

A U.S.-Specific Budget Impact Model (BIM) of Semaglutide 2.4 mg in the Treatment of Metabolic Dysfunction-Associated Steatohepatitis (MASH) Using Most-Favored-Nation (MFN) Pricing

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Aim

A budget impact model (BIM) was developed to estimate the financial impact of adopting semaglutide for MASH treatment using the Most-Favored-Nation (MFN) price.

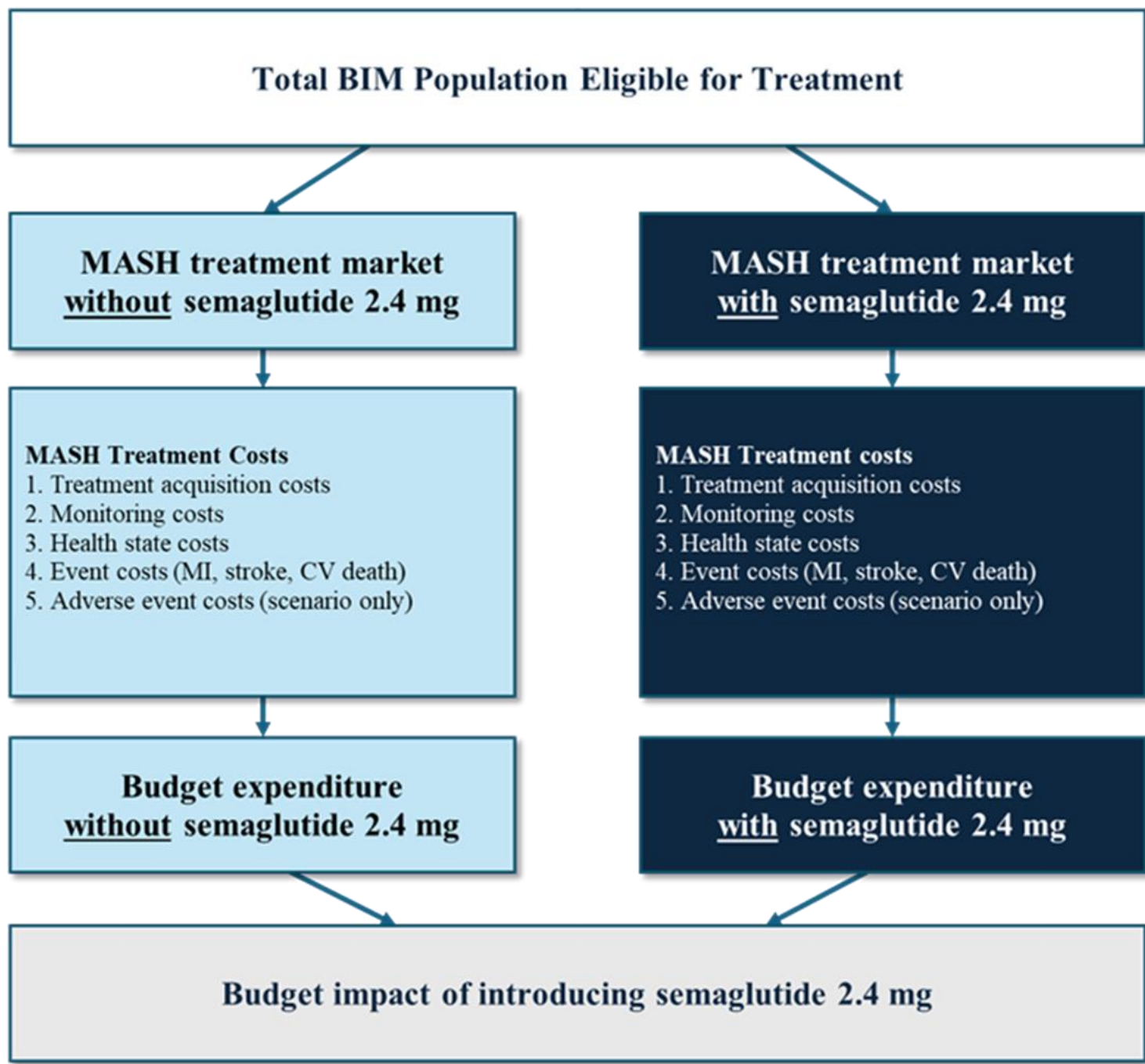
Introduction

- Metabolic dysfunction-associated steatohepatitis (MASH) is a form of liver inflammation and injury caused by nonalcohol-related fat buildup that can eventually progress to serious complications such as cirrhosis, liver failure, and cancer.¹
- Many of the risk factors for MASH include obesity, type 2 diabetes (T2D), high levels of low-density lipoprotein (LDL), and metabolic syndrome, contributing to significant clinical and economic burden.
- Semaglutide was recently approved for the treatment of non-cirrhotic MASH, with moderate to advanced liver fibrosis (consistent with F2 to F3 fibrosis) in adults.²

Methods

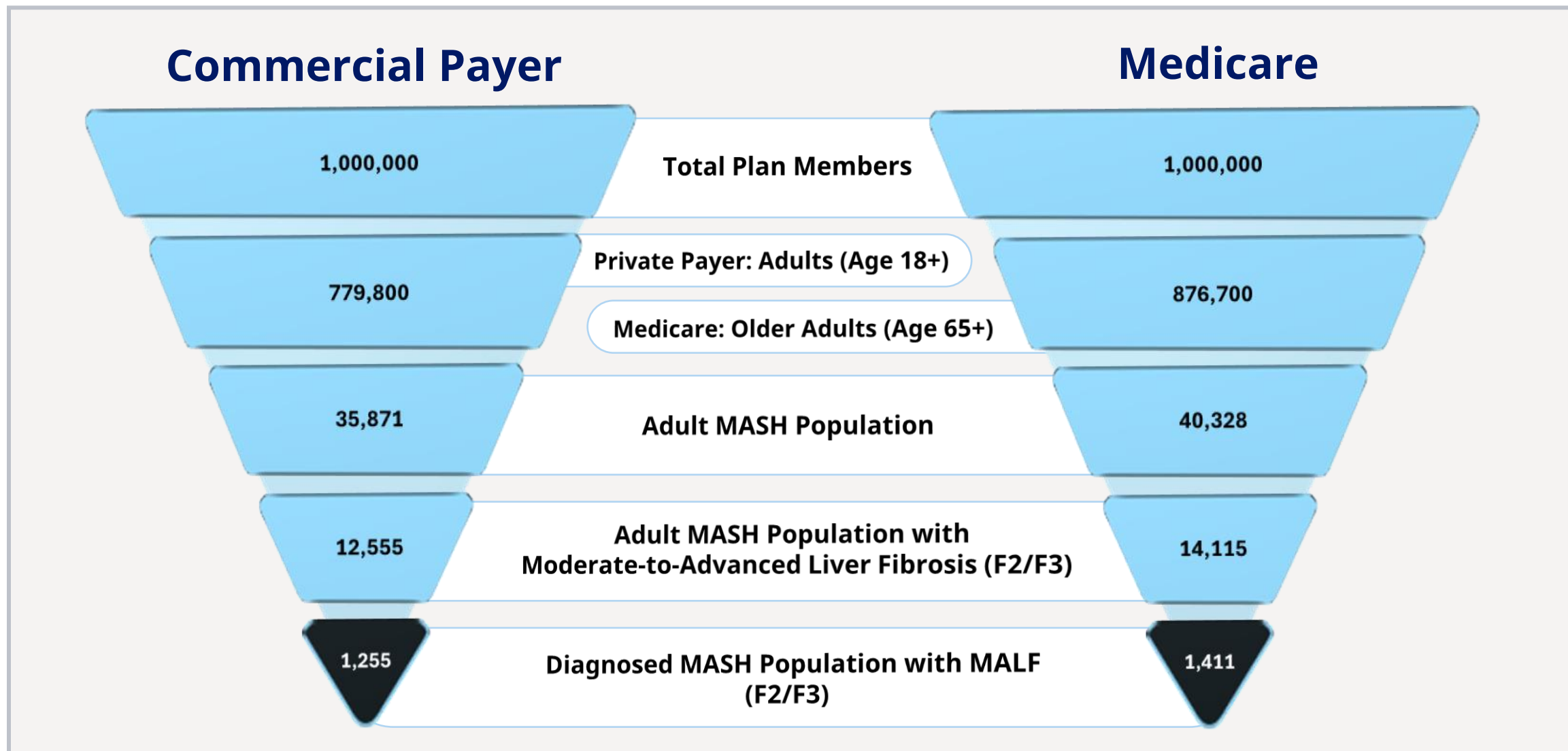
- A BIM was developed from U.S. commercial payer and Medicare perspectives, focusing on direct medical costs, as shown in **Figure 1**.
- Disease state transitions were modeled using a Markov cohort structure.
- Budget impact was calculated by comparing costs between two scenarios where semaglutide is included as a treatment option vs. excluded from the treatment mix.
- The eligible population from each payer perspective was estimated using publicly available national-level data and published literature.^{3,4}

Figure 1: Budget Impact Model Diagram



See bottom right for abbreviations.

Figure 2: Adult MASH Population with Diagnosed Moderate-to-Advanced Liver Fibrosis (F2/F3)^{3,4}



See bottom right for abbreviations.

Table 1: Key Baseline Demographic and Clinical Characteristics of the Model Cohort

	Commercial (Age 18+)	Medicare (Age 65+)
Demographic		
Age, years	56	70
Sex, % (Male)	42.9	34.7
BMI, kg/m ²	34.6	32.0
Fibrosis Stage, %		
F2	31.3%	22.3%
F3	68.8%	77.7%
Comorbidities, %		
Prediabetes	20.7%	21.4%
T2D	55.5%	56.9%
Obesity	72.8%	61.4%
CVD	2.9%	2.9%

See bottom right for abbreviations.

- Patients entered the model in either F2 or F3 health states at baseline.
- The baseline population characteristics were derived from the ESSENCE trial⁵ and published literature.
- Key baseline cohort characteristics are shown in **Table 1**.

Table 2: Model Overview

Attributes	Value
Time Horizon	5 years
Cycle Length	1-year with half-cycle correction
Perspectives	U.S. Commercial Payer and Medicare
Intervention	Semaglutide 2.4 mg once-weekly SC injection
Comparator	SoC [†] , resmetirom 80 mg or 100 mg PO once daily
Inputs	Drug acquisition costs, monitoring costs, health state costs, event costs across liver disease, comorbidities (CVD, prediabetes, T2D, and obesity), treatment-related clinical inputs, disease-related clinical inputs, adverse events [‡] , discontinuation, background and disease-associated mortality
Outputs	Total and annual drug acquisition costs, monitoring costs, adverse event costs, disease management costs
Outcomes	Total and disaggregated costs per subjected population, PMPM, and PTMPM

[†]SoC includes lifestyle modifications (i.e. diet, exercise, weight loss);

[‡]Serious adverse events reported in the trials were included in the base case and assumed to require hospitalization. See bottom right for abbreviations.

- The model attributes are outlined in **Table 2**. Clinical inputs and costs were sourced from clinical trials (e.g. REGENERATE, ESSENCE, MAESTRO-NASH)⁵⁻⁷, and published literature.
- Key cost inputs included drug acquisition costs (WAC) sourced from Micromedex RED BOOK.⁸ For semaglutide, the MFN price was used for the commercial payer (\$350 per month) and Medicare perspectives (\$245 + \$50 copay per month).⁹
- Market share was assumed to be 55.3% by resmetirom and 44.7% by SoC in the absence of semaglutide. With semaglutide included, semaglutide uptake was assumed to be 26.9% at Year 1 and grow to 87.2% by Year 5. Resmetirom's share declined proportionally to 7% by Year 5, with the remaining share allocated to SoC.

Results

- Budget impact estimates from the commercial payer and Medicare perspectives are presented in **Table 3** and **Table 4**, respectively.
- Estimated avoided liver disease events from the commercial payer and Medicare perspectives are presented in **Figure 3** and **Figure 4**, respectively.

Table 3: Incremental Total and Disaggregated Costs from the Commercial Payer Perspective

Budget Impact Summary	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Budget Impact	\$7,559,433	-\$10,830,227	-\$16,347,277	-\$23,263,270	-\$31,577,040	-\$89,577,247
Per Member Per Month (PMPM)	-\$0.630	-\$0.898	-\$1.348	-\$1.908	-\$2.576	-\$1.477
Per Treated Member Per Month (PTMPM)	-\$502	-\$619	-\$803	-\$982	-\$1,147	-\$860

Incremental Results	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Cost Outcomes						
Drug Acquisition Costs	-\$7,400,504	-\$9,880,644	-\$14,226,311	-\$19,583,896	-\$25,949,574	-\$77,040,928
Monitoring Costs	\$22,526	\$31,862	\$47,131	\$66,251	\$89,359	\$257,129
Adverse event costs	\$74,597	\$32,597	\$55,207	\$97,264	\$92,175	\$358,870
Disease Management Costs	-\$255,082	-\$1,814,043	-\$2,221,304	-\$3,812,869	-\$5,789,000	-\$13,105,316
Total Incremental Costs	-\$7,559,433	-\$10,830,227	-\$16,347,277	-\$23,263,270	-\$31,577,040	-\$89,577,247

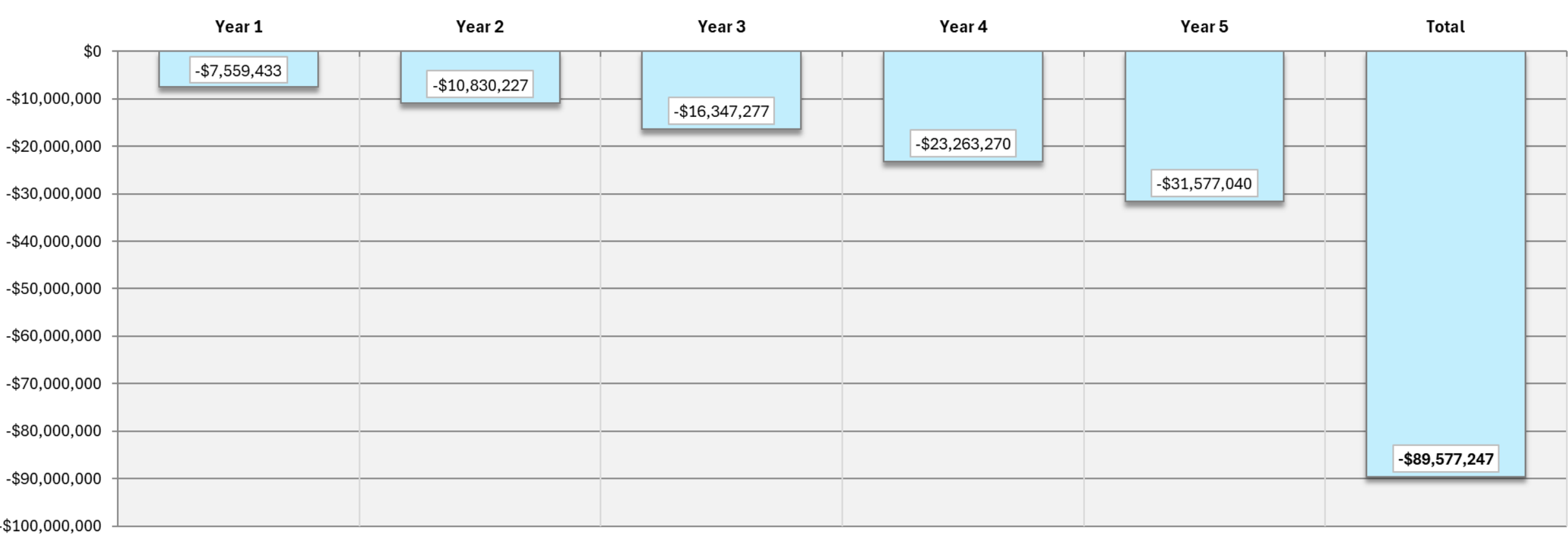
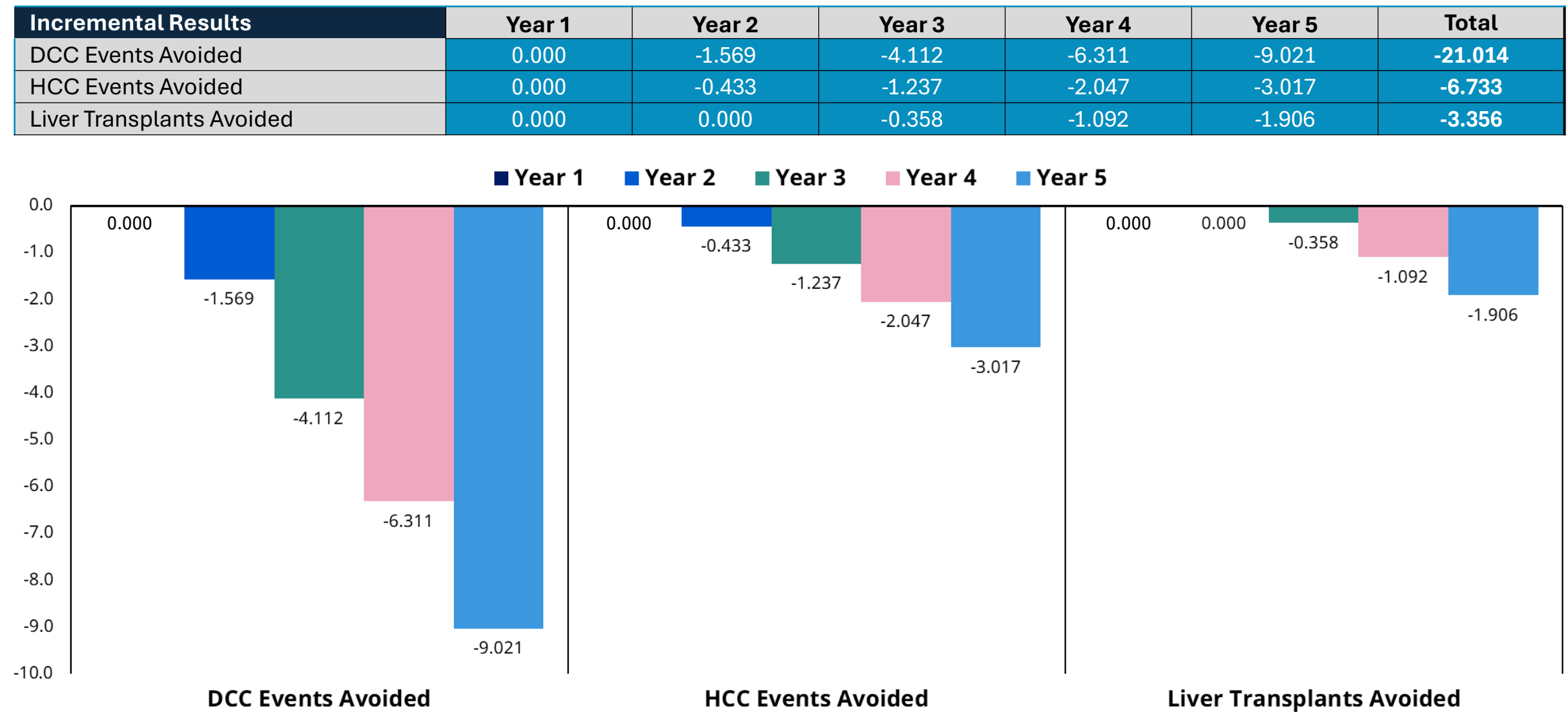


Figure 3: Liver Disease Events Avoided from the Commercial Payer Perspective



- From the commercial perspective over five years, semaglutide at the MFN price generated cumulative cost savings of approximately \$89.6 million, a majority of which was driven by drug acquisition costs. This translated to \$1.48 PMPM and \$860 PTMPM in savings.
- Estimated avoided liver disease events grew each year over five years with the introduction of semaglutide, resulting in a total of 21.01 DCC events, 6.73 HCC events, and 3.36 liver transplant events avoided in the commercially insured population.
- From the Medicare perspective, semaglutide generated cumulative cost savings of approximately \$101.3 million, which translated to savings of \$1.67 PMPM and \$877 PTMPM.
- Among the Medicare population, a total of 39.31 DCC events, 12.86 HCC events, and 8.07 liver transplant events were avoided with the introduction of semaglutide.
- From both perspectives, incremental monitoring costs and adverse event costs were minimal, without a substantial impact on total cost savings.

Table 4: Incremental Total and Disaggregated Costs from the Medicare Perspective

Budget Impact Summary	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Budget Impact	-\$8,527,077	-\$12,062,407	-\$18,507,055	-\$26,427,479	-\$35,820,712	-\$101,344,730
Per Member Per Month (PMPM)	-\$0.711	-\$1.000	-\$1.526	-\$2.168	-\$2.923	-\$1.671
Per Treated Member Per Month (PTMPM)	-\$503	-\$617	-\$818	-\$1,007	-\$1,177	-\$877

Incremental Results	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Cost Outcomes						
Drug Acquisition Costs	-\$8,391,414	-\$11,166,816	-\$16,415,228	-\$22,747,471	-\$30,193,333	-\$88,914,262
Monitoring Costs	\$15,344	\$22,079	\$33,422	\$47,412	\$64,174	\$182,431
Adverse event costs	\$71,942	\$33,749	\$57,075	\$71,657	\$87,551	\$321,974
Disease Management Costs	-\$222,948	-\$951,420	-\$2,182,324	-\$3,799,077	-\$5,779,105	-\$12,934,873
Total Incremental Costs	-\$8,527,077	-\$12,062,407	-\$18,507,055	-\$26,427,479	-\$35,820,712	-\$101,344,730

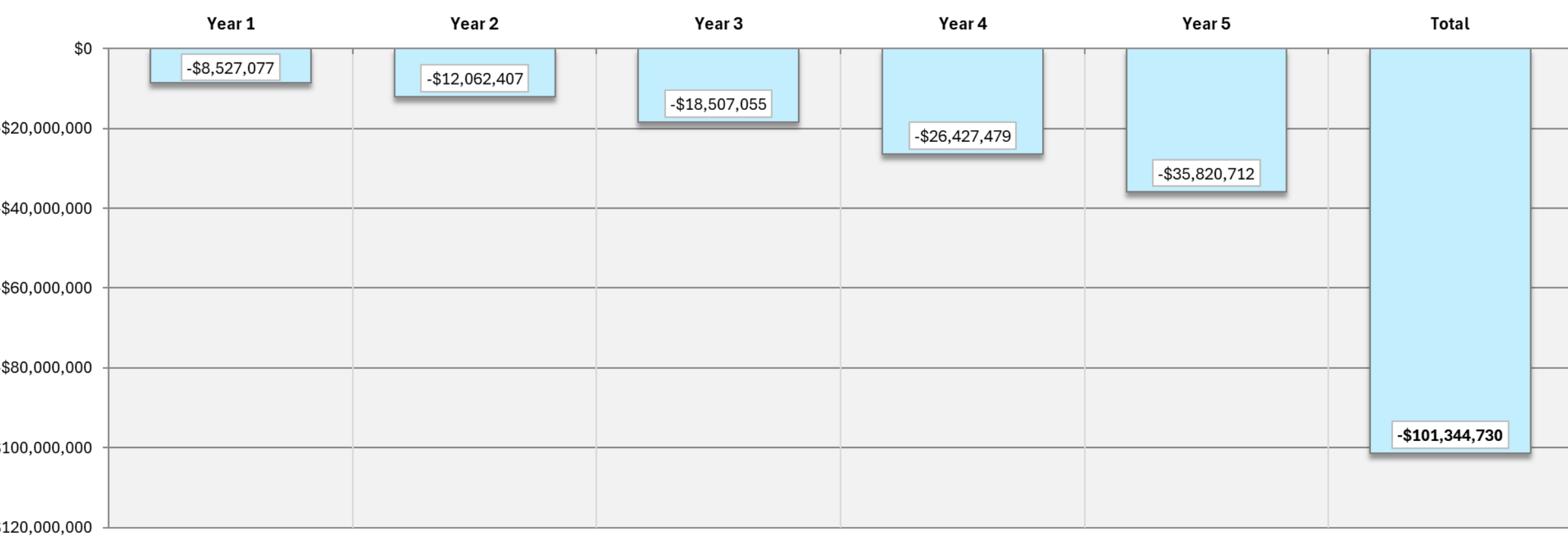
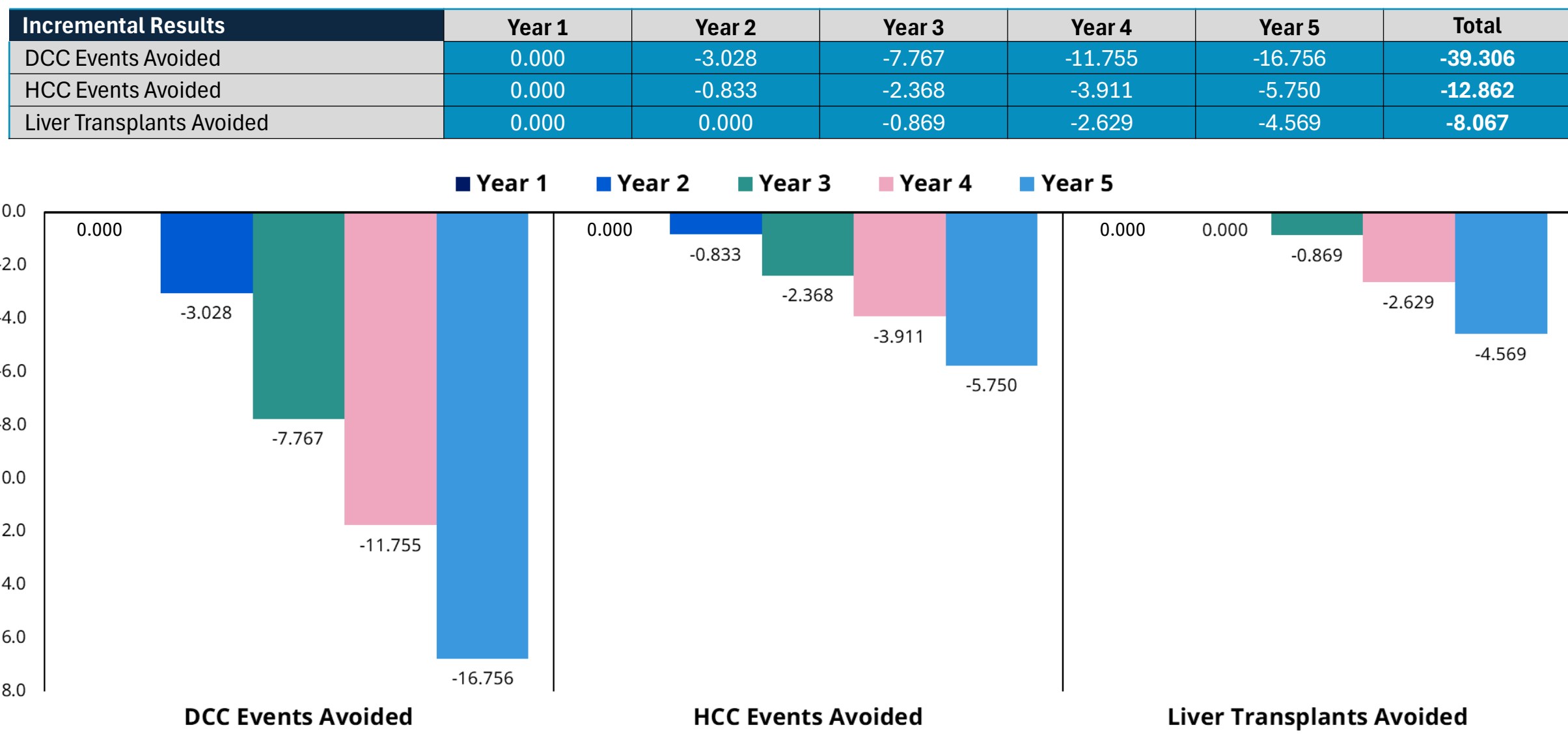


Figure 4: Liver Disease Events Avoided from the Medicare Perspective



Limitations

- The MFN price does not reflect the rebate or negotiated price for commercially insured patients and only applies to patients paying cash for their treatment without insurance coverage.
- Plan size was assumed fixed at 1 million members and may not capture variation across payer types, regional demographics, or benefit structures.
- Market share uptake of semaglutide and resmetirom was based on manufacturer-provided assumption.
- Real-world adherence and long-term effectiveness remain uncertain and could influence future budget impact.

Conclusion

- The introduction of semaglutide for MASH at the MFN price was associated with substantial five-year net savings from the U.S. payer perspectives.
- These savings were largely driven by reduced treatment and disease management costs that outweighed the modest increases in monitoring and adverse event costs.
- This analysis supports considering semaglutide as a treatment option in formulary decision-making.

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Abbreviations: BMI, body mass index; CVD, cardiovascular disease; DCC, decompensated cirrhosis; F2, moderate fibrosis; F3, severe fibrosis; HCC, hepatocellular carcinoma; LDL, low-density lipoprotein; LT, liver transplant; MALF, moderate-to-advanced liver fibrosis; MASH, metabolic dysfunction-associated steatohepatitis; MFN, Most-Favored-Nation; MI, myocardial infarction; PMPM, per member per month; PO, by mouth; PTMPM, per treated member per month; T2D, type 2 diabetes; SC, subcutaneous; SoC, standard of care; WAC, wholesale acquisition cost;

References: (1) Taylor et al. Gastroenterology, 2020; 158: 1611-25; (2) Wegovy [Package Insert]; Plainsboro, NJ: Novo Nordisk, Inc.; 2026; (3) U.S. Census Bureau. "Happy New Year 2024!" Accessed 2024; (4) Fishman et al. J Med Econ. 2024;27(1):1108-1118; (5) Sanyal et al. N Engl J Med. 2025;392(21): 2089–2099; (6) Younossi et al. Lancet 2019; 394(10215): 2184-2196; (7) Harrison et al. N Engl J Med. 2024; 390 (6): 497-509; (8) RED BOOK. IBM Micromedex. 2025; (9) Fact Sheet. The White House Washington. 6 Nov 2025;