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Background

The Balanced Budget Act (BBA) of 1997 established Medicare Part B drug payment at 95 percent of a drug's average wholesale price (AWP).[11] After the model proved to be wasteful because there was no uniform definition for AWP and the price did not incorporate rebates or other discounts, Congress reformed Part B drug payment in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.[12] The law changed Part B drug payment to each drug's volume-weighted, market-wide average sales price (ASP) plus 6 percent, net of rebates and other discounts. The new model was implemented in 2005, and in 2013 the 6 percent add-on was changed to a 4.3 percent add-on because Congress passed a 2 percent budget sequester.[13]

Methodology

Medicare Part B Drug Spending and Utilization data from the Centers for Medicare & Medicaid Services (CMS) for calendar years 2013-2017 were analyzed to estimate future spending, volume, and savings (2020-2024). For future estimates, budget neutrality was assumed based on the current 4.3 percent sequestration-adjusted add-on and annual spending and claims growth were projected according to 2013-2017 compounded average annual growth rates, assuming all else is held equal. Single flat fee payments to replace the percentage add-on were computed assuming budget neutrality within the Medicare Part B drug program.

Year	Budget-Neutral Single Flat Fee	Total Claims	Projected Total 4.3% Add-On Spend
2020	$22.45	72,189,382	$1,620,988,677
2021	$23.98	74,420,800	$1,784,271,628
2022	$25.60	76,721,194	$1,964,002,147
2023	$27.33	79,092,694	$2,161,837,005
2024	$29.18	81,537,499	$2,379,599,862

Any changes to the physician fee schedule were neither assumed nor incorporated, however, adjustments may be warranted to ensure costs for complex conditions and treatment regimens are adequately covered.

Savings were then calculated by identifying less expensive drug substitutes with similar clinical effectiveness that would be utilized more commonly over time if the percentage add-on incentive was replaced with a single flat fee. To identify candidates for substitution with similar clinical effectiveness, the top 40 Medicare Part B drugs, which in aggregate, contributed to the top 77.4 percent of Medicare Part B drug spending in 2017 were analyzed. Of the top 40, ten with substitutes were identified by clinical experts. These drugs make up almost half (47.7 percent) of the spending on the top 40 and 36.9 percent of all Part B drug spending.

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2017 Medicare Part B Spending for Top Ten Drugs that have Less Expensive, Clinically Effective Substitutes

Drug Brand (Generic)	Primary Indication	Medicare Part B Drug Spending, 2017	Portion of Medicare Part B Drug Spending, 2017
Eylea *Aflibercept*	Serious eye conditions	$2.5 B	8.4%
Rituxan *Rituximab*	Cancer	$1.8 B	5.9%
Neulasta *Pegfilgrastim*	Autoimmune	$1.4 B	4.7%
Remicade *Infliximab*	Autoimmune	$1.3 B	4.5%
Prolia *Denosumab**	Bone loss	$1.2 B	4.2%
Lucentis *Ranibizumab*	Serious eye conditions	$1.0 B	3.5%
Herceptin *Trastuzumab*	Cancer	$0.8 B	2.7%
Soliris *Eculizumab*	Blood disorder	$0.3 B	1.1%
Epogen *Epoetin Alfa**	Anemia	$0.3 B	1.0%
Aranesp *Darbepoetin Alfa*	Anemia	$0.3 B	0.9%
Total		**$10.9 B**	**38%**

Once clinically-similar candidates for each top-spend drug were identified, one substitute per drug was selected for the future savings model. To ensure conservative and realistic estimates, when multiple biosimilar substitution candidates were identified for a single drug, only the first to launch was selected. Further, if both a less expensive biologic substitute and biosimilar were candidates for substitution, the existing biologic substitute (e.g., Bevacizumab for Aflibercept) was selected instead of the newer biosimilar (e.g., Mvasi). Six of the substitutes selected for the savings model were biosimilars launched after 2017 and therefore their spending was not included in the CMS data file. To estimate future spending for these drugs, publicly announced/disclosed price discounts of the biosimilars relative to their originators were applied to the spending per claim for the originator product. Spending per claim was assumed to be equal to one administration per day.

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Assumed Biosimilar Price Discounts

Substitute	Price Discount	Source (accessed on December 4, 2019)
Average Biosimilar *(used for not-yet-launched Truxima)*	27%	https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf
Fulphila	33%	https://www.centerforbiosimilars.com/news/mylan-confirms-that-it-has-launched-fulphila-in- the-united-states
Retacrit	34%	https://www.centerforbiosimilars.com/news/pfizer-launches-epoetin-alfa-biosimilar-retacrit- at-335-discount-to-reference-epogen
Inflectra	19%	https://aishealth.com/specialty-pharmacy/second-biosimilar-remicade-launches-priced-at-35-of-wac/
Reflexis	35%	https://aishealth.com/specialty-pharmacy/second-biosimilar-remicade-launches-priced-at- 35-of-wac/
Kanjinti	15%	https://www.centerforbiosimilars.com/news/amgen-and-allergan-launch-mvasi-and-kanjinti- the-first-anticancer-biosimilars-in-the-united-states

To model changes in prescribing behavior following the payment reform, it is assumed that total spending and claims typically continue to grow at the compound annual growth rate observed between 2013-2017 for each drug, but that 5-to-10 percent of claims will shift each year from the expensive drug to the designated substitute. This means that for the mid-range volume shift of 7.5 percent annually, in 2020 the claims shift modeled is 7.5 percent and by 2024 the claims shift is 37.5 percent. In the case of the biosimilars included in this analysis, no further shifting from originator to biosimilar products is assumed.

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