

A Study of Trends in Medicare Protected Classes

Commissioned by: Gilead Sciences, Inc.

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The Medicare Part D program currently requires substantial coverage of a subset of therapeutic treatments,¹ known as “Protected Classes”. At the request of Gilead, we analyzed cost changes over time.

Medicare regulations require Part D plan sponsors to include all available therapies on formulary in six classes or categories:

- Antidepressants
- Antipsychotics
- Anticonvulsants
- Immunosuppressants for treatment of transplant rejection
- Antiretrovirals
- Antineoplastics (except in limited circumstances)

Recent proposals have targeted the protected classes, ranging from abolishing protected classes altogether to introducing specific price controls. Gilead engaged Milliman to study changes in pricing of protected class drugs in the recent years relative to other classes. For purposes of this report, cost trend is the annual percentage change in Wholesale Acquisition Cost (WAC) per unit for highly utilized products in 2018 in Medicare Part D. Gilead’s objective of this analysis was to demonstrate the effect of changes in WAC prices in protected classes are similar to trends observed in the rest of the Part D market.

Results

We calculate that both protected and unprotected classes of medications have an average annual cost trend of -0.5% from 2014 to 2018. Table 1 shows the yearly cost trend for protected and unprotected classes. The negative annual cost trends are driven by the high proportion of generics in the experience, as well as decreasing costs of generic products (in both the protected classes grouping and other). In other words,

WAC prices continue to fluctuate (typically increasing for brands), but the recent mix of utilization is heavily weighted in products with decreasing costs (mostly generic), keeping total costs quite stable. The impact varies, depending on the availability of lower cost generics within each class.

TABLE 1: PROTECTED AND UNPROTECTED CLASS COST WAC TRENDS

Class	2015	2016	2017	2018	4 Yr. Avg
Unprotected	5.3%	-2.8%	-2.8%	-1.4%	-0.5%
Protected	3.9%	0.5%	-3.7%	-2.5%	-0.5%

Methodology

We used Milliman’s proprietary Part D Consolidated Database (PDCD) for utilization experience. This database is based on Medicare Part D experience, including over 40 million member months across 50 states and Puerto Rico. This analysis includes both brand and generic medications. We used 2018 days’ supply as the utilization metric and applied this to all years to eliminate the impact of utilization changes year-over-year to isolate only the cost changes. WAC prices from Medispan as of December 31st of each year were applied to each of the NDCs in the data. We categorized each NDC as protected or unprotected based on the therapeutic class the medication belongs. We calculated the annual cost trends based on NDC WAC prices per unit and weighted by 2018 days supply. This study includes only WAC price changes and excludes the impact of contracting changes over time such as rebates or discounts.

¹ The most recent Fact Sheet governing Part D protected class coverage is available at <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>

Caveats, Limitations, and Qualifications

The results in this document have been prepared for Gilead. We developed this information to calculate the annual WAC cost trends of protected and unprotected therapeutic classes using Medicare Part D data. This information may not be appropriate, and should not be used, for other purposes.

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In preparing our calculations, we used Milliman's Part D proprietary claims database. We relied on WAC prices by NDC from Medispan.

The results presented herein are calculations based on specific assumptions. Differences between these calculations and other calculations depend on the extent other calculations use the same methodology that was used in this work.

We do not provide legal advice, and recommend that readers consult with legal advisors regarding legal matters. This document provides objective quantification of historical data and is not advocating for any potential change or variations of changes, as previously proposed for protected classes. Milliman does not endorse any public policy or advocacy position on matters discussed in this document.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Susan Silseth and Jason Gomberg are actuaries for Milliman. They are members of the American Academy of Actuaries and meet the qualification standards to render the actuarial opinion contained herein.

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