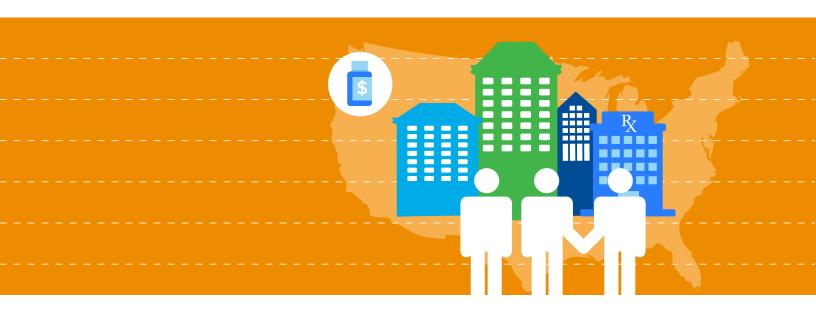


October 2016

Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates

A Study of Original Branded Products in the U.S.



Introduction

The cost of medicines in the U.S. has been the subject of much public discussion in recent years. The drug pricing process is complex and reflects the influence of numerous factors, including manufacturer list prices, confidential negotiated discounts and rebates, insurance plan benefit designs, and patient choices.

This analysis focuses on twelve high volume therapy classes in Medicare Part D, and measures the costs for 30 days of therapy for branded medicines in each class and estimates net cost to payers and patients including estimates of negotiated discounts and rebates.

The study was conducted by the QuintilesIMS Institute with funding support from the Pharmaceutical Research and Manufacturers of America (PhRMA), the national association representing leading research-based pharmaceutical companies in the U.S. It was conducted without any access to any confidential discount or rebate information from any parties. Estimated discounts and rebates have been inferred using methods proprietary to the QuintilesIMS Institute, described in the Methodology Section. The contributions to this healthcare brief of Michael Kleinrock, Mason Tenaglia and Marcella Vokey are gratefully acknowledged.

Murray Aitken

Executive Director QuintilesIMS Institute

QuintilesIMS Institute

100 IMS Drive, Parsippany, NJ 07054, USA

info@quintilesimsinstitute.org www.quintilesimsinstitute.org

Contents

01	Key Findings
02	Background
03	Methodology and Scope
05	Cost of Medicines in Medicare Part D

08 About the QuintilesIMS Institute

Key Findings

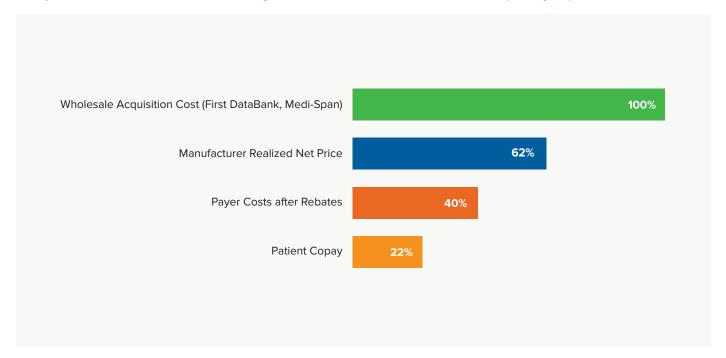
- Insurance plans or their delegates negotiate discounts and rebates with manufacturers to lower the net costs to plans and patients in Medicare Part D.
- Across twelve therapy classes widely used in Medicare Part D, medicine costs to plans and patients in Medicare Part D are 35% below list prices.
- Net costs to Medicare Part D plans alone range from 46 to 69% below list prices.
- Negotiations result in significant cost reductions for most medicines. Most therapy classes in this analysis were between 13 and 62% below list prices in Medicare Part D after accounting for negotiated discounts and rebates.

Background

Insurance plans or their delegates often negotiate discounts and rebates from manufacturers that lower payer net costs. Negotiation also results in reduced copayments for patients, as medicines are placed on preferred formulary tiers in exchange for manufacturer price concessions. Combined patient and payer net costs are therefore often substantially lower than list prices.

The Wholesaler Acquisition Cost (WAC) represents a list price. The difference between the WAC price and the total amount paid by payers and patients includes supply chain discounts, wholesaler and pharmacy profits, and rebates negotiated by payers. This can be illustrated as follows:

Comparison of List and Net Price, and Payer and Patient Net Costs after Rebates (All Payers)



Methodology and Scope

Therapy Classes Analyzed

This study is based on an analysis of branded medicines in the 12 therapy classes most commonly used by patients in Medicare Part D. These classes include ACE inhibitors, angiotensin-II reductase inhibitors including direct renin antagonists, antidepressants, antidiabetes therapies including all treatments, anti-ulcerants, beta blockers, calcium channel blockers, epilepsy and movement disorders, narcotic analgesics, respiratory agents including those for asthma and COPD, statins for cholesterol management, and thyroid therapies. These 12 therapy classes represent 55% of overall prescriptions and 57% of branded prescriptions utilized in Medicare Part D in the U.S. in 2015.

Key terms

List prices: the wholesaler acquisition cost (WAC)

Net price: (Manufacturer realized, all payers) The total net sales for a manufacturer divided by total volumes shipped. Determined through analysis of SEC filings, which are public information, and ex-factory volume data provided to QuintlesIMS in proprietary databases. Net sales / ex-factory volumes = net price across all payers.

Net costs: The payment outlays by various parties after rebates, including Medicare Part D.

Third-Party Payers/Intermediaries: Entities which negotiate with manufacturers to determine price concessions – such as discounts and rebates – that lower the cost of prescription drugs. The most common of these entities are pharmacy benefit managers (PBMs). PBMs can negotiate with pharmacies to set a specific pharmacy price (pharmacy collections), off of which patient cost-sharing amounts are based. The pharmacy price does not incorporate negotiated discounts and rebates, which manufacturers pay separately to third-party payers.

Patient Cost Sharing (Copays): Patient costs in Medicare Part D are based on pharmacy prices before the application of discounts and rebates, and the patient's individual medicine usage during the year, through the phases of the benefit, including the "donut hole". Because the negotiated discounts and rebates are confidential to the negotiating parties, costs to patients are based on the prices charged by pharmacies and are not reduced in the same way as costs to third-party payers. Pharmacy prices, which can be separately negotiated between third-party payers and pharmacies, influence patient exposure to cost by setting the costs which apply in the cost-sharing model.

Estimating Net Costs in Medicare Part D

This study measures the costs for a 30-day prescription for branded medicines and estimates the net costs to Medicare Part D plans and their beneficiaries in the U.S. after negotiations by intermediaries (usually Pharmacy Benefit Managers – PBMs). The estimates are based on a proprietary methodology developed by the QuintilesIMS Institute

Net prices are understood to differ by insurance type and are inferred for Medicare Part D. Net prices used to calculate costs in Medicare Part D are estimated based on public sources, and proprietary datasets from QuintilesIMS, but do not rely upon any confidential discount negotiations or information from plans or manufacturers. The method includes estimates of statutory or negotiated price concessions which reduce companies' publicly reported net sales. These include: Medicaid rebates, insurer negotiated discounts and rebates (including commercial and Medicare Part D plans), copay assistance/coupons in commercial plans, other payments which reduce net sales such as 340B discounts, and Veterans Affairs/Department of Defense (VA/DoD) rebates. The remaining concessions are understood to apply for the total of commercial insurance or Medicare Part D. The exact nature of Medicare Part D rebates are not known to the QuintilesIMS Institute but are understood to be more favorable than commercial plans.

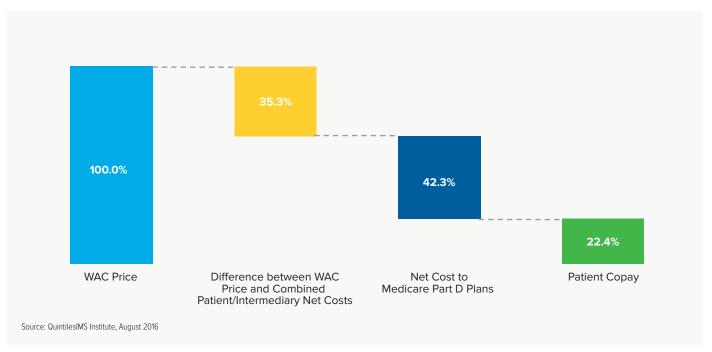
Part D plans often apply a range of tools more strongly than commercial insurers in managing plans and negotiating with manufactures which result in more favorable discounts and rebates. Key reasons for Medicare Part D plans' more favorable negotiated net costs compared to commercial insurance include:

- The practice set in place by the Medicare Modernization Act which requires plans to undertake annual underwriting of Part D plans and prohibits formularies from becoming narrower mid-year, results in once-per-year negotiations with greater risk for plans and encourages both plans and manufacturers to reach more favorable terms
- The wider use of utilization management and multi-tiered and exclusionary formularies in Medicare Part D than in commercial plans creates a greater risk/reward for the exclusion or inclusion of a manufacturer's brand and encourages greater concessions through competitive forces.
- The exemption of Medicare Part D negotiated costs from the Medicaid Best price calculation may enable manufacturers and third-party payers to reach agreements with greater discounts than in commercial plans which would otherwise impact Medicaid pricing.
- The potential for plans to drive competition in therapeutic categories, as well as to restrict beneficiary access for non-preferred products, may make manufacturers more willing and plans more able to negotiate more aggressively than in the commercial market.

Inclusive of all of these factors, Medicare Part D rebates were modeled to be 10 percentage points greater than those negotiated in commercial plans, and final estimates are based on both the estimated nature of price concessions and the volumes of treatments for each type of insurance measured in QuintilesIMS prescription audits.

Negotiated discounts and rebates lower overall net costs to plans and patients in Medicare Part D





- On average, the estimated net cost to Medicare
 Part D plans is 42.3% of the list price, after accounting
 for manufacturer rebates and patient cost sharing.
- Medicine costs to plans and patients in Medicare Part D are 35.3% below manufacturer list prices including supply chain discounts and the negotiations of Part D plans.
- On average, patients are paying 22.4% of the total list-price cost of medicines used, which is a factor of their medicine choices and overall cost-sharing through the year.

Chart notes

Difference between WAC price and combined patient/intermediary net costs demonstrates the impact overall of intermediaries on net costs. The difference includes wholesaler and pharmacy discounts, rebates and profits (see Background). Intermediaries include entities such as pharmacy benefit managers (PBMs) who negotiate rebates with manufacturers; Analysis based on aggregate of 12 therapy classes (see Methodology and Scope). Patient copays are based on Formulary Impact Analyzer (FIA) and reflect the annual copays for Medicare Part D patients in total, including patients at varying degrees of exposure to costs through the phases of the benefit; Patient premiums are not reflected in this chart.

Net costs to Medicare Part D plans range from 31 to 54% of WAC prices across 12 therapy classes

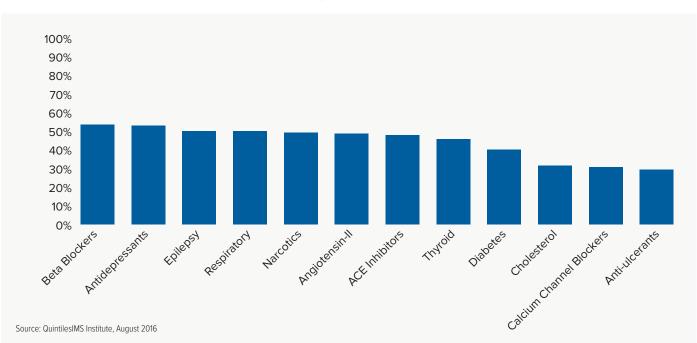


Chart 2: Net Costs to Medicare Part D Plans After Negotiated Discounts, as a Percent of WAC Price

- Across twelve therapy classes widely used in Medicare Part D, net costs for Medicare Part D plans range from 31 to 54% of WAC prices.
- In classes where large numbers of generics are available, patient exposure to higher copays discourages brand usage, but also limits plans' negotiating power and can result in higher costs for those brands which remain.
- Medicare Part D plans are mandated to cover all brands in six "protected" classes. One of these classes is included in this chart —antidepressants and still reflects significant rebates.

Chart Notes:

Analysis is based on 12 therapy classes. Net costs represent the plan's (or intermediary's) responsibility after negotiated discounts. Intermediaries typically reimburse pharmacies for the cost of a prescription minus the patient copayment amount, and then are paid a rebate by drug manufacturers which result in the final net cost.

Net costs to Medicare Part D plans including patient copayments range 38 to 100% of WAC prices

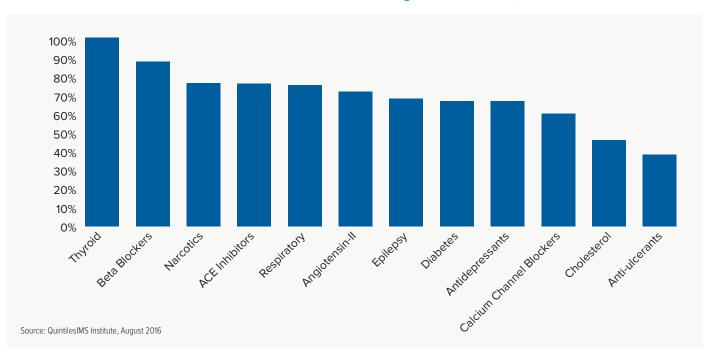


Chart 3: Net Costs to Medicare Part D Plans and Patients After Negotiated Discounts, as a Percent of WAC Price

- Negotiations result in significant cost reductions for most therapy classes. Most classes in this analysis were between 38 to 100% of WAC prices after accounting for negotiated discounts and rebates.
- Copayments in Medicare Part D are based on pharmacy prices, which plans can reduce by negotiating with pharmacies.
- In some classes, such as thyroid treatments, lower cost generics are available but branded medicines remain widely used. Placement of branded medicines on non-preferred tiers by payers and limited rebates by manufacturers result in higher patient cost-sharing and net costs closer to WAC prices.

Chart notes:

Analysis based on aggregate of 12 therapy classes (see Methodology and Scope). Net costs represent the plan's (or intermediary's) responsibility plus that of the patient. Intermediaries typically reimburse pharmacies for the cost of a prescription minus the patient copayment amount, and then are paid a rebate by drug manufacturers which result in the final net cost. Patient copays are based on Formulary Impact Analyzer (FIA) and reflect the annual copays for Medicare Part D patients in total, including patients at varying degrees of exposure to costs through the phases of the benefit.

About the QuintilesIMS Institute

The QuintilesIMS Institute leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision-makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision-making and improved patient care. With access to QuintilesIMS's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using QuintilesIMS information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision-making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.



QuintilesIMS Institute

100 IMS Drive, Parsippany, NJ 07054, USA info@quintilesimsinstitute.org www.quintilesimsinstitute.org