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Hospital Budget Impact Model of TV-46000, a Long-Acting Subcutaneous Formulation of Risperidone, Versus Once-Monthly Paliperidone Palmitate in Adults With Schizophrenia in the United States

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Objective: To evaluate the financial implications of implementing TV-46000 versus paliperidone palmitate for the maintenance treatment of schizophrenia in hospitals in the United States

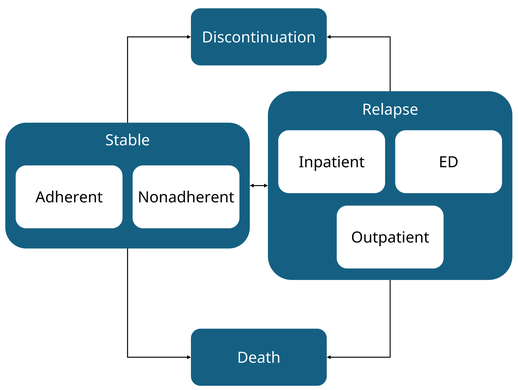
Background

- Schizophrenia is associated with elevated healthcare costs, driven in part by increased emergency department (ED) use and costs associated with hospital admissions[1,2]
- Strategies that reduce relapse-related ED visits or hospitalizations, or shorten length of stay (LOS), may therefore yield substantial cost savings
- Multiple long-acting injectable antipsychotics (LAIs) are available that differ in antipsychotic molecule and formulation characteristics; however, comparative studies between these agents remain limited
- TV-46000, a long-acting subcutaneous formulation of risperidone that can be administered once monthly (q1m) or once every 2 months, significantly prolongs the time to impending relapse, with a safety profile consistent with other formulations of risperidone[3–5]
- Intramuscular LAI paliperidone palmitate can be administered once monthly (PP1m), every 3 months, or every 6 months
- To enable hospital administrators and healthcare providers to assess the economic impact of implementing TV-46000 q1m versus PP1m for the maintenance treatment of schizophrenia, a customizable United States (US) hospital budget impact model (HBIM) was developed

Methods

- An HBIM with time horizons of 1–5 years was developed in Microsoft Excel using a state transition Markov approach
- The HBIM begins with hospitalization for relapse, after which patients are treated with either TV-46000 q1m or PP1m
  - The following health states (sub-states) were considered: stable (treatment adherent vs non-adherent vs discontinued), relapse (inpatient vs ED vs outpatient encounter), and death (**Figure 1**)

Figure 1. HBIM Structure



- The HBIM used epidemiological inputs, schizophrenia treatment eligibility, payer mix (Medicare, Medicaid, commercial insurance), hospital reimbursement, clinical inputs (eg, relapse rates and hospitalization rates), and included costs (eg, drug acquisition costs) (**Table 1**)
  - Drug acquisition costs used in the model were calculated based on publicly available wholesale acquisition costs[6,7]
  - Inputs on LOS for TV-46000 versus PP1m were derived from the results of a US-based, retrospective, observational cohort study[8]

Table 1. Key Model Parameters

	Value
Epidemiological inputs	
Total US population	342,034,432[9]
Population within hospital service area	0.1%
Population aged 18 years and older	78.0%[9]
Annual incidence of schizophrenia in adults	1.1%[10]
Individuals with schizophrenia receiving treatment	60.0%[10]
Treated patients eligible for SGAs (oral and LAI)	95.0%
Clinical inputs	
ED to inpatient conversion proportion	49.40%[1]
Payer mix	
Medicare	35.0%[11]
Medicaid	50.0%[11]
Commercial insurance	10.0%[11]
Other	5.0%
Hospital reimbursement	
Medicare	85.0%[12]
Medicaid	80.0%[13,14]
Commercial insurance	140.0%[15–17]
Other (free sample programs, PAPs, uninsured patients paying direct out of pocket, DSH payments)	25.0%

- For the model, 30-day readmission rates were calculated to represent a general overall relative change in 30-day readmission rates between TV-46000 q1m and PP1m
- Treatment-specific model parameters were based on clinical study results (**Table 2**)

Table 2. Treatment-Specific Model Parameters

	Value
Relapse rate, annual, %	
TV-46000 q1m	8.5%[18]
PP1m	15.2%[19]
Relapses requiring inpatient visits, %	
TV-46000 q1m	19.3%[11]
PP1m	19.3%[11]
Relapses requiring ED visits, %	
TV-46000 q1m	19.0%[11]
PP1m	19.0%[11]
Length of stay per hospitalization, days (SD)	
TV-46000 q1m	12.57 (10.03)[8]
PP1m	15.46 (10.15)[8]
Drug acquisition cost, USD/mg	
TV-46000 q1m	$26.27
PP1m	$15.25

- The base case comprised 1000 US adults with schizophrenia who were eligible for treatment with TV-46000, with a market share split of 0% for TV-46000 q1m and 100% for PP1m
  - Sensitivity analyses varied the market share split of q1m TV-46000
  - Increased use of TV-46000 q1m arose only from substitution of PP1m
- The HBIM was used to estimate total costs (including acquisition and hospital costs), LOS, and relapses resulting in ED or inpatient encounters

A switch from PP1m to TV-46000 q1m is anticipated to reduce total costs, LOS, and relapses resulting in ED or inpatient encounters

- In the base case scenario, the HBIM estimates indicate that changing the market share split from 0% TV-46000 q1m and 100% PP1m to different proportions of market shares ranging from 0% to 100% use of TV-46000 q1m would result in cost savings, with the largest reduction in total costs occurring with a switch to 100% TV-46000 q1m and 0% PP1m (**Figure 2**)
  - For each market share split, the largest reductions in total costs occurred in the first year
- Similarly, changing the market share split to demonstrate increased use of TV-46000 q1m reduced LOS by up to 4282.0 days for every 1000 patients over 5 years (**Table 3**)
- The number of relapses resulting in ED or inpatient encounters was reduced by up to 261.4 encounters per 1000 treated adults over 5 years (**Figure 3**)

Figure 2. Annual and Total 5-Year Cost Savings: Impact of a Changing Market Share Split From 0% TV-46000 and 100% PP1m Up to 100% TV-46000 q1m and 0% PP1m

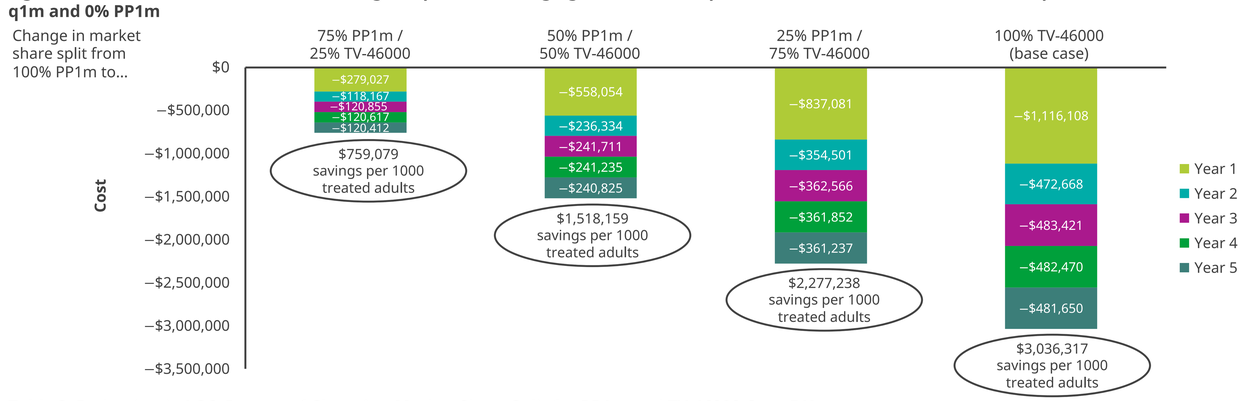
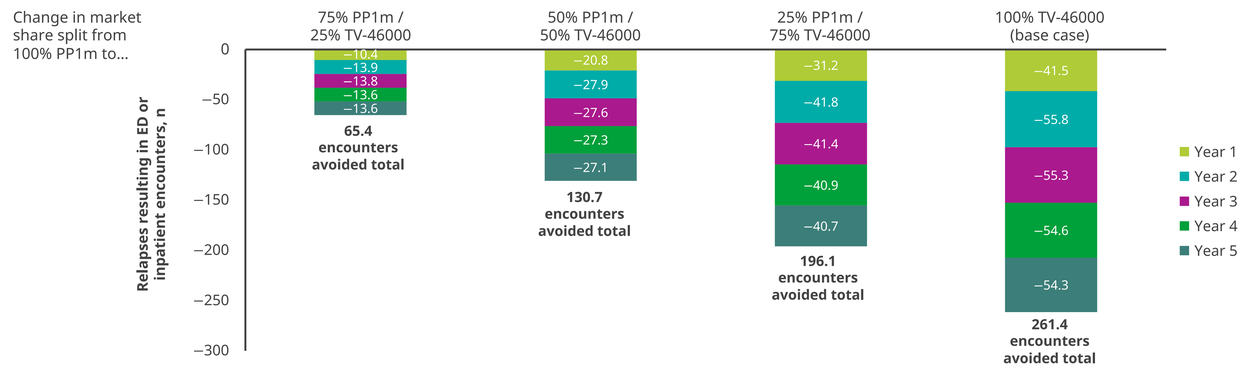


Table 3. Reduction in LOS: Impact of Changing Market Share Split for PP1m and TV-46000 Over 5 Years

Change in market share split from 100% PP1m to:	Reduction in LOS, days					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
75% PP1m / 25% TV-46000	157.4	225.4	229.8	229.2	228.7	1070.5
50% PP1m / 50% TV-46000	314.8	450.7	459.7	458.4	457.4	2141.0
25% PP1m / 75% TV-46000	472.2	676.1	689.5	687.5	686.2	3211.5
100% TV-46000 (base case)	629.6	901.4	919.4	916.7	914.9	4282.0

Figure 3. Annual and Total 5-Year Reductions in Relapses Resulting in ED or Inpatient Encounters: Impact of a Changing Market Share Split From 0% TV-46000 and 100% PP1m Up to 100% TV-46000 q1m and 0% PP1m



Conclusions

- Per the HBIM, smaller market uptake of TV-46000 q1m is projected to lead to smaller reductions in total cost savings, LOS, and relapses resulting in ED or inpatient encounters relative to the base case scenario
- These findings demonstrate the potential economic benefits of TV-46000 q1m versus PP1m for the treatment of adults with schizophrenia from a US hospital perspective

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Abbreviations
DSH = disproportionate share hospital, ED = emergency department, HBIM = hospital budget impact model, LAI = long-acting injectable, LOS = length of stay, PAP = Patient Assistance Program, PP1m = once-monthly paliperidone palmitate, q1m = once monthly, SGA = second-generation antipsychotic, US = United States

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