Estimating the Budgetary Impact of Biosimilar Coding Policies Under Medicare Part B

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Executive Summary

The Centers for Medicare & Medicaid Services (CMS) has finalized a policy that groups all biosimilars to a reference product under a single Healthcare Common Procedure Coding System (HCPCS) billing code and payment rate. This report discusses the potential long-term effects of this policy on Medicare Part B drug spending and the future development of the biosimilars market compared to an alternative policy option, which would provide each biosimilar with its own billing code and separate payment rate.

WHILE CMS' POLICY IS ESTIMATED TO OFFER
$49.9 Billion in savings to the Medicare program over 10 years, an alternative coding policy could increase savings by an additional

$15.1 BILLION OR 30%

($65.0B in total over 10 years)

This report details the findings of a budget impact analyses, which shows that over time, a separate coding and payment policy could offer even greater savings to the Medicare program, as it could encourage greater price competition and uptake of biosimilar products in the marketplace.

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What Is a Biosimilar?

A biosimilar is a biological product licensed by the Food and Drug Administration (FDA) based on its comparability to an already FDA-approved reference product. A biosimilar is highly similar, but not identical, to its reference product, and has been proven to have the same clinical effect.[1] Licensure of a biosimilar follows an abbreviated regulatory pathway created by the Affordable Care Act (ACA).[2]

Biosimilars offer opportunities for significant cost savings relative to the reference products from which they are developed. Bringing a brand drug to market is estimated to cost $2.6 billion and take 10 or more years, while a single biosimilar is projected to take between 8 to 10 years to develop, at a cost of $100 million to $200 million.[3,4] The lower development costs and abbreviated licensing pathway mean biosimilars are likely to be offered at prices lower than those of branded reference drugs. **Policy experts have estimated that biosimilars could yield discounts of 20% to 40% compared to reference products, offering considerable savings to federal and state governments, health insurers, employers, and patients.[5,6]**

It is important to note, however, that the cost to develop complex biosimilars is significantly higher than generics, which are manufactured via relatively simple chemical synthesis. Traditional, small-molecule generics typically take 3 to 5 years to develop, at a cost of $1 million to $5 million, because their composition does not require the incorporation of biological sources.[4]

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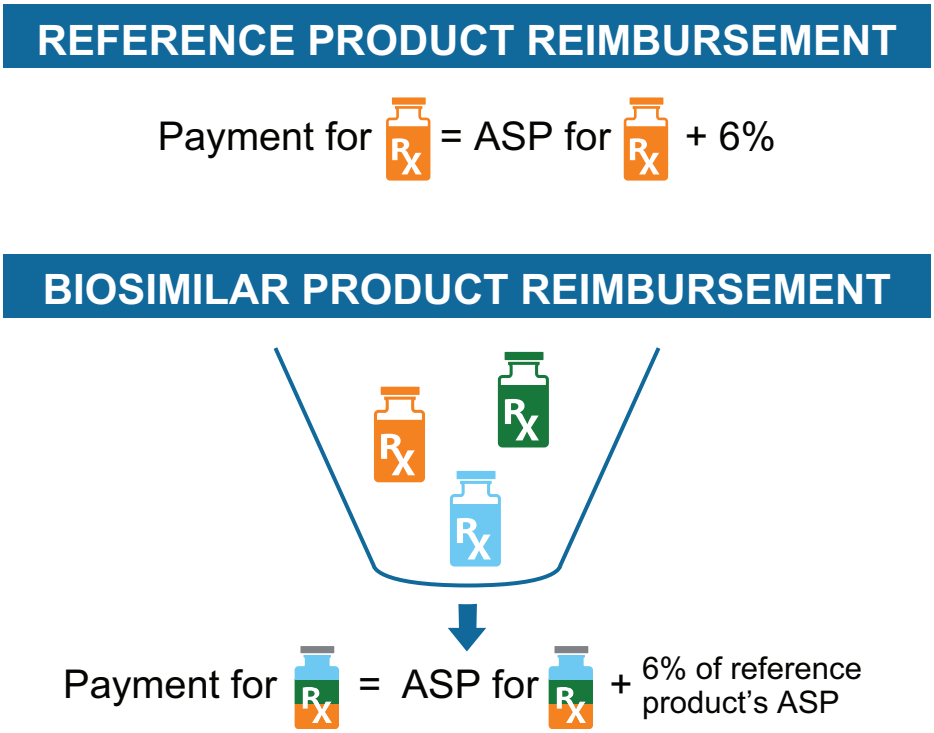
Biosimilars Reimbursement Landscape

The current estimated biosimilars pipeline suggests that the majority of biosimilars coming to market are anticipated to be physician-administered products that treat conditions prevalent in the Medicare population. Because of this, the Medicare Part B program, administered by CMS, is likely to be a significant payer for biosimilars in the US.

In November 2015, CMS finalized a controversial, and potentially debilitating, payment rule for biosimilars (often referred to as the J-code issue).[7] It announced that as of January 1, 2016, all biosimilars relative to the same reference product will also share the same HCPCS code and payment rate, separate from the reference product. This creates a single, blended Medicare reimbursement rate for the biosimilars based on the average sales price (ASP) of all biosimilars to a reference product, plus 6% of the ASP for the reference biologic.[a] According to the Medicare payment rule, reference products still maintain their separate HCPCS codes and individual ASPs.



[a] By law, biosimilars receive 6% of the reference product's ASP. Due to sequestration, however, the effective add-on payment amount is 4.3%.

CMS' decision to group biosimilars into a single HCPCS code with a blended payment rate for provider use is a striking contradiction to the complexity associated with biologics, and therefore, biosimilars. CMS itself recognizes some complications around its own policy; for example, rather than provide separate HCPCS and payment rates for simplicity, Medicare is requiring providers to add a modifier (eg, ABCD) to their Part B claims to specify which biosimilar manufacturer's product was administered to the patient.[8] In contrast, CMS is not requiring use of modifiers for the reference product. The use of a modifier is a partial solution that pertains only to Medicare claims; many private payers and state Medicaid programs do not have billing systems that support the use of the CMS-assigned modifier, yet they do have requirements to use HCPCS codes as determined by CMS.

Many stakeholders have expressed serious concern with this blended ASP approach for biosimilars that CMS adopted, as they believe CMS is circumventing how Congress intended Medicare to reimburse biosimilars, as written in the ACA.[9] Because CMS also administers the Medicaid program, and private payers often look to Medicare for guidance on payment policy, this coding policy could cause unintended consequences across the entire marketplace.

Additionally, because biosimilars may only be approved for some of the indications as their reference product, and not all biosimilars may be approved for the same indications, grouping these products together under a single HCPCS code and payment rate could also cause confusion among physicians and patients.[10,b] A lack of assurance that all products reported under one code share indications could lead to unintended off-label use. This could actually prompt physicians to continue using reference drugs, with their clearer coding guidance, instead of making the switch to biosimilars.

Reimbursement policies must be structured to incentivize physician uptake and manufacturer participation to ensure a robust market. Manufacturers will be critical in encouraging uptake of biosimilars through increased competition, marketing, and education, as low prices and limited uptake alone will not sustain a market. While CMS' payment policy for biosimilars may reap short-term cost savings, it could also have a chilling effect on future manufacturer investment in biosimilars due to uncertainty over the ability to recoup development costs.

[b] Biosimilars may be approved for different indications based on manufacturer determination, patent protections, orphan designations, or other reasons as determined by the FDA.

Estimating Medicare Part B Savings for Biosimilars

The Biosimilars Forum has pursued an effort aimed at defining and quantifying the impact of the CMS coding and payment biosimilars policy on the Medicare Part B program. Three budget impact models were developed to demonstrate the effect that biosimilars could have on Medicare Part B drug spending:

Baseline	Assumes the non-existence of biosimilars. Medicare Part B drug spending in 2015 for reference products likely to have a biosimilar by 2027 was used to project annual spending through 2027 using annual growth rates estimated by the Congressional Budget Office (CBO) June 2017 Medicare baseline[11]
CMS Current Policy	Assigns a separate HCPCS code and payment rate for all biosimilars to a specified reference biologic
Alternative Model	Assumes each biosimilar would be assigned its own HCPCS code, as guidance provided on biosimilar coding does not suggest other coding alternatives (eg, grouping reference products and biosimilars into a single HCPCS code)

Methodology

The models were built based on 19 reference products that are anticipated to have biosimilar counterparts by 2027 (**Table 1**). These 19 reference products represented approximately 58% of total Part B drug spending in 2015 ($9.1B out of $15.9B).[c]

[c] Medicare 5% Part B Standard Analytic Files. Data are weighted to reflect national estimates for the entire Medicare fee-for-service population.

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The year of biosimilar availability was based on when the reference product is expected to lose its exclusivity or 2018, whichever is later. Additionally, reference products were placed in either the "high-penetration group" or the "low-penetration group," based on Medicare Part B spending in 2015.[d] Reference products in the high-penetration group were likely to attract more biosimilar manufacturers due to their higher utilization potential, resulting in a greater number of market entrants. This could increase the availability and awareness of biosimilar alternatives in these markets.

Table 1. Reference Products Expected to Have Biosimilars by 2027

Reference Product	Estimated 2015 Medicare Part B Spending, USD ($ millions)*	First Year Biosimilar Could Be Available (ie, year exclusivity expires or 2018, whichever is later)	Market Penetration Category
ACTEMRA®	$135.4	2022	Low
Aranesp®	$217.2	2018	High
AVASTIN®	$775.3	2018	High
BOTOX®	$213.6	2018	Low
ERBITUX®	$124.9	2018	Low
EYLEA®	$1,967.7	2023	High
Herceptin®	$418.1	2018	High
Lucentis®	$1,242.6	2018	High
Neulasta®	$806.6	2018	High
NEUPOGEN®	$91.3	2015	Low
ORENCIA®	$370.0	2018	High
PROCRIT®	$268.9	2018	High
REMICADE®	$925.3	2016	High
RITUXAN®	$1,040.9	2018	High
SIMPONI®	$105.8	2025	Low
Soliris®	$100.4	2019	Low
STELARA®	$5.7	2025	Low
TYSABRI®	$177.3	2018	Low
XOLAIR®	$161.8	2018	Low
TOTAL SPENDING	**$9,148.7**		

*Source: Medicare 5% Standard Analytics Files, 2015 Part B physician office and hospital outpatient facility claims. Estimates are weighted to represent the US Medicare fee-for-service population.

[d] Products in the high-penetration group had >$200 million in estimated Medicare payments in 2015.

Uptake Rate

For the CMS Current Policy, Year 1 uptake was estimated at 15%, increasing to 35% by Year 10. These estimates were based on the 2008 pre-ACA CBO estimates of biosimilar uptake. CBO's Year 1 estimate of 10% was increased slightly to 15% for this model, as it appeared artificially low; however, it was included in the sensitivity analyses as presented in Appendix B.[5] Under the Alternative Model, uptake in Year 1 for low-penetration products was assumed to be slightly higher for new patients and follow CMS policy for all other patients; for high-penetration products, estimated uptake was increased by 5% (25% for new patients and 20% for all other patients in Year 1). The uptake for high-penetration products was increased slightly to reflect the additional awareness manufacturers may raise around these products in the marketplace compared to low-penetration products.

Table 2. Estimated Uptake Rate of Biosimilars at Year 1 and Year 10

		CMS Current Policy (High-penetration and Low-penetration)	Alternative Model	
			High-penetration	Low-penetration
Year 1	New patients	15%	25%	20%
	Other	15%	20%	15%
Year 10	New patients	35%	65%	60%
	Other	35%	60%	55%

Year 10 uptake rate estimates were set higher than the CBO estimates used for the CMS policy for the following reasons:

- The Alternative Model would increase physician confidence in using biosimilars from a reimbursement perspective. Under current CMS policy, physicians may be encouraged to continue using the reference product to eliminate uncertainty around reimbursement. With separate HCPCS codes and payment rates, physicians would be able to buy the lower-cost biosimilars without the concern of losing money when CMS publishes quarterly ASP files.[e]
- Assigning biosimilars to their own separate HCPCS codes and payment rates could encourage more biosimilar manufacturers to develop and market products, as well as provide assistance services to patients and healthcare providers to encourage uptake.

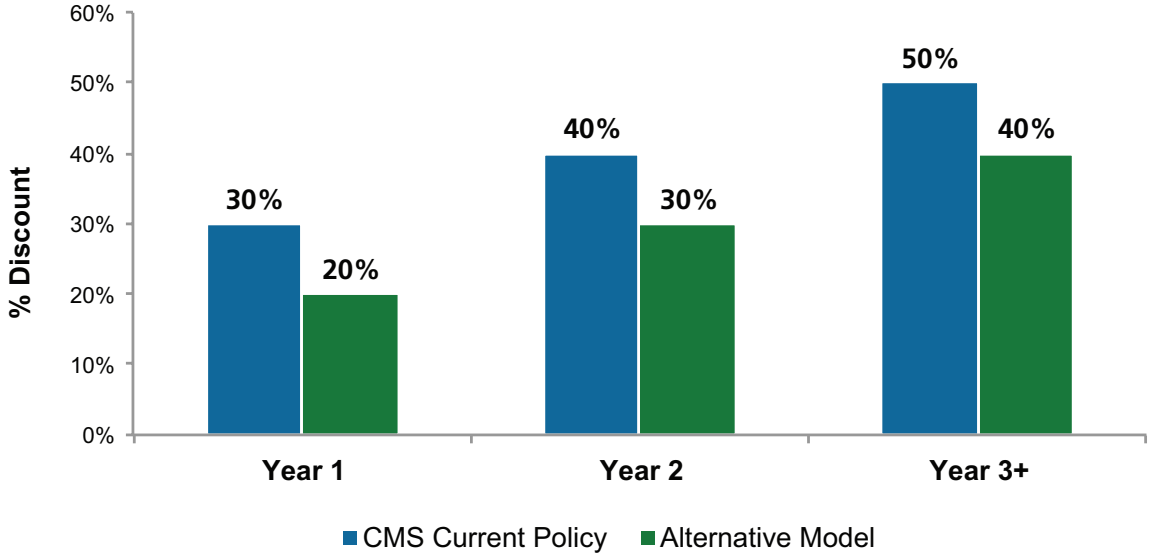
A logarithmic growth rate was applied to all products in the CMS Current Policy model, as well as the Alternative Model high-penetration biosimilars, to calculate expected uptake in Years 2 through 9. This assumes that uptake will increase year-over-year, but will level-out in the future as a product has been in the market for several years and providers have become comfortable with its use. For the Alternative Model low-penetration reference products, it was assumed there would be simple, linear growth to reflect fewer manufacturers developing and marketing these products from the start.

[e] ASP files are updated quarterly and reflect the ASP for a drug from 2 quarters back (ie, 2017 Q3 ASP payment rates are based on 2017 Q1 ASP filings from the manufacturer). Therefore, if the ASP for a product is continuously decreasing, practices may choose to use products that have their own established ASP with less fluctuation.

ASP for Biosimilar Products Compared to Reference Product

According to many estimates, biosimilars are expected to be discounted, on average, by 20% to 40% relative to reference products; these ranges have been included in the Alternative Model.[5,6] Under the CMS Current Policy, it is anticipated that grouping all biosimilars to a reference product under a single HCPCS code could result in deeper discounts (10% larger discount per year, 30–50%), as biosimilars sharing a code would likely have a "race to the bottom" on pricing. The ASP-based payment methodology benefits manufacturers who offer the least expensive products; therefore, each biosimilar entering the market would enter at a lower price than those currently on the market, driving the volume-weighted ASP downward toward an unsustainable rate. As a result, manufacturers could choose to exit the market, or not even enter it at all.[12]

Figure 1. Estimated Discounts for Biosimilars by Year

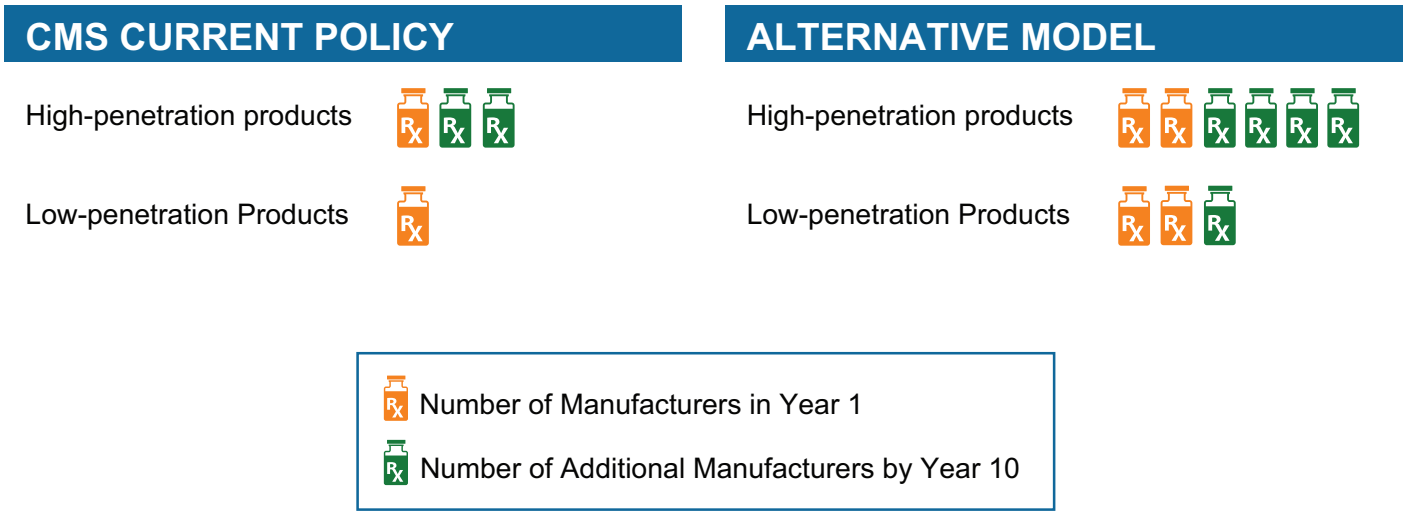


Manufacturers Developing and Marketing Biosimilars

In addition to considering pricing for biosimilars, the availability of products in the marketplace could have a significant effect on uptake. Under the CMS Current Policy, this model assumes there will be between 1 and 3 biosimilar manufacturers bringing products to market for high-penetration reference products over 10 years, as suggested by the CBO, and potentially a sole manufacturer for low-penetration products.[5]

Under the Alternative Model, competition is likely to increase over the long term, giving the opportunity for manufacturers to make the business case to bring these products to market; therefore, this model assumes that 2 to 6 manufacturers could develop biosimilars for high-penetration reference products over 10 years, and 2 to 3 manufacturers could develop biosimilars for low-penetration reference products. A linear year-to-year growth rate was assumed for the number of manufacturers between Years 2 through 9.

Figure 2. Estimated Number of Biosimilar Manufacturers by Year



Change in ASP for the Reference Product

Under the CMS Current Policy, the model assumes the ASP for the reference product will be unaffected by the introduction of biosimilars. Since the reference product will maintain its own, separate HCPCS code and payment rate, it would not be forced to respond to the entrance of biosimilars in the marketplace. Healthcare providers may be more willing to continue prescribing these products because the price will fluctuate less, and the reference product's reimbursement will remain steady as a result.

Under the Alternative Model, the ASP for the reference product could decrease slightly as a result of a more vibrant, competitive marketplace with biosimilars controlling their own ASP and naturally competing more aggressively with the reference product in addition to competing among themselves. In this case, the biosimilar would be on a more even footing with the reference product, which could force the reference product's manufacturer to respond to market pressures by lowering prices. This model assumes the ASP for the reference product would decrease by 3% in Year 2 after losing exclusivity, and by 5% by Year 3.

Results: Model Estimates

The baseline model predicts that Medicare Part B drug spending for the 19 reference products included in this analysis will increase from **$9.1B in 2015 to $20.5B by 2027**.[f] While both the CMS Current Policy and the Alternative Model suggest this baseline spending could be reduced with the introduction of biosimilars to the marketplace, the long-term savings of the Alternative Model are significantly higher due to the estimated increase in product uptake and the willingness of manufacturers to bring products to patients.

Cost savings are estimated to be $49.9B for the CMS Current Policy and $65.0B over 10 years for the Alternative Model. The Alternative Model suggests a 30% increase in cost savings over 10 years ($15.1B) relative to the CMS Current Policy. Over the long term, the differential in cost savings, as shown in Figure 3, could continue to grow, offering even greater savings to the Medicare program if biosimilars were assigned separate HCPCS codes and payment rates.

Table 3. Estimated Savings to Medicare Part B Drug Spending ($ Millions)

	5-Year Total 2018-2022	10-Year Total 2018-2027
CMS Current Policy	$9,735	$49,919
Alternative Model	$11,969	$65,010
Difference (Alternative Model – CMS Current Policy)	$2,235 (23%)	$15,091 (30%)

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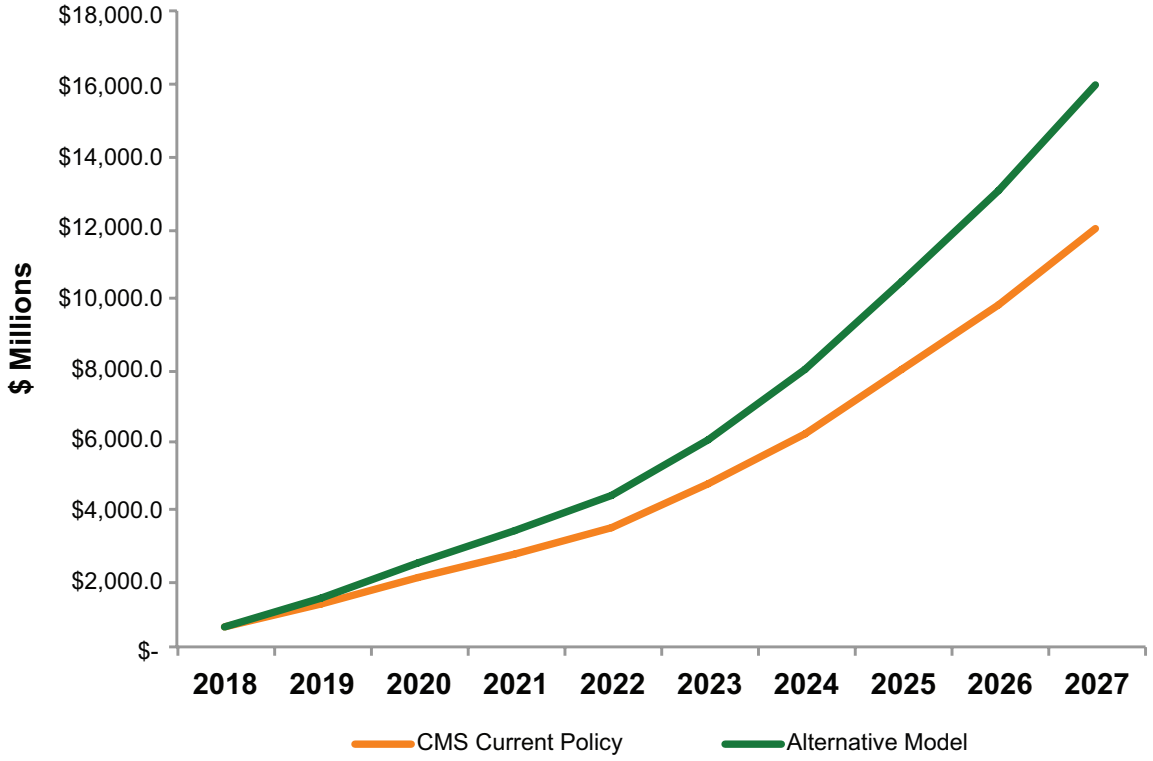
[f] These estimates include Medicare spending only and do not include payments made by secondary payers or beneficiary copayments.

Figure 3. Estimated Medicare Part B Savings for the CMS Current Policy and the Alternative Model, 2018–2027 ($ Millions)



Sensitivity analyses were developed to compare alternative uptake rates across the 2 policies. The Alternative Model is favorable in almost every scenario, suggesting it produces a more robust biosimilars market over time. Additional detail is provided in Appendix B.

Conclusion

Budget impact modeling indicates that while the CMS Current Policy for biosimilars could offer short-term savings to the Medicare program, an alternative policy that allows each biosimilar to have its own, unique HCPCS code and separate payment rate could produce even greater savings. A vibrant, competitive biosimilars marketplace could increase awareness of biosimilars as a whole, as more manufacturers would be contributing to provider and patient education initiatives to drive long-term uptake of these products. The CMS Current Policy on payment for biosimilars is likely to dissuade investment in biosimilar research and production from the outset. This could ultimately limit access to these products for Medicare patients, as well as those covered by other payers who use Medicare policy as guidance for coverage, coding, and payment determinations. Faced with the reality of grouped pricing that does not take into account each biosimilar being different from the other (unlike small-molecule generics), manufacturers will likely delay or forego investment in developing biosimilars. **It is imperative that steps are taken immediately to ensure policymakers are aware of the long-term effects associated with CMS' policy, as it will have a significant impact on the growth of the biosimilars market over the next 5 to 10 years.**

To avoid the shortcomings of CMS' biosimilar coding and pricing policy, manufacturers may leave the marketplace entirely or decide to sidestep the biosimilar regulatory pathway in favor of pursuing the longer, more expensive route of submitting a competitive Biologics License Application. Since this route would drive the costs of competitive development up to traditional biologic levels, the resultant product would have to be priced accordingly to recoup development costs. Consequently, this pathway would diminish the potential cost savings of a biosimilar, and, in turn could ultimately delay patient access to more affordable medications.

Ultimately, patients who could benefit from the availability of biosimilars are likely to lose the most. Under Medicare's payment policy for biosimilars, manufacturers and physicians would both shy away from adoption, thereby increasing costs and limiting treatment options available to patients. Patients would benefit the most from a payment policy that achieves long-term savings and supports a competitive marketplace.

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Appendix A. Annual Model Estimates

Estimated Medicare Savings ($ Millions)

	Baseline (19 Reference Products)	CMS Policy	Alternative Model	Difference in Estimated Cost-savings (Alternative-CMS)
2018	$10,722	$588	$586	$(2)
2019	$11,398	$1,199	$1,379	$180
2020	$12,218	$1,964	$2,412	$448
2021	$13,233	$2,614	$3,285	$671
2022	$14,265	$3,370	$4,308	$938
2023	$15,349	$4,601	$5,852	$1,252
2024	$16,500	$6,083	$7,881	$1,799
2025	$17,688	$7,893	$10,406	$2,513
2026	$18,908	$9,723	$12,952	$3,229
2027	$20,459	$11,885	$15,948	$4,063
5-Year Total	**$61,836**	**$9,735**	**$11,969**	**$2,235**
10-Year Total	**$150,740**	**$49,919**	**$65,010**	**$15,091**

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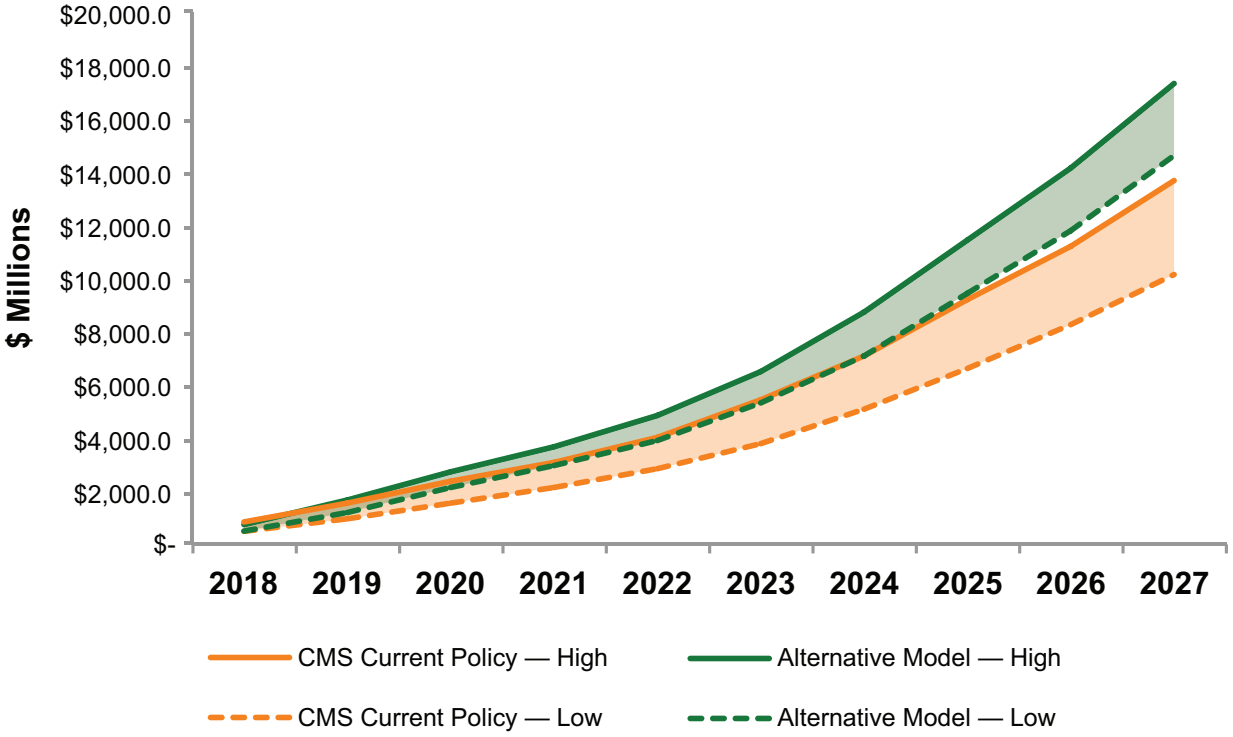
Appendix B. Sensitivity Analysis

Because the marketplace for biosimilars is still relatively unknown, sensitivity analyses were completed around uptake rate estimates, as these were the most significant drivers of the model (followed by biosimilar discounts). For the lower uptake rate analysis, all estimates in Table 2 were reduced by 5 percentage points; for the higher bound uptake rate analysis, they were increased by 5 percentage points. This analysis suggests that the Alternative Model could offer up to $71.4B in annual savings over 10 years, whereas the CMS best-case uptake scenario could only offer up to $58.2B.

Estimated Medicare Part B Savings for the CMS Current Policy and the Alternative Model, With Varying Uptake Rates 2018–2027 ($ Millions)



References

1. Food & Drug Administration. Information for healthcare professionals (biosimilars). https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm241719.htm. Accessed August 17, 2017.
2. Food and Drug Administration. Affordable Care Act. §7002: Approval pathway for biosimilar biological products. May 1, 2010. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/ucm216146.pdf. Accessed August 17, 2017.
3. DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics. 2016;47:20-33. http://www.sciencedirect.com/science/article/pii/S0167629616000291. Accessed August 17, 2017.
4. Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. June 2009. https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report. Accessed August 17, 2017.
5. Congressional Budget Office. Cost Estimate of S. 1695, Biologics Price Competition and Innovation Act of 2007. June 25, 2008. https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/costestimate/s16950.pdf. Accessed August 17, 2017.
6. Mulcahy A, Predmore Z, and Soeren M. The cost savings potential of biosimilar drugs in the United States. Santa Monica, CA: RAND Corporation, 2014. http://www.rand.org/pubs/perspectives/PE127.html. Accessed August 17, 2017.
7. Centers for Medicare & Medicaid Services. Federal Register: Revisions to payment policies under the Physician Fee Schedule and other revisions to Part B for CY 2016; Final Rule: §70885. November 16, 2015. https://www.federalregister.gov/documents/2015/11/16/2015-28005/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions. Accessed August 17, 2017.
8. Centers for Medicare & Medicaid Services Manual System. Pub 100-20 one-time notification. Transmittal 1542. Implementation of biosimilar claim modifiers. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1542OTN.pdf. Accessed August 17, 2017.
9. Affordable Care Act. §3139: Payment for biological biosimilar products. May 1, 2010. https://www.hhs.gov/sites/default/files/ppacacon.pdf. Accessed August 17, 2017.
10. Food & Drug Administration. Labeling for biosimilar products: guidance for industry. March 2016. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM493439.pdf. Accessed August 17, 2017.
11. Congressional Budget Office. March 2015 Medicare baseline. June 2017 Medicare baseline. https://www.cbo.gov/sites/default/files/recurringdata/51302-2017-06-medicare.pdf. Accessed August 17, 2017.
12. The Moran Company. The role of coding in the development of the biosimilar market: considerations for policymakers. July 2015. http://www.biosimilarsforum.org/sites/default/files/uploads/press-releases/the_role_of_cms_coding_in_the_development_of_the_us_biosimilar_market_20_.pdf. Accessed August 17, 2017.

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