



*Advising the Congress on Medicare issues*

# Biosimilars in Medicare Part D

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# Presentation overview

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- 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

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- **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

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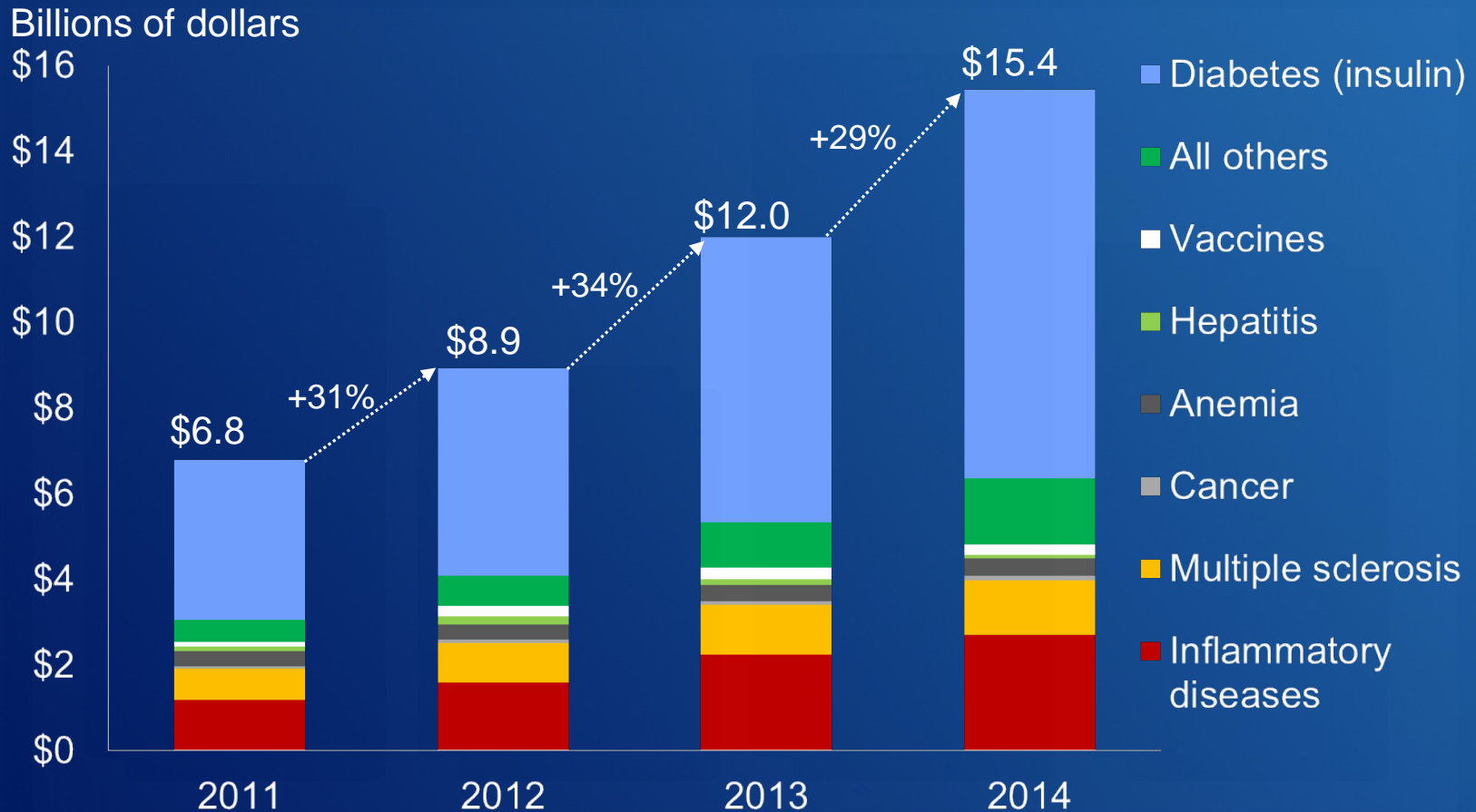
- Prices typically high
- Nationwide, biologics account for:
  - <1% of prescriptions, but 28% of spending
  - Faster spending growth than most other medicines
- High prices and spending growth raise concerns for Part D:
  - Beneficiary out-of-pocket costs (OOP) and access
  - Medicare program's financial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

# How Medicare pays for biologics and biosimilars in Part D

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- 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

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- 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

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- 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

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- 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

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- 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
<b>Use <u>reference biologic</u> (\$3,000)</b>			
Plan liability	25%	\$750	\$0
Gap discount	50%	\$1,500	\$1,500
Beneficiary coinsurance	25%	\$750	\$750
<b>Total</b>	<b>100%</b>	<b>\$3,000</b>	<b>\$2,250</b>
<b>Use <u>biosimilar</u> (\$2,550)</b>			
Plan liability	75%	\$1,913	\$0
Gap discount	0%	\$0	\$0
Beneficiary coinsurance	25%	\$638	\$638
<b>Total</b>	<b>100%</b>	<b>\$2,550</b>	<b>\$638</b>

# Mixed incentives for plan formularies: biosimilars vs. reference biologic

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- 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

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- 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

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