

Budget Impact of Sevabertinib for HER2-Mutated Locally Advanced or Metastatic Non-Squamous NSCLC from a United States Payer Perspective

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BACKGROUND

- Activating HER2 mutations are found in 2-4% of advanced non-small cell lung cancers (NSCLC) with an estimated incidence of 0.6 per cases of HER2-mutant NSCLC per 100,000 people in the United States.^{1,2}
- Sevabertinib was granted FDA approval for the treatment of HER2-mutated locally advanced or metastatic non-squamous (NS) NSCLC following systemic therapy based on efficacy and safety demonstrated in the SOHO-01 trial.^{3,4}
- There is a need for US healthcare plans to understand the potential economic impact of the use of sevabertinib as second-line therapy following systemic therapy (2L) for the treatment of HER2-mutant NS NSCLC.

RESEARCH OBJECTIVE

- To estimate the budget impact of sevabertinib for the treatment of 2L NS NSCLC from a US payer perspective.

METHODS

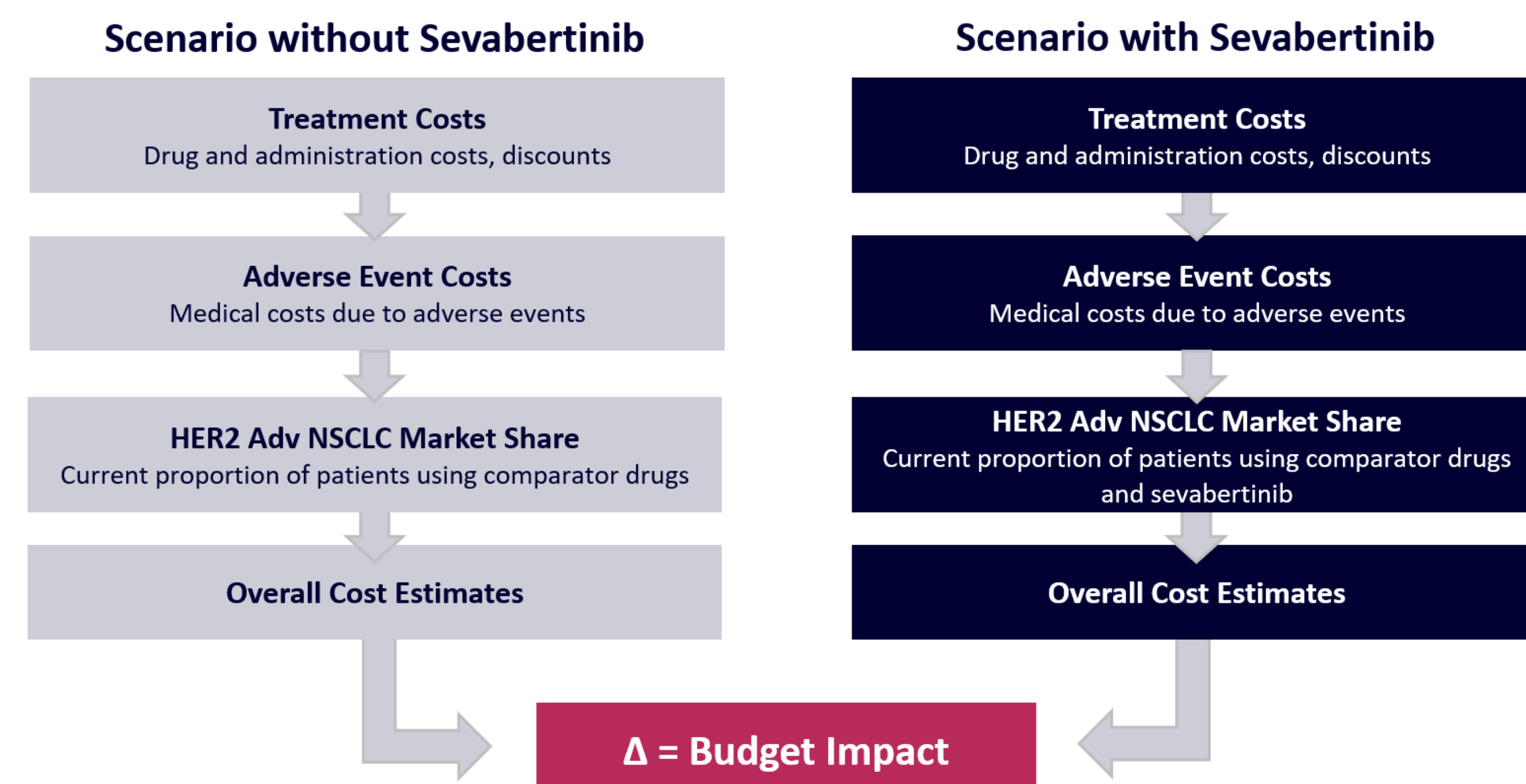
MODEL OVERVIEW

- An Excel-based budget impact model (BIM) was developed to evaluate the incremental costs between scenarios without and with sevabertinib on formulary for a 1-million-member US plan (commercial and Medicare) over a one-year time horizon (Figure 1).
- A one-way sensitivity analysis (OWSA) was conducted by varying each input by ±20% to assess parameter uncertainties and explore key model drivers.

KEY MODEL INPUTS AND ASSUMPTIONS

- The annual number of patients with HER2-mutant locally advanced or metastatic NS NSCLC eligible for treatment with sevabertinib among 1 million members in a commercial (78%) / Medicare (22%) health plan was estimated from published data.^{2,5-8}
- The BIM accounted for the costs of drug acquisition, administration, monitoring, and adverse event (AE) management. Treatment dosing, duration, and AE rates were obtained from clinical trial publications and product prescribing information.

Figure 1. Model Structure



Drug Acquisition, Administration, and Monitoring

- Costs were based on the WACs from Red Book[®] as of November 2025 (Table 1).⁹
- Administration costs for IV infusions and subcutaneous injections based on the CMS Physician Fee Schedule and Laboratory Fee Schedule.^{11,12}
- Monitoring requirements were derived from product prescribing information.^{4,12,13} Costs were based on Red Book[®], the CMS Physician Fee Schedule, and the CMS Laboratory Fee Schedule, as applicable.⁹⁻¹¹
- After the median duration of response for each drug, patients switch to therapy with the alternative mechanism of action.

Adverse Event Management

- AE costs were included for grade ≥3 AEs that occurred for ≥2 included treatment comparators, plus any AEs of interest based on the sevabertinib Warnings & Precautions and were inflation-adjusted to 2025 USD.^{4,12-14}
 - AE costs are from the AHRQ Healthcare Cost and Utilization Project (HCUP) and are only based on primary treatment.^{14,15}
 - AEs included: diarrhea, nausea, rash, vomiting, fatigue, constipation, interstitial lung disease, hepatotoxicity, dyspnea, LVEF dysfunction, amylase/lipase elevation.

Market Dynamics

- Utilization of tyrosine kinase inhibitors (TKIs) as a class was assumed to increase from 16.1% to 73.3% in the scenario with sevabertinib, as market share of monoclonal antibodies (mAbs) decreased.**
 - Sevabertinib was assumed to have 24.0% market share in the first year.
 - Market share of NS NSCLC treatments was derived from a demand study of expert physicians¹⁶ conducted by Bayer.

RESULTS

BASE CASE

- Each year an estimated 3 patients within a 1-million-member plan will be eligible for treatment with HER2-targeted therapy after systemic therapy (Figure 2).
- The incremental cost from providing access to sevabertinib and the increase in utilization of the TKI class overall was \$0.003 on a per-member per-month basis over the 1-year time horizon (Table 2).
 - Total budget impact costs were \$34,870.
- Higher drug acquisition costs were **partially offset by lower AE and administration/monitoring-related costs.**
 - Sevabertinib had the lowest AE management costs with higher comparator costs driven by hepatotoxicity and interstitial lung disease.

Table 2. Budget Impact Model Base Case Results

Budget Impact Summary	Without Sevabertinib	With Sevabertinib	Difference
Total Cost	\$853,322	\$888,191	\$34,870
Drug costs (primary)	\$519,349	\$526,898	\$7,549
Admin/Monitoring (primary)	\$23,534	\$9,721	-\$13,813
AE costs (primary)	\$10,061	\$9,294	-\$767
Subsequent Treatment costs	\$300,378	\$342,279	\$41,901
Per Member Results			
Δ PMPM Cost			\$0.003
Δ PMPY Cost			\$0.03
Δ PTMPM Cost			\$836
Δ PTMPY Cost			\$10,038

PMPM – per-member per-month; PMPY – per-member per-year; PTMPM – per-treated-member per-month; PTMPY – per-treated-member per-year.

LIMITATIONS

- This model does not include overall healthcare resource use or cost of disease progression.
- Default dosing is based on recommended dosing and administration on respective product labels, which may not reflect real-world treatment patterns.
- The results are heavily dependent on the market share assumptions, which are subject to significant uncertainty.
- The model does not include long-term health consequences or ongoing costs associated with AEs beyond the modeled time horizon.

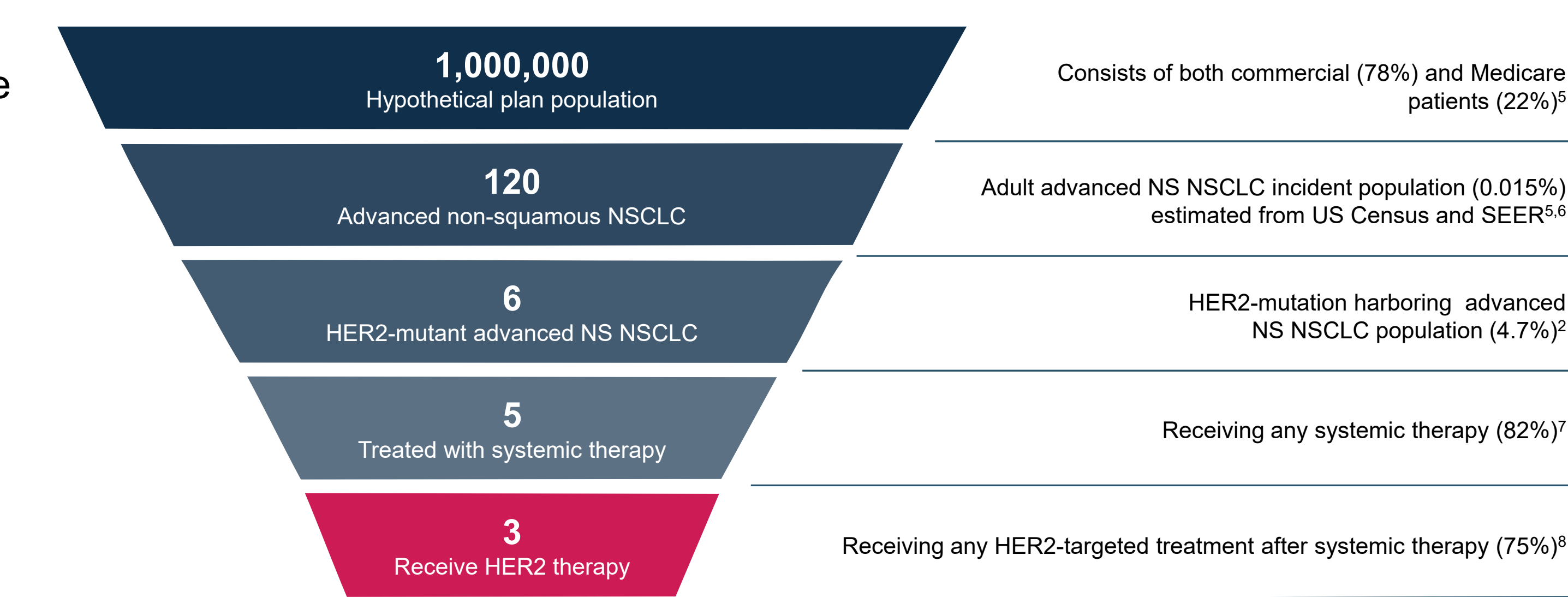
CONCLUSION

- In a 1-million-member health plan, an estimated 3 patients are eligible and receive HER2-directed therapy annually for locally advanced or metastatic NS NSCLC.**
- For US health plans, providing access to sevabertinib for the treatment of HER2-mutant NS NSCLC and an overall increase in utilization of TKIs for this indication results in minimal budget impact.**
- The budget impact of sevabertinib was partially offset by savings in drug administration, monitoring, and AE costs.**

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Figure 2. Model Population



ONE-WAY SENSITIVITY ANALYSIS

- Across all sensitivity analyses, inclusion of sevabertinib on formulary and the increase in TKI utilization had a minimal budget impact.
- OWSA showed that the budget impact on healthcare costs was most sensitive to sevabertinib brand package cost (Figure 5).

Figure 5. One-Way Sensitivity Analysis

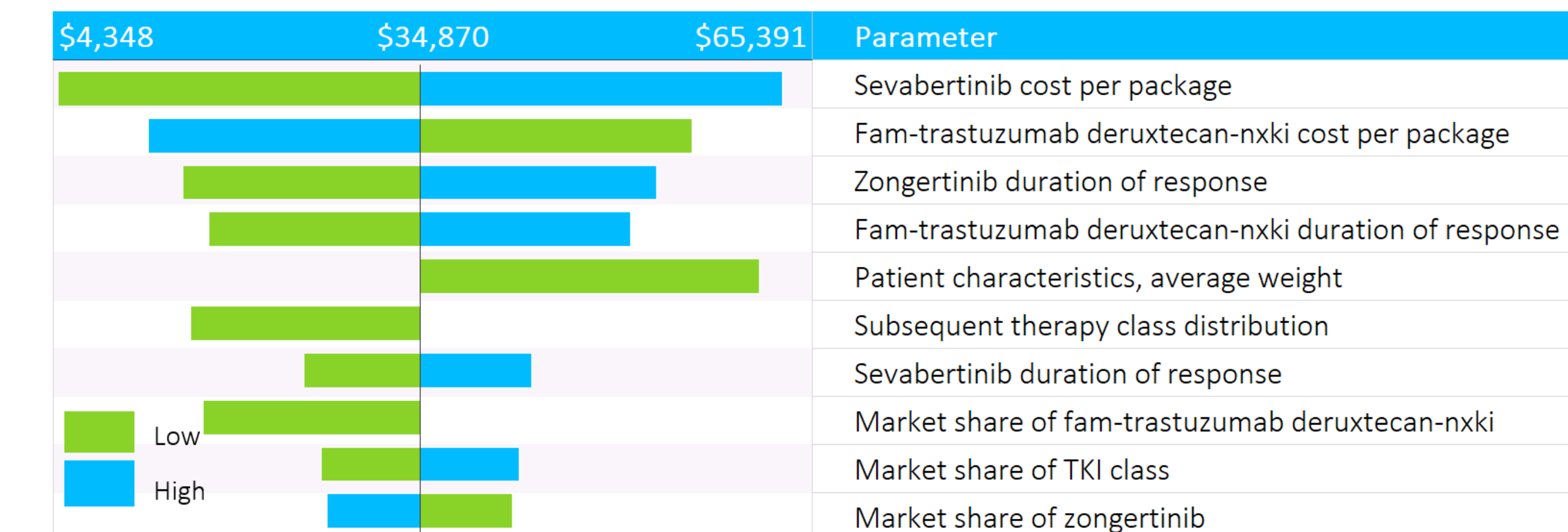


Table 1. Drug Dosing, Duration, and Treatment Costs

Treatment Regimen	Dosing Regimen	Monthly Cost*	Median Duration (months)	Admin/Monitoring Costs (primary)	AE Costs (primary)	Treatment Costs (subsequent)†
Sevabertinib	Two 10 mg tablets twice daily	\$24,022	9.2	\$207	\$2,334	\$51,909
Zongertinib	120 mg (<90 kg) or 180 mg (≥90 kg) once daily	\$24,110	5.4	\$1,201	\$2,620	\$122,356
Fam-trastuzumab deruxtecan-nxki	5.4 mg/kg IV once every 3 weeks	\$18,539	8.7	\$7,846	\$2,949	\$79,494

*Monthly costs are based on reported wholesale acquisition cost (WAC).

†Treatment costs for subsequent therapy are based on a basket monthly cost of the opposite drug class using a weighted average distribution of drug costs using estimated market share, multiplied by the remaining duration of the year.

