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

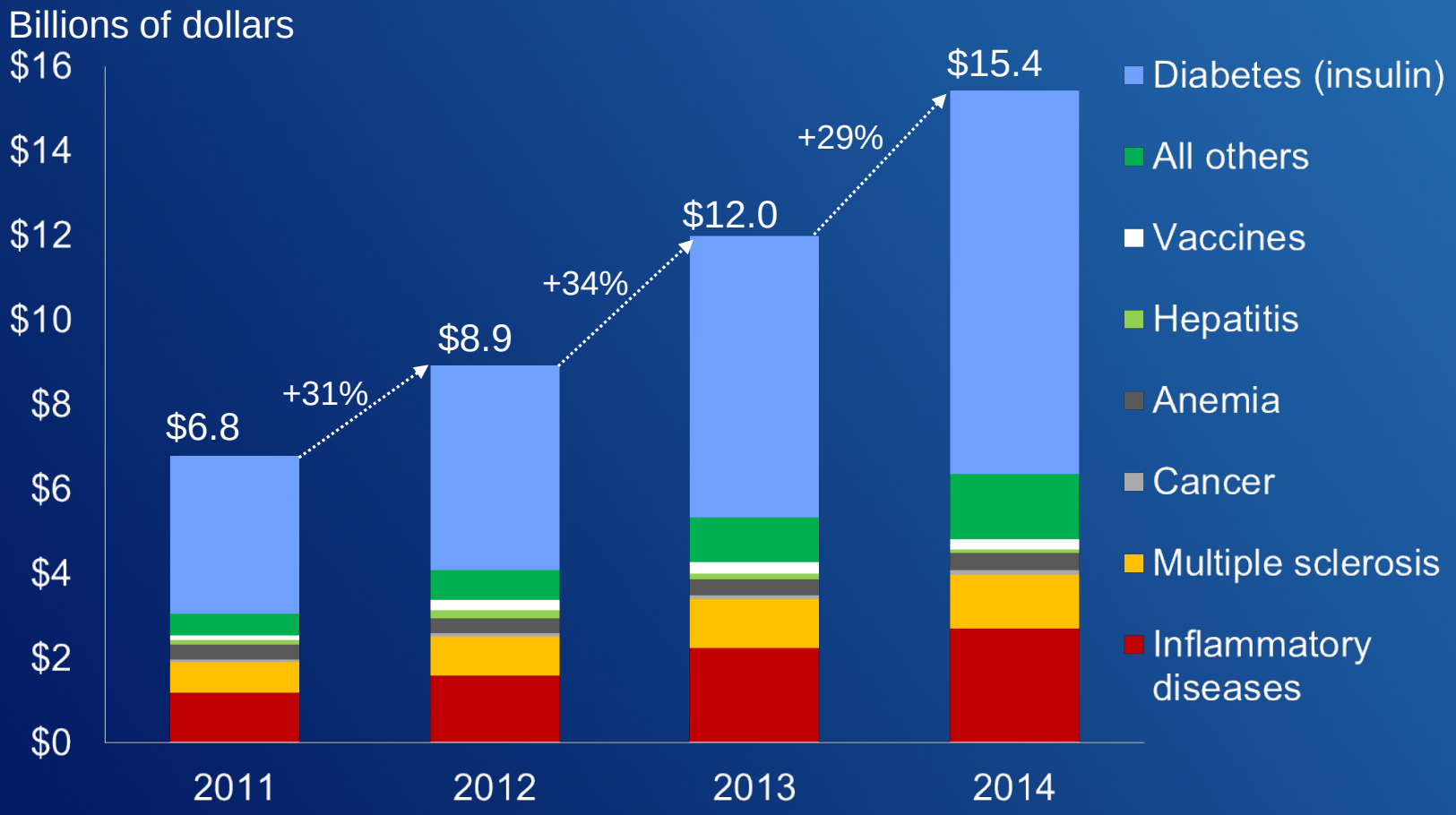
Most biologics are specialty drugs

- 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.

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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 reference biologic ($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 biosimilar ($2,550)			
Plan liability	75%	$1,913	$0
Gap discount	0%	$0	$0
Beneficiary coinsurance	25%	$638	$638
Total	100%	$2,550	$638

Note: OOP (out-of-pocket). Figures used in this hypothetical example do not reflect other manufacturer rebates or discounts. Although coverage gap will be phased out by 2020, CMS will continue to track what would have been the coverage gap in order to calculate the amount of discount owed by brand manufacturers.

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