

Slouching Towards BIMtopia

Is It Time to Rethink Budget Impact Analysis?

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BIMs: The Good, The Bad, and The Ugly



BIMs and Gene Therapy: The Good, the Bad, and the Ugly



The Good

- A staple of health insurance plan formulary submission dossiers
- The workhorses of many health outcomes research units
- ISPOR and AMCP have published guidance to encourage standardization.



The Bad

- In a standard BIM, the insurer pays the entire cost upfront
- Downstream savings may occur far beyond the typical BIM time horizon of 3-5 years
- Standard BIMs may not be fair to patients or manufacturers can create perverse incentives



The Ugly

- 7 of the 10 most expensive drugs were approved between 2020 and 2023, ranging between \$1 and \$3 million
- 6 of these were gene therapies: in theory administered once in a patient's lifetime and (likely) guaranteeing a cure

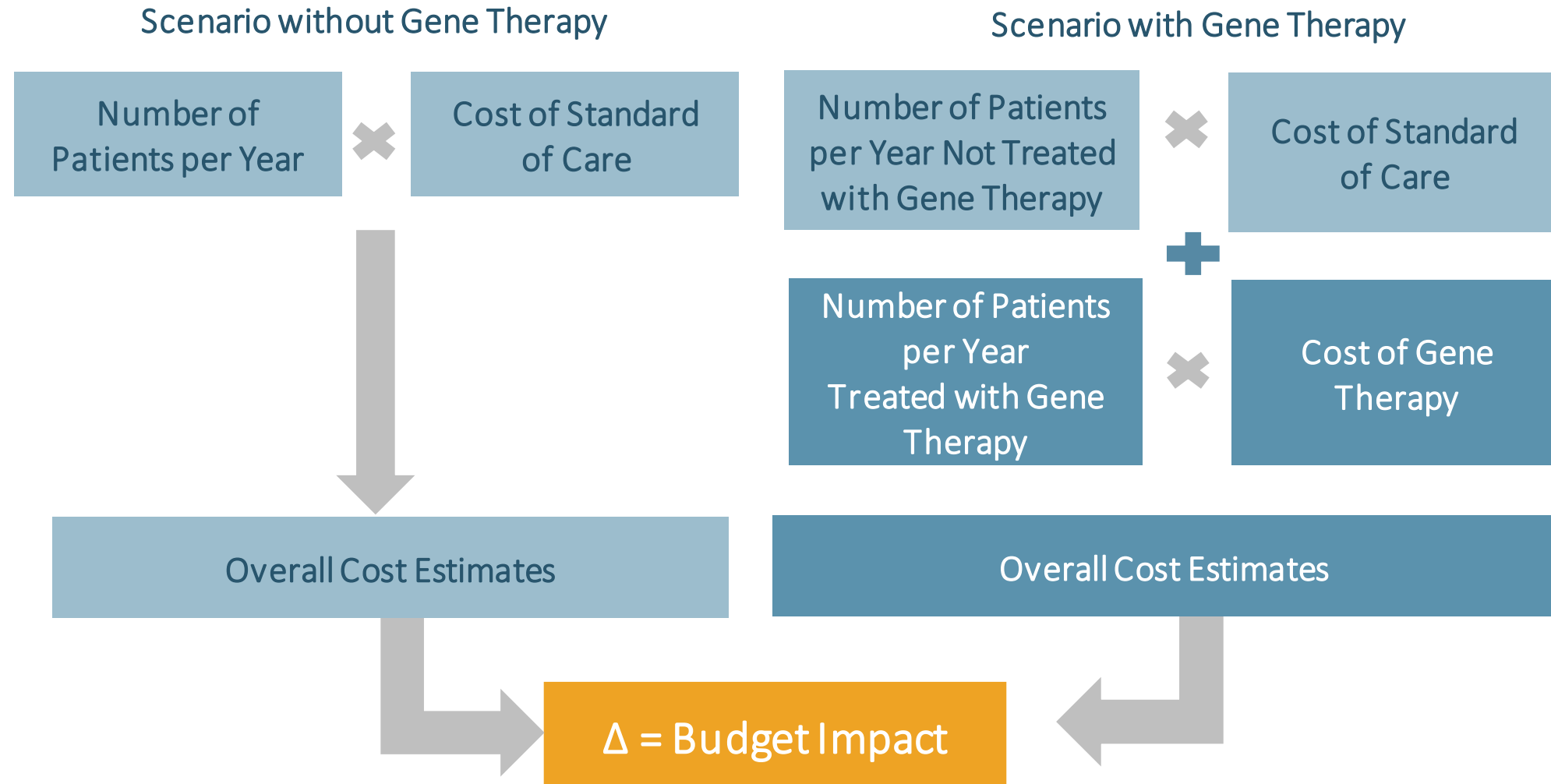
BIMs: The Good, the Bad, and the Ugly

>60 gene therapies are expected to be approved by 2030, all very likely to cost (much) more than \$1 million

The standard approach for BIMs may not be fair to patients and manufacturers and can create perverse incentives



Example: Gene Therapy for Sickle Cell Disease



Hypothetical Inputs: Gene Therapy for Sickle Cell Disease

Feature	Description	Input
Plan Enrollment	Plan size	1,000,000 members
	Average duration of enrollment (SD)	3.1 years (1.0)
Epidemiology	Prevalence of sickle cell disease	5 per million
	Proportion eligible for gene therapy	20%
	Proportion of eligible patients who receive gene therapy each year	25%
Clinical Inputs	Gene therapy responder rate	80%
Costs	One-time cost of gene therapy	\$3,000,000
	Annual cost of care with successful gene therapy	\$50,000
	Annual cost of care without and non-responders to gene therapy	\$250,000



Alternative BIM Approaches and Resultant Outcomes

■ Traditional Approach

■ Patient-Level Simulation

- Accounts for year-to-year unpredictability for rare diseases

■ Amortization

- Cost of therapy is spread out over multiple payments, with interest

■ Outcomes-Based Risk Sharing

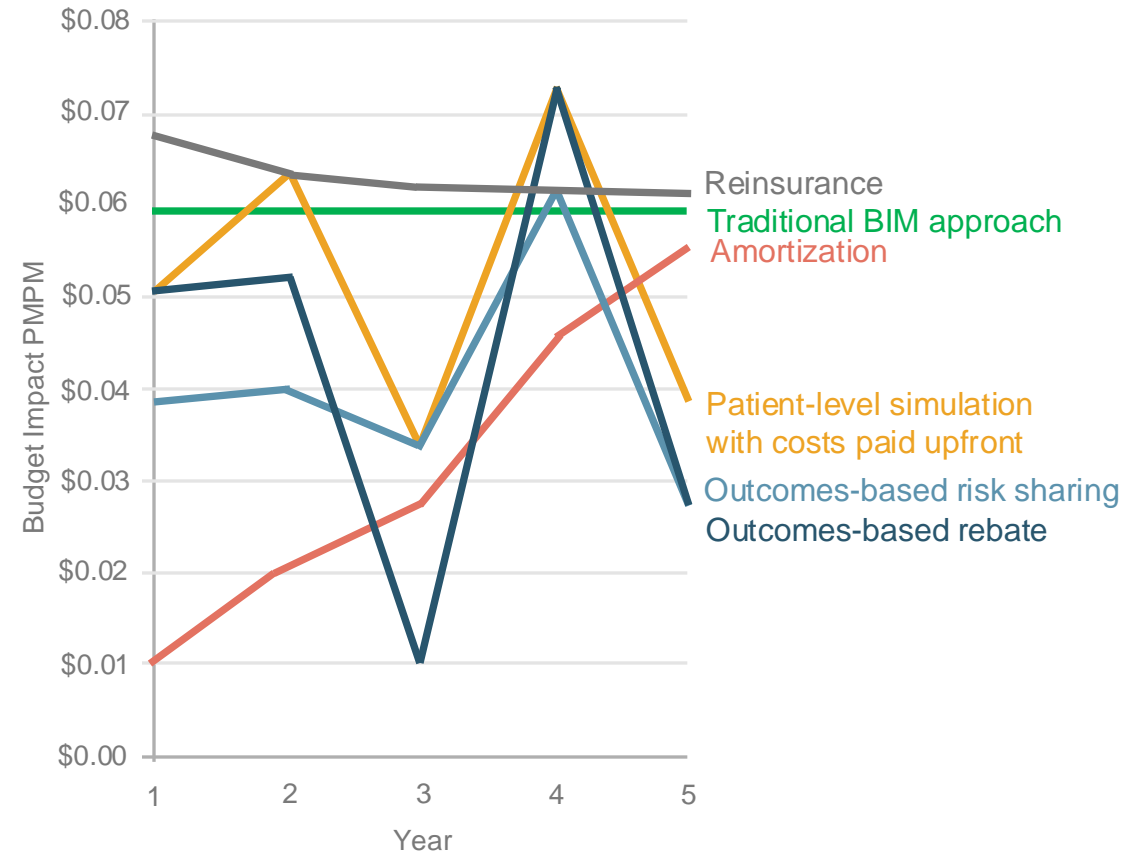
- Payer only if the patient is a responder

■ Outcomes-Based Rebate

- Payer receives a rebate from the manufacturer if the patient is a non-responder

■ Re-Insurance

- Payer pays a premium per member to third-party reinsurer. The reinsurer then covers the cost of gene therapy



Suggestions



Consider implementing alternative BIM structures in addition to standard approaches to reflect novel payment mechanisms for high-cost therapies



Consider a more dynamic and open communication between payers and manufacturers during BIM development, iterating as payment negotiations progress



Develop standards for creating and presenting BIMs under the most common outcomes-based agreements



Consider payer policies aimed at avoiding moral hazard (patients leaving an insurer after getting a very high-cost treatment)



Implement multiple payment models as scenario analyses



Ask payers what would be most useful to them in a BIM

BIMs aren't going away, but...

- BIMs continue to serve a useful purpose as part of the dialogue between manufacturers and payers
- The current BIM approach is less relevant for the highest cost (and highest profile) products—particularly those like gene therapies that load all treatment costs into a single, huge up-front payment
- Modernized BIMs could be an accelerator for alternative payment models if they serve to remove some of the uncertainty that surrounds them and provide a transparent tool for negotiations.

The BIM community must accommodate and incorporate the changing payment landscape for these therapies



References

1. Basu A, Winn AN, Johnson KM, et al. Gene Therapy Versus Common Care for Eligible Individuals With Sickle Cell Disease in the United States : A Cost-Effectiveness Analysis. *Ann Intern Med.* 177(2):155-164.
2. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget Impact Analysis-Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value Health.* 2014;17(1):5-14.
3. Academy of Managed Care Pharmacy (AMCP) Guidance on Submission of Pre-Approval and Post-Approval Clinical and Economic Information and Evidence, Version 4.1.
4. 10 of the Most Expensive Drugs in the U.S. January 15, 2024.<https://www.drugs.com/article/top-10-most-expensive-drugs.html>.
5. Young CM, Quinn C, Trusheim MR. Durable Cell and Gene Therapy Potential Patient and Financial Impact: US Projections of Product Approvals, Patients Treated, and Product Revenues. *Drug Discov Today.* 2022;27(1):17-30.
6. Horrow C, Kesselheim AS. Confronting High Costs And Clinical Uncertainty: Innovative Payment Models For Gene Therapies. *Health Aff (Millwood).* 2023;42(11):1532-1540.
7. Centers for Medicare & Medicaid Services. Cell and Gene Therapy (CGT) Access Model.

Thank You

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