Updated Budget Impact Analysis of Vibegron for the Treatment of Overactive Bladder in the United States

EE108

Ian Gould, PhD[1]; Jeff Lee, PharmD, FCCP[1]; Jeffrey Nesheim, PharmD, MS[2]; Adam Carrera, PharmD[2]

[1]Lumanity Inc., Morristown, NJ, USA; [2]Sumitomo Pharma America, Inc., Marlborough, MA, USA

Background

- Overactive bladder (OAB) is a chronic condition characterized by urinary urgency, increased daytime frequency, and nocturia, with or without urinary incontinence[1]
  - OAB is common in both men and women, and its prevalence increases with age[2]
- OAB is associated with a substantial socioeconomic burden in the United States; total direct costs of managing patients with OAB has been shown to be 1.4- to >2-fold greater than the healthcare costs of individuals without OAB[3]
- Treatment options for OAB include behavioral therapy, pharmacotherapy (eg, oral anticholinergics and/or β_3-adrenergic receptor agonists), and minimally invasive procedures (eg, botulinum toxin injection, percutaneous tibial nerve stimulation, and sacral neuromodulation)[1]
  - The use of anticholinergics in patients with OAB is associated with low persistence, often related to side effects such as dry mouth and constipation[4]; increasing anticholinergic burden (ACB) is also associated with an increased risk of dementia,[5] as well as falls and fractures[6]
- Vibegron is a β_3-adrenergic receptor agonist that is approved by the US Food and Drug Administration for the treatment of adults with OAB and for the treatment of symptoms of OAB in adult males on pharmacologic therapy for benign prostatic hyperplasia (BPH)[7]
- A budget impact model (BIM) developed in 2021 showed that introducing vibegron to a health plan formulary was associated with modest cost increases for US commercial payors and Medicare that were partially offset by savings related to a lower use of minimally invasive procedures, decreased incidence of adverse events (AEs) and comorbidities, reduced drug–drug interactions, and lower ACB[8]
  - Since the 2021 BIM, new factors, including the availability of generic mirabegron and additional evidence on outcomes and healthcare costs related to ACB, have been identified that may impact the costs of including vibegron in health plans

Objective

- To assess how the recent introduction of generic mirabegron and developments on ACB-related costs and clinical outcomes impact US commercial payor and Medicare budgets when introducing vibegron to their formulary

Methods

- A BIM with 5-year time horizon was developed using projected market shares for 1-million-member US commercial and Medicare plans and a top down, prevalence-based approach
  - The current BIM was based on the previously established model,[8] with modifications made as necessary to estimate the impact of new developments (eg, generic mirabegron and updated ACB-related costs, treatment persistence, and market shares)
  - Age and sex distributions for enrollees with commercial insurance and Medicare coverage and OAB prevalence were estimated as previously described[8]
- The target population consisted of patients seeking oral pharmacotherapy for OAB
  - The BIM specifically considered the general OAB population without regard to presence of BPH diagnosis or pharmacotherapy
- The BIM included vibegron 75 mg, branded and generic mirabegron 25 and 50 mg, and generic anticholinergics and calculated the respective market shares based on an internal market analysis
- The monthly cost for all treatments was based on the 2024 drug wholesale acquisition cost (WAC)
  - The cost of mirabegron was calculated as a weighted average of branded and generic WAC based on payor perspective (50% generic for commercial plans, 10% generic for Medicare part D), which was held steady for the time horizon of the model
- The model incorporated changes in clinical outcomes, including efficacy (defined by reduction in mean daily incontinence episodes at 3 and 12 months), the cost of mirabegron and CYP2D6 substrate drug–drug interactions, ACB (modeled by increased use of healthcare resources, increased medical and pharmacy costs, and increased risk of dementia and falls/fractures[9]), OAB-related comorbidities (depression, urinary tract infection, and skin infections), and AEs (blurred vision, dry mouth, constipation, and tachycardia)
  - The percentage of patients concurrently prescribed mirabegron and a CYP2D6 substrate was obtained from a retrospective claims analysis[10] for either the full population (commercial) or those ≥65 years of age (Medicare)
- Treatment persistence was modeled from a real-world analysis of OAB medication persistence over 12 months in patients who were prescribed an OAB medication between April 1, 2021, and August 31, 2022[11]
- Economic outcomes are provided as costs per member per month (PMPM) and per treated member per month (PTMPM)
- One-way sensitivity analyses (OWSAs) were performed to quantify the impact in response to changes in key variables

Results

- For a 1-million-member plan, the estimated number of patients with OAB treated with prescription medication was 31,456 from the commercial payor perspective and 56,684 from the Medicare perspective
  - The estimated number of patients with incontinence receiving prescription medication for OAB was 20,936 and 37,276 from the US commercial payor and Medicare perspectives, respectively
- Including vibegron in a health plan formulary was associated with a moderate increase in PMPM cost over 5 years of $0.92 (range for 2025-2029, $0.50-$1.28) for commercial payors and $1.76 (range for 2025-2029, $0.95-$2.46) for Medicare (**Table 1**)
- The total incremental increase in PTMPM cost was $23.47 (range for 2025-2029, $13.44-$31.00) for commercial payors and $25.62 (range for 2025-2029, $14.50-$34.15) for Medicare (**Table 1**)
  - Higher pharmacy costs were partially offset by cost savings in all other categories (including minimally invasive procedures, AEs, comorbidities, and ACB) totaling approximately $27.9 and $40.5 million in 5 years for commercial and Medicare payors, respectively

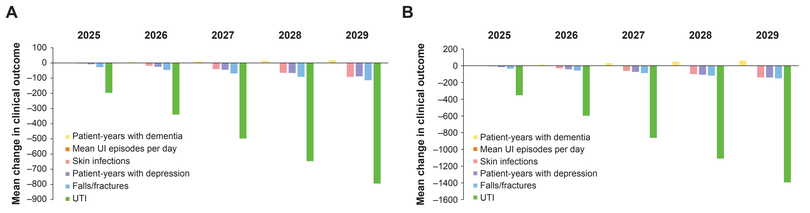
Table 1. Budget Impact of Adding Vibegron to a Formulary

	2025	2026	2027	2028	2029	2025-2029
Market share for vibegron 75 mg, %[a]	10.89	13.13	16.00	18.00	20.00	–
US commercial payor incremental costs, $						
Total incremental cost	6,021,698	8,837,597	11,517,609	13,542,295	15,300,388	55,219,586
OAB treatment	8,891,758	12,995,357	17,176,256	20,500,074	23,521,916	83,085,362
Minimally invasive procedures	0	–769,152	–1,329,940	–1,799,212	–2,143,459	–6,041,762
AE	–24,654	–36,293	–48,980	–59,810	–70,170	–239,906
Comorbidity	–62,307	–108,882	–151,547	–186,418	–216,623	–725,777
Minimally invasive procedure comorbidity	0	–30,993	–80,550	–142,985	–211,843	–466,371
ACB	–2,783,100	–3,212,440	–4,047,631	–4,769,353	–5,579,434	–20,391,959
PMPM	0.50	0.74	0.96	1.13	1.28	0.92
PTMPM	13.44	18.59	23.52	27.41	31.00	23.47
Medicare incremental costs, $						
Total incremental cost	11,351,135	16,849,432	22,075,033	26,045,781	29,485,485	105,806,866
OAB treatment	15,683,909	22,919,408	30,270,963	36,098,541	41,381,883	146,354,705
Minimally invasive procedures	0	–829,262	–1,433,875	–1,939,822	–2,310,971	–6,513,929
AE	–32,909	–48,445	–65,381	–79,837	–93,666	–320,238
Comorbidity	–115,859	–208,133	–291,837	–360,553	–419,839	–1,396,221
Minimally invasive procedure comorbidity	0	–54,766	–142,351	–252,703	–374,411	–824,230
ACB	–4,184,006	–4,929,371	–6,262,486	–7,419,845	–8,697,512	–31,493,220
PMPM	0.95	1.40	1.84	2.17	2.46	1.76
PTMPM	14.50	20.35	25.90	30.22	34.15	25.62

ACB, anticholinergic burden; AE, adverse event; OAB, overactive bladder; PMPM, per member per month; PTMPM, per treated member per month.
[a]Presented as percentage of the OAB market.

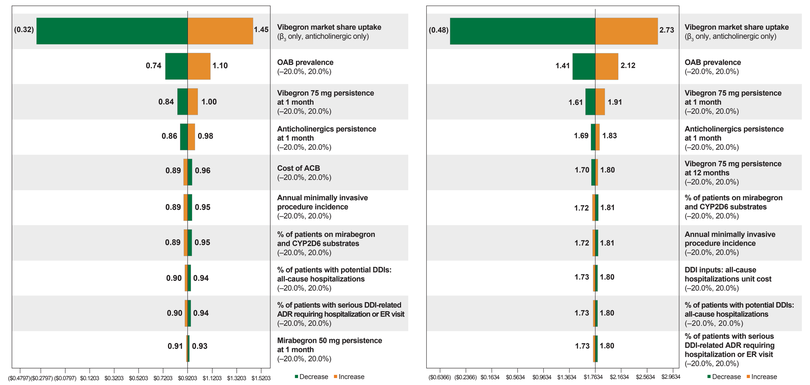
- Adding vibegron to a formulary was associated with a reduction in comorbid events and lower healthcare resource utilization for commercial payors (**Figure 1A**) and for Medicare (**Figure 1B**)
- OWSAs indicated that PMPM costs were most sensitive to vibegron market share assumptions, OAB prevalence, and vibegron persistence at 1 month for commercial payors (**Figure 2A**) and Medicare (**Figure 2B**)

Figure 1. Incremental Changes to Clinical Outcomes per Year Due to Inclusion of Vibegron in a (A) Commercial Plan Formulary and (B) Medicare Formulary



UI, urinary incontinence; UTI, urinary tract infection.

Figure 2. Top 10 Variables From OWSAs for 5-Year Incremental PMPMs From (A) Commercial Payor and (B) Medicare Perspectives



ACB, anticholinergic burden; ADR, adverse drug reaction; CYP, cytochrome P450; DDI, drug–drug interaction; ER, emergency room; OAB, overactive bladder; OWSA, one-way sensitivity analysis; PMPM, per member per month.

Conclusions

- A limitation of the model is that clinical and economic outcomes are not tracked once a patient is no longer on any form of treatment; that is, patients who discontinue β_3-adrenergic agonists or anticholinergics and do not switch to a minimally invasive treatment are no longer tracked by the model, impacting both clinical and economic outcomes
- The updated BIM suggests that vibegron continues to have modest budget impact on health plans over a 5-year time frame despite the introduction of generic mirabegron
  - The BIM was designed to factor in the uptake of vibegron in postlaunch years, an important consideration when evaluating PMPM estimates
- Reducing healthcare resource utilization related to minimally invasive therapies, AEs, comorbidities, drug–drug interactions, and clinical outcomes associated with ACB may increase the cost offset from the higher pharmacy costs associated with vibegron
- OWSAs revealed that the BIM for commercial payors and Medicare were most sensitive to vibegron market share assumptions, OAB prevalence, and vibegron persistence

References **1.** Cameron AP, et al. *J Urol*. 2024;212(1):11-20. **2.** Coyne KS, et al. *Neurourol Urodyn*. 2013;32(3):230-237. **3.** Powell LC, et al. *Neurourol Urodyn*. 2018;37(4):1241-1249. **4.** Rai BP, et al. *Cochrane Database Syst Rev*. 2012;12(12):CD003193. **5.** Dmochowski RR, et al. *Neurourol Urodyn*. 2021;40(1):28-37. **6.** Szabo SM, et al. *BMJ Open*. 2019;9(5):e026391. **7.** GEMTESA® (vibegron). Full Prescribing Information. Sumitomo Pharma America, Inc.; 2025. **8.** Chen JV, et al. *Pharmacoeconomics*. 2022;40(10):979-988. **9.** Richter HE, et al. Anticholinergic burden in patients with overactive bladder and association with health outcomes: a retrospective database claims analysis. Presented at: Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction; February 20–24, 2024; Fort Lauderdale, FL. **10.** Ritchey ME, et al. *Drugs Real World Outcomes*. 2023;10(1):119-129. **11.** Chastek B, et al. *Neurourol Urodyn*. 2024;43(7):1504-1513.

Acknowledgments Medical writing support was provided by The Curry Rockefeller Group, LLC, a Citrus Health Group, Inc., company (Chicago, Illinois), and was funded by Sumitomo Pharma America, Inc. (Marlborough, Massachusetts).

Funding This study was funded by Sumitomo Pharma America, Inc. (Marlborough, Massachusetts).

Disclosures **Ian Gould** and **Jeff Lee** are employees of Lumanity Inc. **Jeffrey Nesheim** and **Adam Carrera** are employees of Sumitomo Pharma America, Inc.