



Budget Impact of Introducing Bepirovirsen for Chronic Hepatitis B in a Mixed Commercial and Medicare Health Plan: A Five-Year Budget Impact Model

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INTRODUCTION

Disease Burden: Chronic hepatitis B (CHB) is a lifelong infection that can lead to serious liver-related complications, including cirrhosis, hepatocellular carcinoma (HCC), liver failure, and death¹.

• Approximately 640,000 U.S. adults are estimated to have CHB²

Unmet Need: Nucleoside analogue (NA) therapies suppress HBV replication and reduce liver-related complications but rarely achieve functional cure³

Economic Burden: Healthcare resource utilization and costs increase with disease severity and differ by payer

• Among Medicare patients with decompensated cirrhosis, mean annual all-cause healthcare costs reached \$184,215 per patient in a U.S. claims analysis⁴

Emerging Functional Cure Therapy: Bepirovirsen; investigational antisense oligonucleotide targeting HBV RNA

OBJECTIVE

To estimate the 5-year budget impact of introducing bepirovirsen plus standard NA therapy compared with standard NA therapy alone among eligible adults with CHB from the perspective of a hypothetical U.S. mixed commercial and Medicare health plan.

METHODOLOGY

TREATMENT & COST ASSUMPTIONS

- Bepirovirsen was modeled as 300 mg SC weekly for 24 weeks (+2 loading doses) in addition to standard NA therapy⁵
- Scenario 2 Year 1: 20% of the eligible population was assumed to initiate bepirovirsen; uptake increased by 20% annually thereafter
- Bepirovirsen acquisition cost was estimated using finite-duration HCV antiviral pricing analogues

Table 1: HCV Antiviral Pricing Analogues Used to Estimate Bepirovirsen Acquisition Cost^{6,7}

Treatment	WAC per 4 weeks	Treatment Duration	Total Treatment Cost
MAVIRET [®] (glecaprevir/patrasvir)	\$12,200 ⁸	8 weeks (treatment-naïve)	\$26,400
Bepirovirsen (estimated)	\$19,880	24 weeks + 2 loading doses⁹	\$123,880
EPCLUSA [™] (sofosbuvir/velpatasvir)	\$24,620 ⁹	12 weeks (treatment-naïve)	\$174,760

WAC = wholesale acquisition cost

- NA acquisition costs reflected weighted utilization of entecavir, tenofovir-based therapies, and other NAs
- Eligible patients discontinued (DC'd) NA therapy at Week 48, with functional cure (FC) assessed at Week 72¹⁰
- Costs included drug acquisition and modeled medication management of NA-associated osteoporosis and chronic kidney disease (CKD)
- Bepirovirsen acquisition cost was estimated using finite-duration HCV antiviral pricing analogues

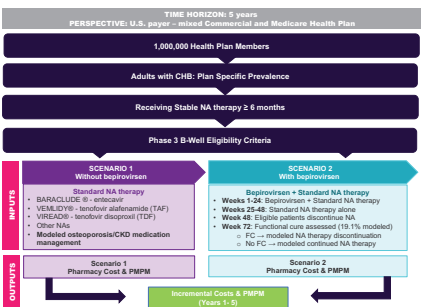
Table 2: Key Pharmacy Cost Inputs and Post-NA Discontinuation Utilization Inputs (WAC)¹¹

NA Therapies	Dose Regimen ¹	WAC ²	Annual Cost per Member	Post-NA Discontinuation Utilization (%)			
				Y1	Y2	Y3	Y4
BARACLUDE [®] - entecavir	0.5 mg PO daily	\$7,248/box	\$2,643				
VELMIDY [®] - lenvovir alafenamide (TAF)	20 mg PO daily	\$2,739/box	\$967				
VRACOR [®] - lenvovir dispersol (TDF)	300 mg PO daily	\$14,246/box	\$5,199				
Other NAs	PO daily						
Osteoporosis medication management							
Azelastron	70 mg PO weekly	\$4,783/box	\$249	50.4%	25.4%	12.8%	6.5%
Risedronate	35 mg PO weekly	\$28,278/box	\$1,474	50.5%	25.5%	12.8%	6.5%
Zoledronic acid	5mg IV yearly	\$242,918/box	\$243	100%	100%	0%	0%
Denosumab	60 mg SC every 6 months	\$1,931,691/box	\$3,863	82.7%	71.6%	59.2%	49%
Teniposide	20 mg SC daily	\$78,373/box	\$28,806	50.4%	0%	100%	100%
TYNEDIY [®] - dasiposide	80 mg SC daily	\$88,956/box	\$14,489	50.4%	0%	0%	0%
EVENTHY [®] - venetoclamil	210 mg SC monthly	\$2,763,378/box	\$33,124	0%	0%	0%	0%
CKD medication management							
ACE inhibitor / ARB	Once PO daily	\$1,639/box	\$593	90%	80%	70%	60%

Table 3: Summary of Parameter Characteristics

Parameter	Scenario 1 (without bepirovirsen)		Scenario 2 (with bepirovirsen)	
	Commercial	Medicare	Commercial	Medicare
Health plan population distribution (%)				
CHB prevalence (%)	66.1%	33.9% ¹	66.1%	33.9% ¹
CHB incidence (%)	0.048% ¹	0.082% ¹	0.048% ¹	0.082% ¹
CHB incidence (%)	0.0064% ¹	0.0059% ¹	0.0064% ¹	0.0059% ¹
Members with CHB receiving NA 8 months (%)	32.67% ¹	22.34% ¹	32.67% ¹	22.34% ¹
Percentage of members who start on bepirovirsen Year 1 among the targeted population			20%	20%
Percentage of members who develop cure on bepirovirsen after 6 months (%)			19.15%	19.15%
Percentage market increases per year for bepirovirsen (%)			30%	30%

Figure 1: Modeled Population Flow for Scenarios 1 and 2¹⁴



PLAN CHARACTERISTICS

- Commercial and Medicare populations are modeled separately using payer-specific CHB prevalence and healthcare utilization/cost inputs when available
- Modeled eligibility reflects the Phase 3 B-Well population¹⁵
- Adults with CHB receiving stable NA therapy
 - HBsAg 100-3,000 IU/mL
 - HBV DNA < 90 IU/mL
 - ALT < 2x upper limit of normal
- Functional cure (FC) definition¹⁶
 - HBsAg loss (<0.05 IU/mL) and HBV DNA < lower limit of quantification (<20 IU/mL or not detected), sustained for ≥24 weeks of all HBV treatment

RESULTS

Table 4: Annual Pharmacy Cost by Coverage Scenario

Year	Scenario 1 (Without bepirovirsen)	Scenario 2 (With bepirovirsen)
1	\$0.47M	\$4.58M
2	\$0.53M	\$5.85M
3	\$0.58M	\$7.48M
4	\$0.63M	\$9.60M
5	\$0.68M	\$12.32M

Figure 2: Annual Pharmacy Cost by Coverage Scenario

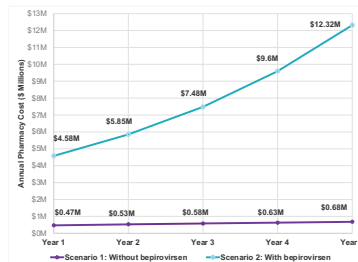


Table 7: Cumulative Incremental PMPM Cost Spending by Line of Business

Line of Business	Bepirovirsen PMPM	Total NA PMPM	Side Effects/Medication Management PMPM	Net Incremental PMPM
Commercial	\$2.93	-\$0.01	\$0.00	\$2.91
Medicare	\$3.42	-\$0.01	\$0.00	\$3.40

Table 8: Pharmacy Budget Impact by Coverage Scenario and Line of Business

Line of Business	Year 1	Year 2	Year 3	Year 4	Year 5	5-Year Total
Scenario 1	\$0.30M	\$0.34M	\$0.38M	\$0.42M	\$0.45M	\$1.88M
Scenario 2	\$2.86M	\$3.67M	\$4.69M	\$6.02M	\$7.73M	\$24.98M
Incremental Pharmacy Cost	\$2.57M	\$3.33M	\$4.32M	\$5.61M	\$7.28M	\$23.10M
Incremental PMPM Cost	\$0.32	\$0.42	\$0.54	\$0.71	\$0.92	\$2.91
Medicare (n = 339,000)						
Scenario 1	\$0.18M	\$0.19M	\$0.20M	\$0.23M	\$0.23M	\$1.02M
Scenario 2	\$1.72M	\$2.19M	\$2.79M	\$3.57M	\$4.59M	\$14.85M
Incremental Pharmacy Cost	\$1.54M	\$1.99M	\$2.59M	\$3.36M	\$4.36M	\$13.84M
Incremental PMPM Cost	\$0.38	\$0.49	\$0.64	\$0.83	\$1.07	\$3.40
Total Health Plan (N = 1,000,000)						
Scenario 1	\$0.47M	\$0.53M	\$0.58M	\$0.63M	\$0.68M	\$2.89M
Scenario 2	\$4.58M	\$5.85M	\$7.48M	\$9.60M	\$12.32M	\$39.83M
Incremental Pharmacy Cost	\$4.11M	\$5.32M	\$6.90M	\$8.97M	\$11.64M	\$36.94M
Incremental PMPM Cost	\$0.34	\$0.44	\$0.58	\$0.75	\$0.97	\$3.08
\$36.94 Million						
5-Year Cumulative Incremental Pharmacy Cost						

DISCUSSION

Impact of Introducing Bepirovirsen

- Expected increase in pharmacy expenditures driven by upfront bepirovirsen acquisition
- Functional cure generated modest pharmacy cost savings through reduced NA acquisition and modeled osteoporosis/CKD medication management
- Pharmacy cost offsets were relatively small and did not meaningfully offset modeled bepirovirsen acquisition costs within the 5-year horizon
- Budget impact increased over time as modeled bepirovirsen uptake increased

Payer Population Impact

- Commercial generated greater absolute incremental pharmacy costs (\$23.10M vs \$13.84M), whereas Medicare had greater cumulative incremental PMPM spending (\$3.40 vs \$2.91)
- Payer-specific results highlight the importance of evaluating the budget-impact of functional cure therapies by line of business

Limitations of the Model

- Bepirovirsen price and future uptake assumption-based
- HCV antivirals used as pricing analogues¹⁶
- CHB-related medical care management and HCRU/costs not yet incorporated
- Sensitivity analysis not yet conducted
- The 5-year horizon may not capture the full long-term economic consequences of functional cure
- Long-term functional cure durability and post-cure utilization remain uncertain
- Does not account for rebates

Next Steps

- Incorporate CHB-related medical management and disease-progression costs
- Conduct sensitivity analyses of key model inputs

CONCLUSION

- Introducing bepirovirsen increased modeled pharmacy spending, with incremental PMPM cost increasing from \$0.34 PMPM in Year 1 to \$0.97 PMPM in Year 5
- The model estimated \$36.94M in cumulative incremental pharmacy costs over 5 years
- Commercial contributed greater absolute incremental pharmacy costs, while Medicare had greater incremental PMPM costs
- Future analysis will incorporate CHB-related medical utilization, costs, and sensitivity analyses to estimate broader payer impact and potential longer-term economic consequences of functional cure

ACKNOWLEDGEMENTS

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