A Budget Impact Analysis of Introducing OPSYNVI for the Treatment of Adult Patients Diagnosed with Pulmonary Arterial Hypertension

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Background

- Pulmonary arterial hypertension (PAH) is a rare and progressive condition, characterized by elevated pulmonary vascular resistance, which can lead to right heart failure and premature death.
- J&J has developed OPSYNVI® (10 mg macitentan + 40 mg tadalafil) as a fixed-dose, dual combination (FDC) treatment for PAH that targets the endothelial receptor antagonist (ERA) and phosphodiesterase 5 (PDE5) pathways.
- Here, we examine the budget impact of introducing OPSYVNI® to formulary and evaluate the relative impact to Commercial and Medicare Advantage plan members over a 3-year horizon.

Methods

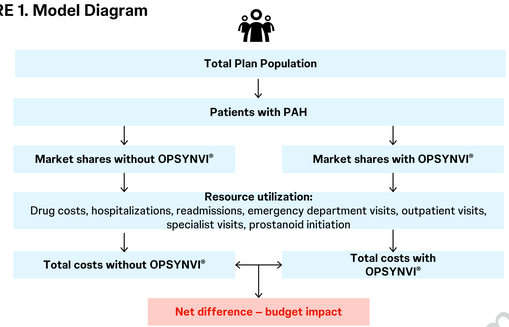
- A 3-year budget impact model (BIM) was developed from a US third-party payer perspective (commercial and Medicare Advantage) to examine the incremental costs of adopting OPSYNVI® (macitentan + tadalafil) in a hypothetical 1,000,000-member health plan.
- The model calculated total costs associated with PAH-related healthcare resource utilization (see **Table 1**) among a population of adult patients diagnosed with PAH (defined as WHO Group 1).
- Two scenarios were compared — one with vs. one without OPSYNVI® — to estimate the net budget impact over a 3-year time horizon, reported on a per-member per-month basis (**Figure 1**).
- Each scenario estimated costs across a diverse landscape of 6 alternative PAH therapies, including a loose dose combination (LDC) of ERA+PDE5i (as an alternative to the fixed dose combination offered by OPSYNVI).
- See **Tables 2-4** for market share assumptions and HCRUs by product (obtained from clinical trials), which served as the key inputs to the model.

TABLE 1. Model Overview

Overview	Description
Objective	To estimate the budget impact of using OPSYVNI® (macitentan + tadalafil) for the treatment of PAH
Population	Adult patients diagnosed with PAH
Interventions	OPSYNVI® (macitentan + tadalafil)
Comparators	• Tadalafil monotherapy • Macitentan monotherapy • Sildenafil monotherapy • ERA + PDE5i Loose Dose Combination • Ambrisentan monotherapy • Bosentan monotherapy
Perspective	US third-party payer (commercial and Medicare Advantage)
Time Horizon	3-Years
Key Inputs	• Drug acquisition costs • ED visits • HCRU costs • Outpatient visits • Inpatient days • Specialist visits • Prostanoid Initiation • Readmission rate
Outcomes	• Total costs • Incremental HCRU • Incremental costs by category • Per-member per-month budget impact

ED, emergency department; ERA, endothelial receptor antagonist; HCRU: Healthcare Resource Utilization; PAH, pulmonary arterial hypertension; PDE5i, phosphodiesterase 5 inhibitors.

FIGURE 1. Model Diagram



ED, emergency department; PAH, pulmonary arterial hypertension.

TABLE 2. Scenario without OPSYNVI®

Market Shares x Product	Year 1	Year 2	Year 3
OPSYNVI®	0.00%	0.00%	0.00%
ERA + PDE5i LDC	40.54%	40.54%	40.54%
Macitentan	7.98%	7.98%	7.98%
Ambrisentan	7.12%	7.12%	7.12%
Bosentan	1.11%	1.11%	1.11%
Tadalafil	21.62%	21.62%	21.62%
Sildenafil	21.62%	21.62%	21.62%
Total	**100%**	**100%**	**100%**

TABLE 3. Scenario with* OPSYNVI®

Market Shares x Product	Year 1	Year 2	Year 3
OPSYNVI®	0.80%	3.60%	4.80%
ERA + PDE5i LDC	40.38%	39.82%	39.58%
Macitentan	7.94%	7.80%	7.74%
Ambrisentan	7.09%	6.97%	6.91%
Bosentan	1.11%	1.09%	1.08%
Tadalafil	21.34%	20.36%	19.94%
Sildenafil	21.34%	20.36%	19.94%
Total	**100%**	**100%**	**100%**

*OPSYNVI® market uptake was derived from pre-launch shares of PDE5i mono (70%), ERA mono (10%) and loose dose dual ERA+PDE5i (20%). ERA, endothelial receptor antagonist; LDC, loose dose combination; PDE5i, phosphodiesterase 5 inhibitor.

TABLE 4. Per-Patient Per-Month Healthcare Resource Utilization

HCRU Inputs	OPSYNVI®	ERA + PDE5i LDC	Macitentan monotherapy	Ambrisentan monotherapy	Bosentan monotherapy†	Tadalafil monotherapy	Sildenafil monotherapy‡	Source
Number of inpatient admissions	0.0092	0.0175	0.0085	0.0300	0.0300	0.0317	0.0317	Janssen ADUE, 2023,[5] Channick et al. 2015,[2] Gaile et al. 2015[3]
Average length of stay per admission (days)	9.600	9.600	9.600	9.600	9.600	9.600	9.600	
Inpatient days*	0.089	0.168	0.082	0.288	0.288	0.304	0.304	
ED visits	0.011	0.011	0.012	0.012	0.012	0.009	0.009	Janssen PostHoc PAH, 2023[4]
Outpatient visits	0.485	0.485	0.447	0.447	0.447	0.324	0.324	
Specialist visits	1.427	1.427	1.238	1.238	1.238	1.070	1.070	

*Inpatient days were calculated by multiplying the number of inpatient admissions to the average length of stay per admission. For OPSYNVI®, inpatient days were calculated by taking the total reported PAH-related hospitalization (144) divided by the number of subject years in the study (135.16) to calculate the per-patient per-year rate, then dividing by 12 to calculate the per-patient per-month rate. †Bosentan number of inpatient admissions assumed to be same as Ambrisentan. ‡Sildenafil number of inpatient admissions assumed to be same as Tadalafil. ED, emergency department; ERA, endothelial receptor antagonist; IP, inpatient; PDE5i, phosphodiesterase 5 inhibitors.

Results

- The total and incremental budget impact of introducing OPSYNVI® from Year 1 to Year 3 from the Commercial perspective are shown in Figure 2 and Table 5. Results from the Medicare perspective are illustrated in Figure 3 and Table 6.
- Introducing OPSYVNI® to formulary was found to have a minimal budget impact for both commercial (**Figure 2**) and Medicare Advantage (**Figure 3**) plans.
  - For Commercial members, the addition of OPSYVNI® resulted in a total net difference of $305,223 over 3-years – equivalent to $0.01 per member per month (**Table 5**).
  - For Medicaid Advantage members, the addition of OPSYVNI® resulted in a total net difference of $160,580 over 3-years – equivalent to $0.00 per member per month (**Table 6**).
- These results suggest that adding OPSYVNI® can improve patient outcomes (e.g., reduce patients' hospitalization days, readmissions, and progression to prostanoid) for negligible additional costs.

FIGURE 2. Total Budget Impact for Commercial Plan Members

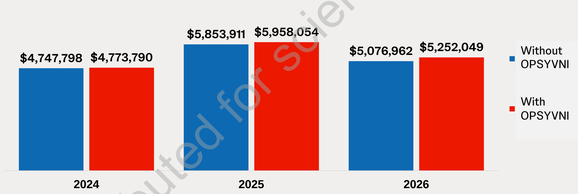


TABLE 5. Incremental Budget Impact for Commercial Plan Members

Differences across scenarios by year and aggregated over 3 years

	Year 1	Year 2	Year 3	Net difference over 3-Years
Drug acquisition costs	$41,591	$206,207	$349,657	$597,455
Inpatient day costs	-$7,206	-$35,727	-$52,034	-$94,967
Readmission costs	-$2,955	-$14,652	-$21,339	-$38,946
ED visit costs	$15	$74	$107	$196
Outpatient day costs	$58	$286	$417	$761
Specialist visit costs	$188	$932	$1,358	$2,478
Prostanoid initiation	-$5,697	-$52,978	-$103,078	-$161,753
Total net difference	**$25,993**	**$104,143**	**$175,087**	**$305,223**
Per member per year	$0.03	$0.10	$0.18	$0.10
Per member per month	**$0.00**	**$0.01**	**$0.01**	**$0.01**

FIGURE 3. Total Budget Impact for Medicare Advantage Plan Members

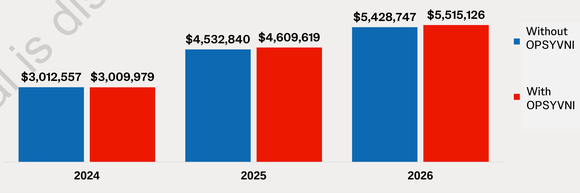


TABLE 6. Incremental Budget Impact for Medicare Advantage Plan Members

Differences across scenarios by year and aggregated over 3 years

	Year 1	Year 2	Year 3	Net difference over 3-Years
Drug acquisition costs	$12,257	$184,157	$278,933	$475,347
Inpatient day costs	-$5,820	-$28,927	-$42,318	-$77,065
Readmission costs	-$1,538	-$7,646	-$11,185	-$20,369
ED visit costs	$12	$60	$87	$159
Outpatient day costs	$57	$282	$413	$752
Specialist visit costs	$185	$919	$1,344	$2,448
Prostanoid initiation	-$7,730	-$72,067	-$140,895	-$220,692
Total net difference	**-$2,578**	**$76,779**	**$86,379**	**$160,580**
Per member per year	$0.00	$0.07	$0.08	$0.05
Per member per month	**$0.00**	**$0.01**	**$0.01**	**$0.00**

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References:

1. Data on File, Janssen Market Shares. 2023.
2. Channick RN, et al. JAAC Heart Fail. 2015;3(1):1-8.
3. Gaile N, et al. N Engl J Med. 2015;373:834.
4. Data on File, Janssen PostHoc PAH Study 2023.
5. Data on File, Janssen ADUE Trial Clinical Study Report 2023.

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Key Takeaway

OPSYNVI® significantly reduces hospitalizations and readmissions—key cost drivers in PAH management—resulting in a minimal net budget impact of under $0.01 per member per month.

Conclusions

Introducing OPSYNVI® to the market had a minimal budget impact of less than $0.01 per-member per-month over a 3-year time horizon for both the commercial and Medicare plans. In addition, OPSYNVI® is priced at parity to branded macitentan.[2]

The increase in drug acquisition costs were partially offset because OPSYNVI® patients had reduced hospitalizations and readmissions compared to other patients, which were substantial drivers of the model results.

These results suggest that adding OPSYVNI® to formulary can improve patient outcomes while contributing negligible additional costs to both Commercial and Medicare payers.

Model Assumptions and Limitations

- Acquisition costs for OPSYNVI® were assumed to be the same as OPSUMIT® (macitentan 10 mg).
- OPSUMIT® loses market exclusivity at the end of 2025.
- Costs for the ERA + PDE5I loose dose combination was calculated using a combination of costs for macitentan, ambrisentan, or bosentan + sildenafil or tadalafil, weighted based on available market share data.
- HCRU for ERA monotherapies were assumed to be the same for all ERAs, due to a lack of product-specific data.
- HCRU for PDE5-I monotherapies was assumed to be the same for all PDE5-Is due to a lack of product-specific data.
- Inpatient days PPPM were calculated based on the number of inpatient admissions PPPM and the average length of stay per admission.
- PAH-related readmission rates were assumed to be the same for all therapies in the model due to a lack of publicly available data.
- Mortality was not considered in this model.
- Adverse events were not considered in this model.

Disclosures

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Therapeutic Area:

Cardiovascular Disorders; Respiratory-Related Disorders

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