



Advising the Congress on Medicare issues

Biosimilars in Medicare Part D

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Presentation overview

- Background on biologics and biosimilars
- Related issues in Medicare Part D
 - Recent use of and spending for biologics
 - Factors affecting take up of biosimilars
 - CMS guidance to plans on biosimilars
 - Biosimilars and the coverage-gap discount
- Discussion

Background on biologics and biosimilars

- **Biologics:** Large-molecule therapies synthesized from living cells or organisms
 - Used for treating diseases such as diabetes, rheumatoid arthritis, multiple sclerosis
 - Injected or infused
- **Biosimilars:** Follow-on products that are highly similar to reference biologic
 - Like generics, may introduce price competition
 - But unlike generics:
 - Active substance not identical to reference biologic's
 - More expensive to develop and produce

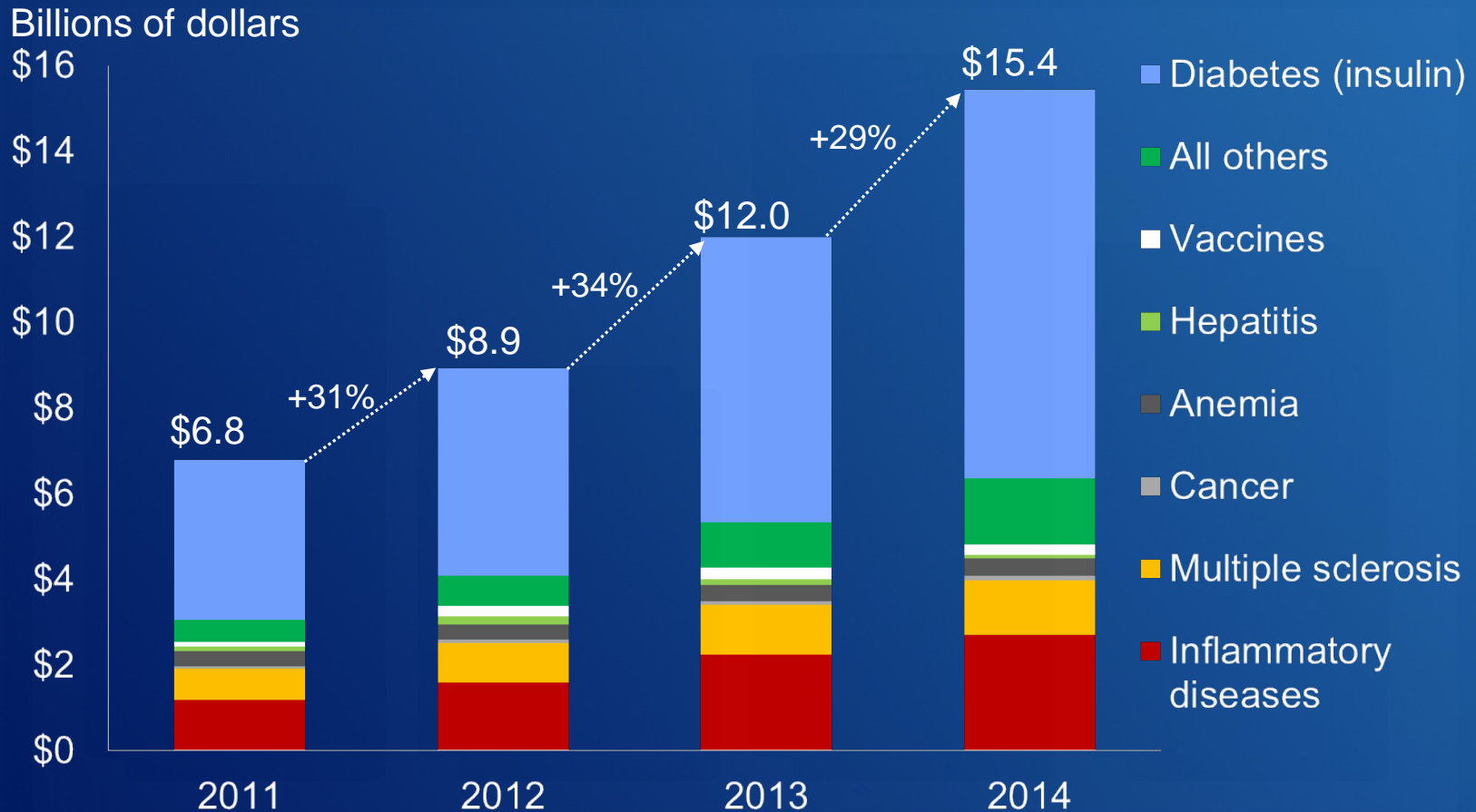
Most biologics are specialty drugs

- Prices typically high
- Nationwide, biologics account for:
 - <1% of prescriptions, but 28% of spending
 - Faster spending growth than most other medicines
- High prices and spending growth raise concerns for Part D:
 - Beneficiary out-of-pocket costs (OOP) and access
 - Medicare program's financial sustainability

How Medicare pays for biologics and biosimilars in Part D

- Spending for biologics is part of plans' bids
 - Medicare pays plans
 - Capitated amount (direct subsidy)
 - 80% reinsurance above OOP threshold
 - Plan sponsors negotiate
 - Pharmacy payment rates, discounts, and fees
 - Rebates from manufacturers
- Enrollees who use high-priced biologics tend to reach the OOP threshold
 - Beneficiary pays 5% cost sharing
 - Medicare bearing most of catastrophic costs

Insulin makes up the largest share of gross spending for biologics in Part D



Source: MedPAC analysis of Part D prescription drug event data.

Note: Data are preliminary and subject to change. Spending does not reflect retrospective rebates, discounts, or fees paid by manufacturers and pharmacies to Part D plans.

Effect of price competition from biosimilar entry

- CBO estimate (2008)
 - 20% – 40% lower prices, varies by product and over time
 - Overall savings, even with expanded use
- European experience over the past decade
 - Prices have fallen over time, but varies across countries
 - Higher use of biosimilars associated with “winner take all” procurement
 - Larger effects when countries encourage biosimilar use (e.g., effectiveness studies, prescriber outreach)
- Some PBMs and insurers putting biosimilars on commercial formularies, excluding reference biologics

Take up of biosimilars will depend on many factors

- Patients' and prescribers' perceptions about safety and effectiveness
 - Concerns about immunogenicity (immune response)
 - Interchangeability and state substitution laws
 - Naming conventions
- For payers and patients, relative prices and OOP costs compared to reference biologics
- Part D law and regulations on biosimilars

Part D law and regulations on biosimilars

- Formulary treatment of biosimilars and reference biologic
 - Covering reference biologic and its biosimilar will not satisfy 2 drugs per class requirement (i.e., not considered distinct drugs)
 - Considered separate products for transition fills
- Mid-year formulary change
 - Adding a biosimilar and removing a reference biologic treated as a non-maintenance change

Part D law and regulations on biosimilars – continued

- LIS copay amount for biosimilars same as for reference biologic
- No coverage gap discount for biosimilars
 - Beneficiaries
 - Higher coinsurance for biosimilar (before 2020)
 - Reach OOP threshold more quickly, with lower OOP costs, using reference biologic
 - Plan sponsors
 - Gap discount reduces costs for reference biologic
 - More spending in catastrophic phase where Medicare pays 80% in reinsurance

Hypothetical example: coverage-gap discount and incentive to use biosimilars

Spending during the “gap” phase in 2020			
	Benefit structure	Gross spending	“True OOP” spending
Use <u>reference biologic</u> (\$3,000)			
Plan liability	25%	\$750	\$0
Gap discount	50%	\$1,500	\$1,500
Beneficiary coinsurance	25%	\$750	\$750
Total	100%	\$3,000	\$2,250
Use <u>biosimilar</u> (\$2,550)			
Plan liability	75%	\$1,913	\$0
Gap discount	0%	\$0	\$0
Beneficiary coinsurance	25%	\$638	\$638
Total	100%	\$2,550	\$638

Mixed incentives for plan formularies: biosimilars vs. reference biologic

- Incentives to encourage enrollees to use lower-cost products such as biosimilars to keep premiums low
- vs.
- Potential financial advantage of reference biologics because of the gap discount
- One option: Apply the gap discount to biosimilars
- Note that the Commission's June 2016 recommendations would exclude gap discount from true OOP spending
- Standardize the treatment of all drugs and biologics in the coverage gap, ensure plan incentives to encourage the use of lower-cost products

Summary

- Part D spending for biologics is growing
- High prices raise concerns about access and Part D's financial sustainability
- Biosimilars potentially could address concerns
- But take up is uncertain:
 - Prescriber and patient safety concerns
 - Part D law and regulations

Discussion

- Questions about this presentation
- Level of interest in pursuing further?
 - Formulary rules around biosimilars
 - Treatment of biosimilars in the coverage gap
- Other related issues