. Finally, more stringent evidence requirements for FDA approvals and enforcement of post marketing commitments for drugs with accelerated approval would provide more information for value-based management

This research suggests that OBCs are now established and are valuable contracting options for payers and manufacturers in the EU-5 and the United States. The primary research interviews showed that OBC activity has been growing in the EU-5 and the United States over the past 5 years and is expected to continue to increase over the next 5 years. While much of this OBC activity appears to remain confidential, the targeted literature review of publicized OBCs indicated a positive trend. While some research based on publicized OBC activity suggested a potential slow-down in EU activity after 2011, this review indicates that the slowdown pattern appears to be primarily driven by the non-inclusion of AIFA's OBCs during this period.

OBCs are increasingly used by manufacturers and payers in the United States and the EU-5 to address risk associated with certain products and appear to have become an established feature of the market access landscape in the EU-5. Particularly in the United States, recent OBC activity indicates that interest in the market has increased significantly. For example, since January 2015, Cigna has publicly disclosed at least 5 OBCs for new products used to treat diabetes, cholesterol, heart failure, and hepatitis C. Regional payers and pharmacy benefit managers have also agreed to several OBCs with large manufacturers, including Harvard Pilgrim and Express Scripts. These arrangements seem to provide benefits to payers (national and regional) and manufacturers, particularly for high-cost and/or high-budget products, or to mitigate uncertainty.

Our research on OBCs illustrates some of the growth opportunities and challenges in increasing shared accountability of diverse health care stakeholders while improving patient outcomes. The transition towards health care accountability in the EU-5 and the United States

and continued budget pressures are key factors expected to support the trend towards more OBCs. At the same time, OBCs are not a replacement for traditional arrangements, since OBCs may not be appropriate for every product, particularly given costs, complexity, availability of data, or resource requirements. Similarly, OBCs may not be currently feasible nor desirable for every health care stakeholder (e.g., payer, pharmacy benefit manager, and employer). Consistent with previous literature, we found that significant barriers, such as insufficient data infrastructure and high administrative or initiation burdens, hinder the implementation of OBCs for some health care organizations more than others.

The absence of pragmatic frameworks in the United States is a significant hurdle for OBC growth. Yet, the emergence of widely accepted OBC frameworks can be challenging, particularly given the highly fragmented U.S. health care system. Integrated delivery networks, closed systems with well-established data capabilities (e.g., large private payers), or CMS have a unique opportunity to play a key role in the introduction of such OBC frameworks.

VBPCs may have the capacity to improve the value metric of pharmaceuticals by reducing health expenditures, incentivizing favorable clinical outcomes, and improving access to drugs. Nevertheless, challenges remain with VBPCs including limited real-world evidence on the impact of VBPCs, selection of appropriate surrogate outcomes for evaluating drug efficacy, the lack of evidence that they directly reduce drug costs, and low patient volume affected by VBPCs. Measures can be taken to overcome these challenges and realize their benefits. First and most importantly, VBPCs should focus on medications that clearly offer clinically meaningful benefits to patients. Second, VBPCs should be paired with more overarching payer drug cost reduction strategies because VBPCs are unlikely to reduce costs in isolation. In conjunction, it is imperative that manufacturers take on greater risk in VBPCs. Future work should evaluate more integrated models that use VBPCs as one of the tools to align incentives on all fronts, with a focus on whether patients benefit in tangible ways.

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