



BXCL501 Commercial Opportunity in the At-Home Setting for Bipolar Disorders and Schizophrenia

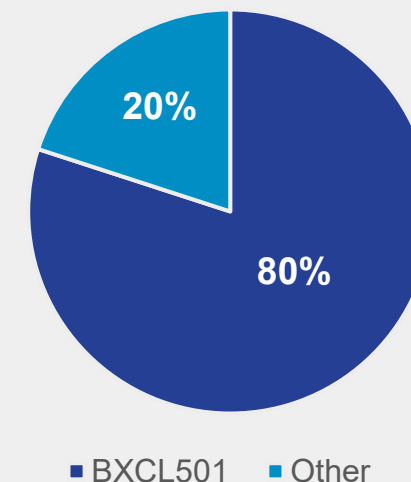
August 2025

The At-Home Market for BXCL501 in Bipolar Disorders and Schizophrenia: Summary

The potential for BXCL501 in the at-home setting reflects significant unmet need and attractiveness to patients

- **Our market research indicates approximately 3 episodes of agitation per month in the home setting**
 - Previous estimate of 23M annual episodes was based on historic claims data (~1.2 episodes per month)
 - Due to the lack of approved treatment options, the claims data likely underestimate the true episode frequency
 - Consequently, the total addressable market (TAM) is significantly higher than previously reported
- **Based on the target product profile, HCPs indicated that they would treat ~16% of their patients with BXCL501**
- **HCPs believe that the most significant unmet need is the lack of effective and fast-acting treatments for the at-home setting**
- **Patients are the primary stakeholder for the treatment of their agitation episodes**
 - Patients feel that they lack control over their thoughts and actions during agitation episodes, which occur approximately three times per month on average
 - Patients want to treat the episode as soon as it begins and before it escalates in severity
- **Patients research suggests that they would use BXCL501 in 80% of the episodes experienced at-home**
- **Pricing flexibility in the market may allow up to \$1,400+ per prescription**
- **Attractive market access factors**

**Anticipated Episodic Patient Choice
(Future Market)**
(% of Episodes, Market research, n=240)



Agitation Characteristics

A behavioral emergency with highly variable clinical definitions and diagnoses¹⁻³



Agitation is characterized by¹



Emotional signs and symptoms

- Hyperresponsiveness
- Racing thoughts
- Emotional tension



Behavioral signs and symptoms

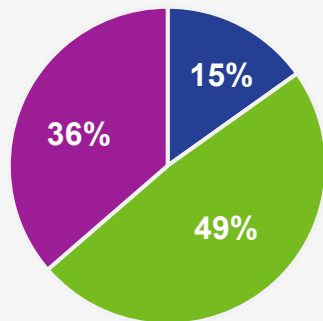
- Inability to stay calm or still
- Motor and verbal hyperactivity
- Communication impairments

1. Martínez-Raga J, et al. *Front Psychiatry*. 2018;9(54).
2. Roppolo LP, et al. *J Am Coll Emerg Physicians Open*. 2020;1(5):898-907.
3. Zeller SL, Rhoades WP. *Clin Ther*. 2010;32(3):403-425.

Episode Frequency in Patients Experiencing Agitation

Agitation episodes expected to occur 3-4 times per month based on multiple data sources

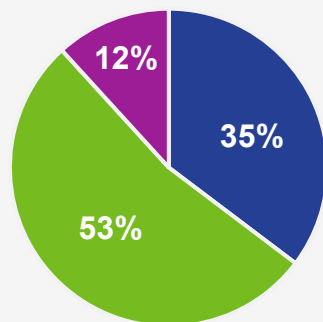
Primary Market Research (N=80)¹



Schizophrenia (n=20)

35 Episodes per year
(~3/month)

■ Mild ■ Moderate ■ Severe



Bipolar Disorder (n=60)

38 Episodes per year
(~3/month)

■ Mild ■ Moderate ■ Severe

Published Survey (N=583)²

Severity	Number of episodes/year
Mild	22.4
Moderate	15.4
Moderate-intense	6.8
Severe	2.9
Total	47.5 (~4/month)

BXCL501 Serenity at Home Pivotal Phase 3 Trial

Data from more than 2,200
episodes collected

¹Source: InVibe Feb 2023 Q4: In the past month, about how many agitation episodes [IF PATIENT SHOW "have you" IF CG SHOW "has your loved one"] experienced?
Q5. Of the [XX] agitation episodes you experienced in the past month, how many would you categorize as mild, moderate, or severe?

²Roberts et al. BMC Psychiatry (2018) 18:104

At-Home Intervention: Early Intervention May Prevent Severity Escalation

Potentially reduced ER visits, hospitalizations, or first responder interventions

The market opportunity at home is expected to be much larger than 23 M annually originally estimated

BXCL501 CLINICAL DEVELOPMENT

23M EPISODES¹

 AT HOME SETTING



OPTIMAL INTERVENTION

 HOSPITAL SETTING

16M EPISODES

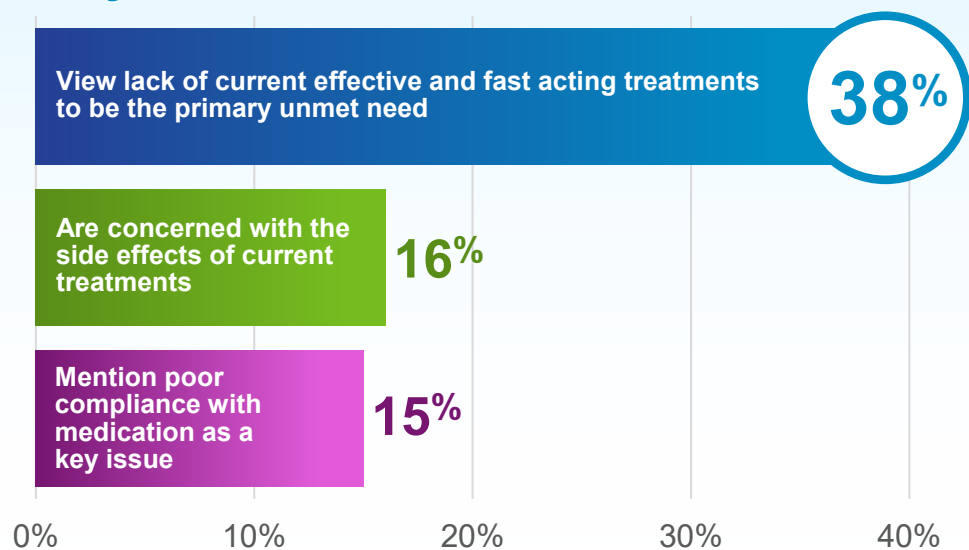

Igalmi™
(dexmedetomidine)
sublingual film - 120 mcg, 180 mcg

¹Number of schizophrenia/bipolar patients with agitation: Kwong, M et al., Presented at the Academy of Managed Care Pharmacy Nexus 2021, October 18-21, 2021; Number of episodes per patient: Symphony claims data

Agitation as an Unmet Need

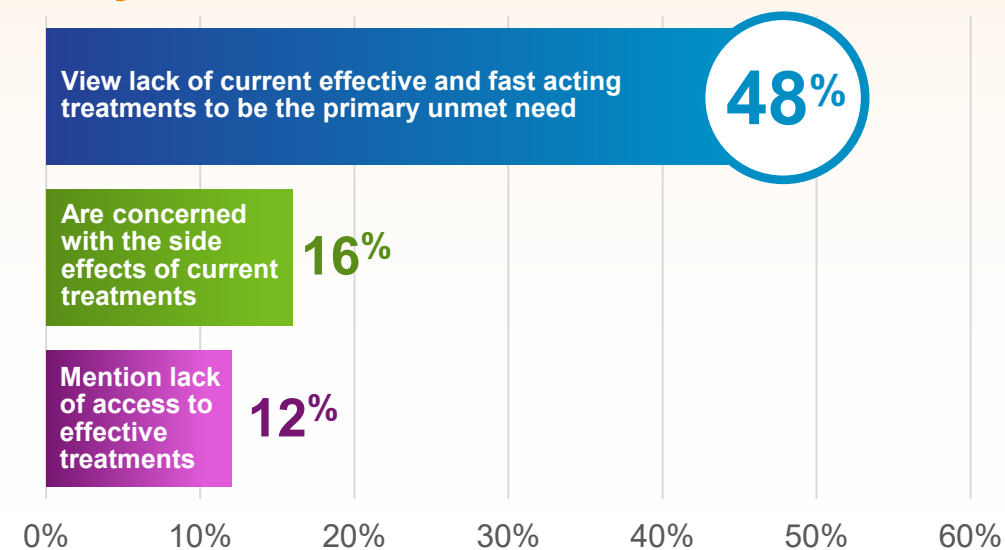
Market seeks effective, fast-acting, more tolerable treatment for agitation in bipolar and schizophrenia agitation for at-home use

Key unmet needs in BP



“ The available drugs either work too slowly or have unacceptable side effects.”
– Psychiatrist

Key unmet needs in SCZ



“ Other than the sedative effects of antipsychotics there really aren't any good options for managing agitation without just making the patient drowsy.”
– Psychiatrist

HCP Preference Estimate

HCPs view lack of effective, tolerable, and fast acting treatments to be the primary unmet need; in addition, no products are currently approved in the at-home setting

Agitation associated with	BXCL501 Peak Market Share Based on Target at-home Product Profile
Bipolar Disorder & Schizophrenia	~16%

Methodology:

Current Management: Respondents provide information about their patients and the treatment of each indication, including: Perceived unmet need, Estimated patient insurance mix, Guidelines used in treatment, Involvement of patients' caregivers

Current Allocation: Respondents estimate their current use of pharmaceutical treatments in the last 100 episodes of acute agitation for each indication.

BXCL501 Evaluation: Respondents review the BXCL501 TPP for each indication and evaluate: Their perception of the profile, The patient types best suited for BXCL501, The likelihood of prescribing BXCL501 in the future

Future Allocation: Respondents repeat the allocation exercise assuming BXCL501 is available (in low and high doses for AD) in the following scenarios: Independent of cost sharing, Preferred Tier, Non-preferred Tier

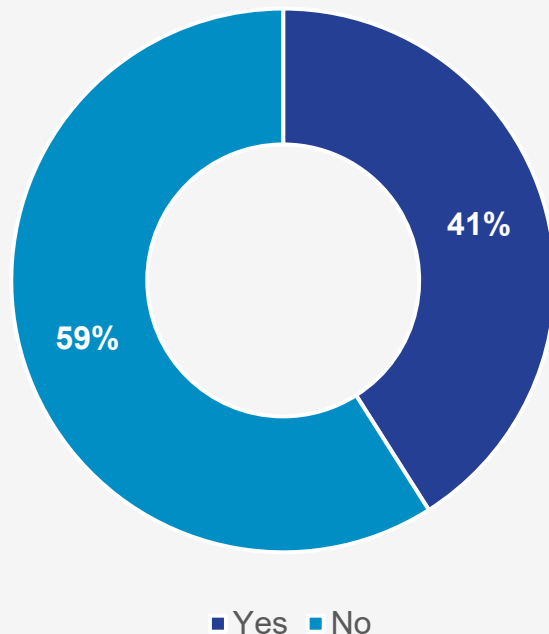
Allocation exercise assumptions:

- Percent of last 100 adult patients with breakthrough agitation seen the community setting who would receive BXCL501
- “Community setting” = patients seen in:
 - ✓ Provider office, clinic, outpatient mental health center, assisted living facility and supportive housing
- 10 films per prescription

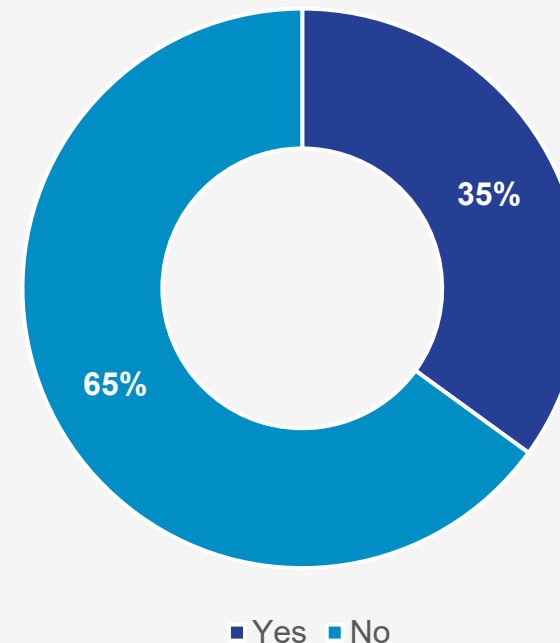
Recognition and Treatment of Agitation

Patients experiencing agitation indicate that they are not typically diagnosed, nor treated, for this symptom. This creates an opportunity and need for HCP education and market conditioning.

Agitation Diagnosis
(% of Total PT/CGs, n=80)



Prescribed a Treatment for Agitation
(% of Total PT/CGs, n=80)



Q1. Have you ever been diagnosed with agitation specifically? This can be a related but separate diagnosis to other mental health conditions
Q2. Have you ever been prescribed a treatment specifically for agitation episodes?
Q3. What was the treatment you were prescribed for agitation episodes?
Source: InVibe Feb 2023

Patients Perspectives of At-Home Agitation

Difficult for patients to articulate; patients feel a sense of helplessness

Overall Quality Descriptors



- Beyond their control
- Different from ordinary fear and anger.
- Feeling a lack of agency over their own thoughts and actions
- Likely to escalate
- Emotional experience of agitation likely makes it harder to make concrete, proactive decisions on when to seek help



Patient Quote

CLICK FOR VOICE



[I]t feels like there's something inside of me telling me **there's something wrong**, and I can't sit still, and I feel like my body's about to jump out of my skin. It's just really annoying, and **you get short-tempered** because of it and angry and snappy at people. **It's hard to describe** because you can't get it to go away, and it's just there, and **you're stuck with it**, and **there's nothing you can do** to make it go away.”

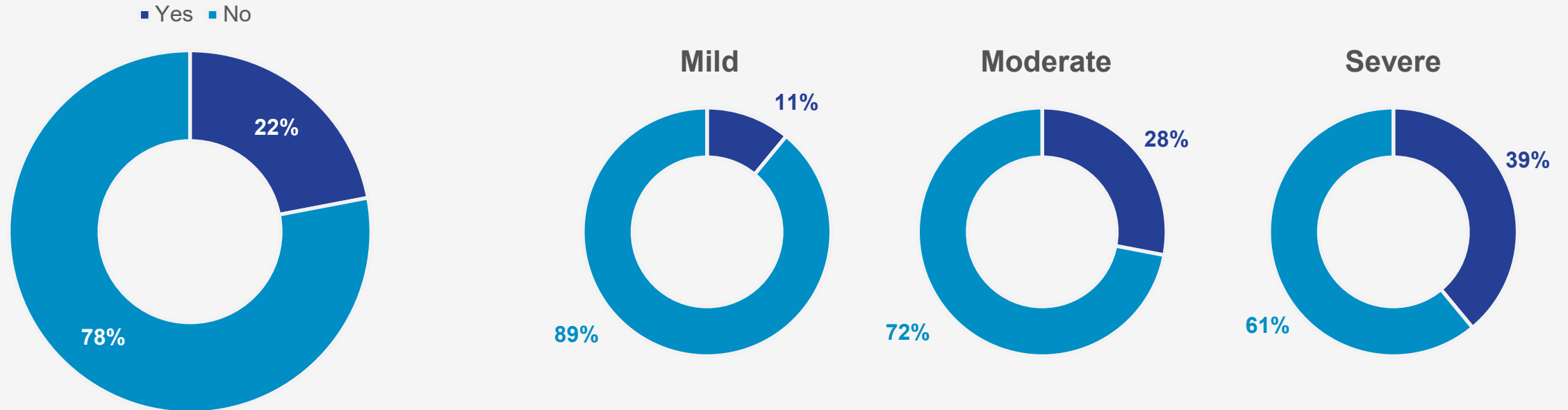
(Q1, R10, PT, SCZ)

Patient Aura

Patients experience a prodromal phenomenon with agitation incidents, which increases with episode severity.

Advance Knowledge of Agitation Episodes

(% of Episodes, n=240*)



* These data are compiled from 3 episodes described by each patient (N=80 pts/cgs *3 = 240)

Caregivers and patients were equally likely to have advance knowledge of an episode (22% for both groups)

Episode Intervention Target

Patients indicate that they want to manage the episode with BXCL501 either just before or at the first sign of escalation in the at-home setting.

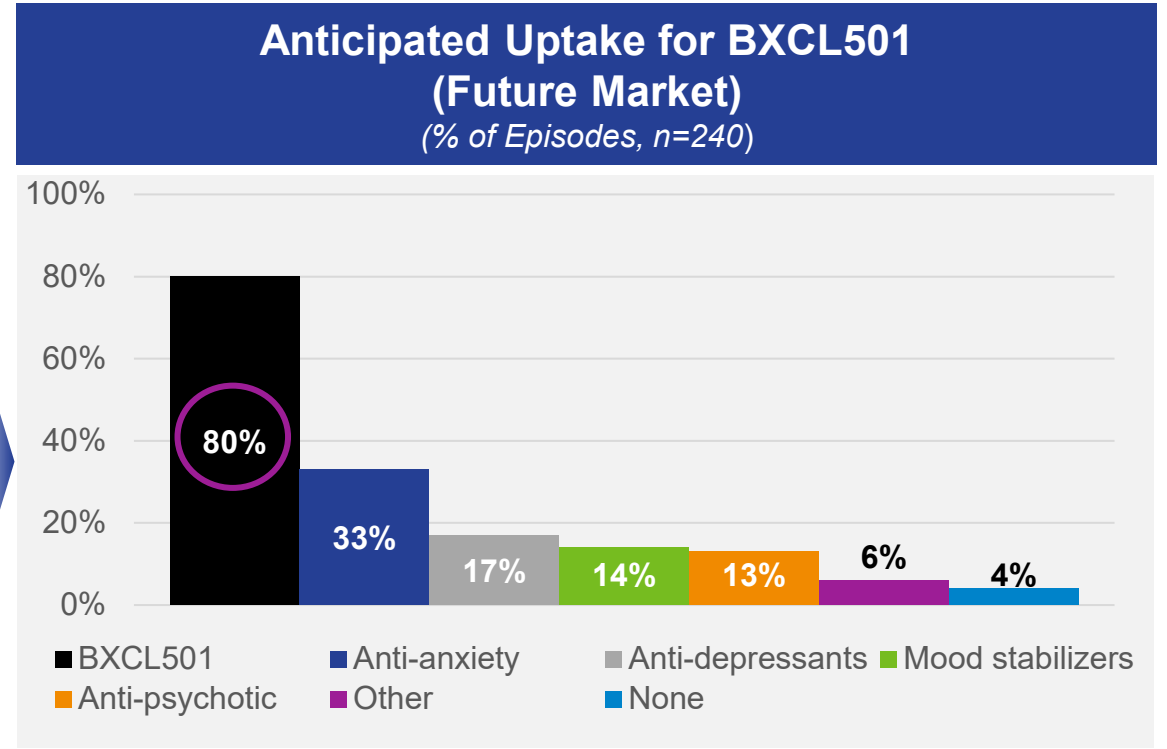
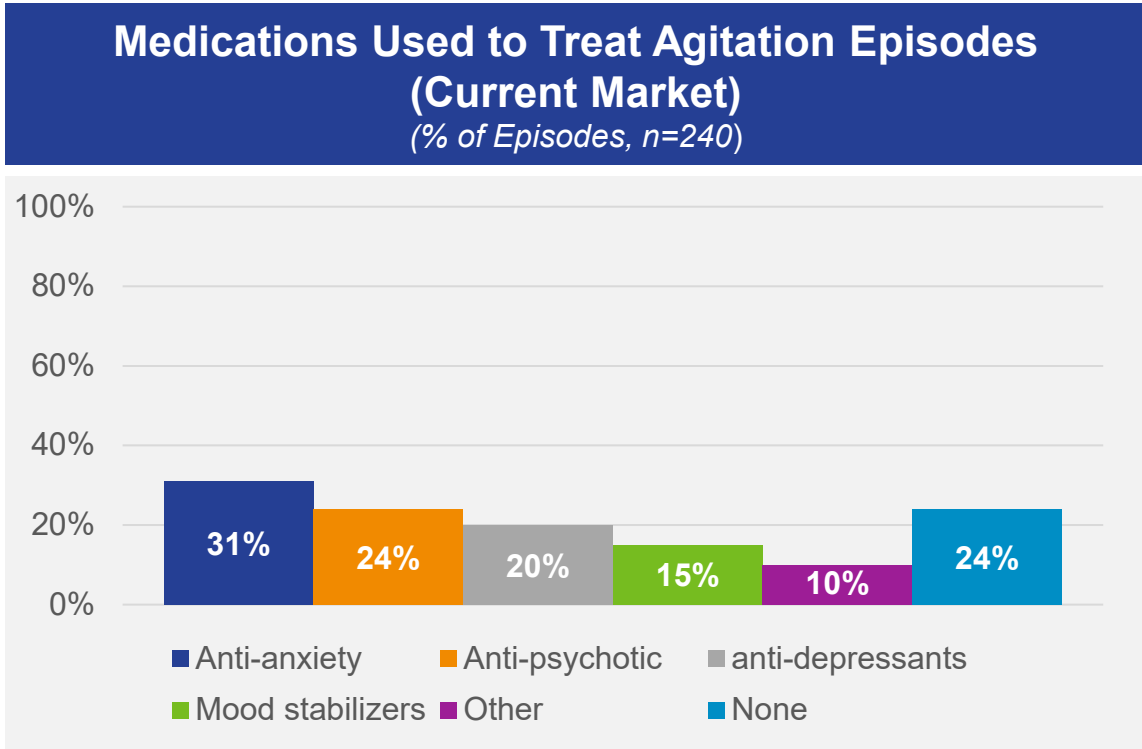
Best Time To Take Igalmi
(% PTs/CGs n=80)



“ I would love to be able to have it available **when I knew an episode was coming**. That it would help bite it in the butt, so to say. That would be such a benefit for me.”
(VR4, R8, PT, BPD, age 57)

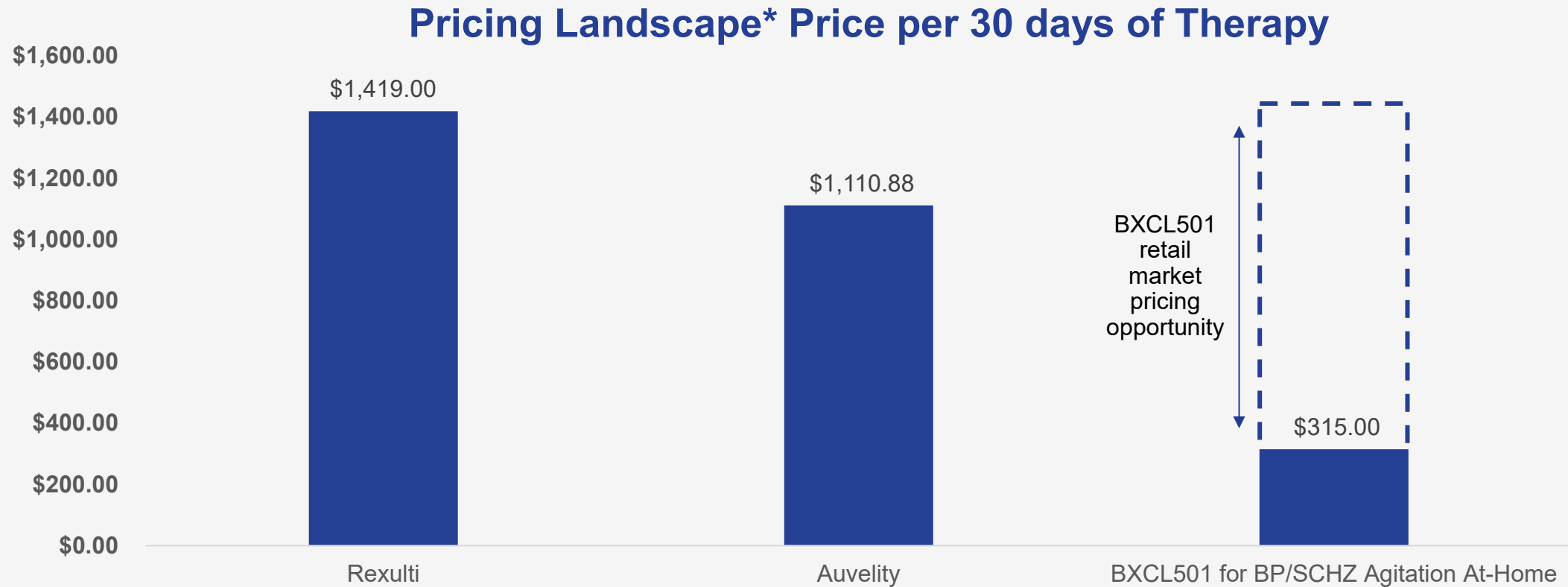
Patients Preference Estimate

Based on a target product profile, patients say they would use BXCL501 for 80% of their episodes



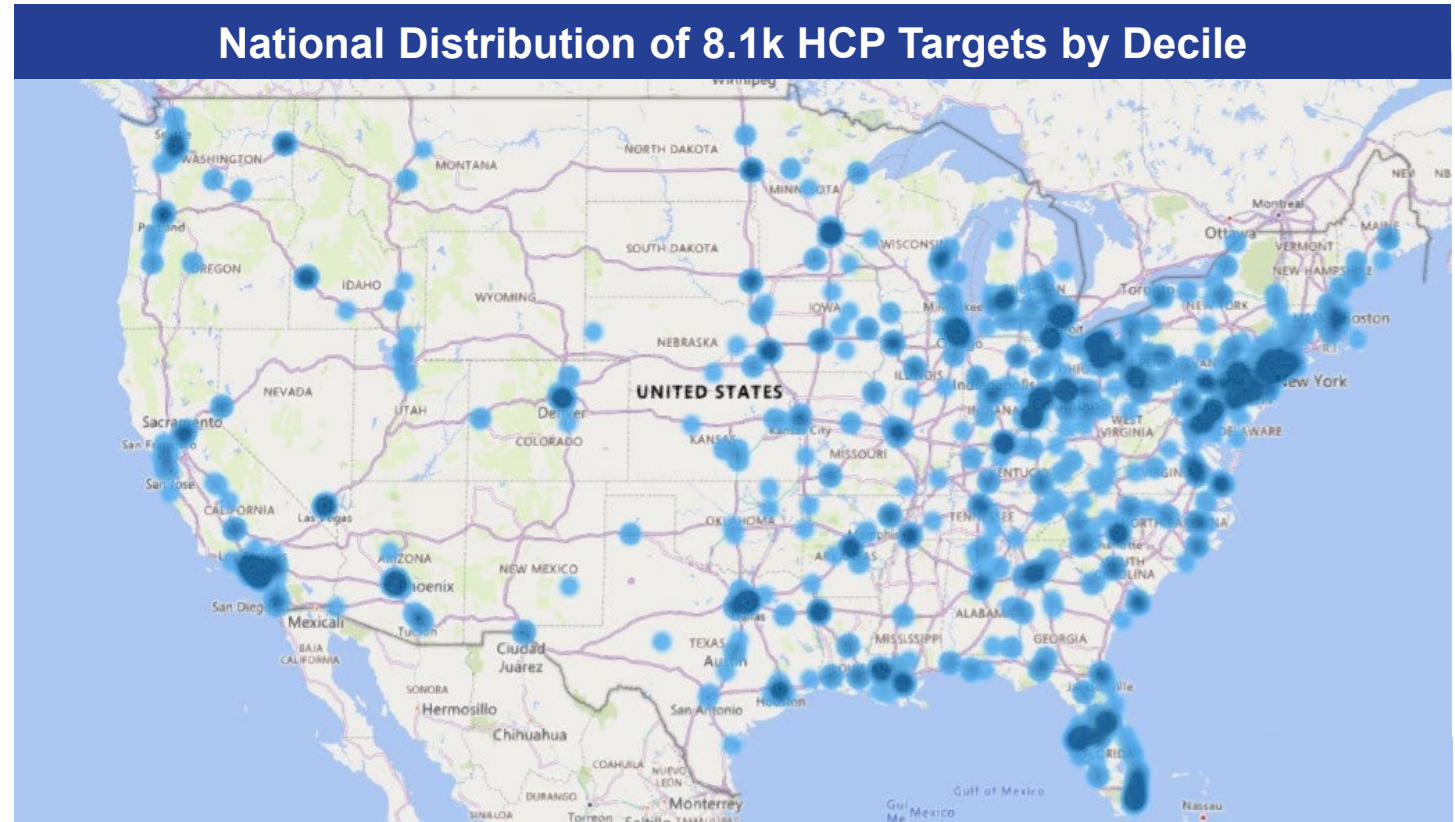
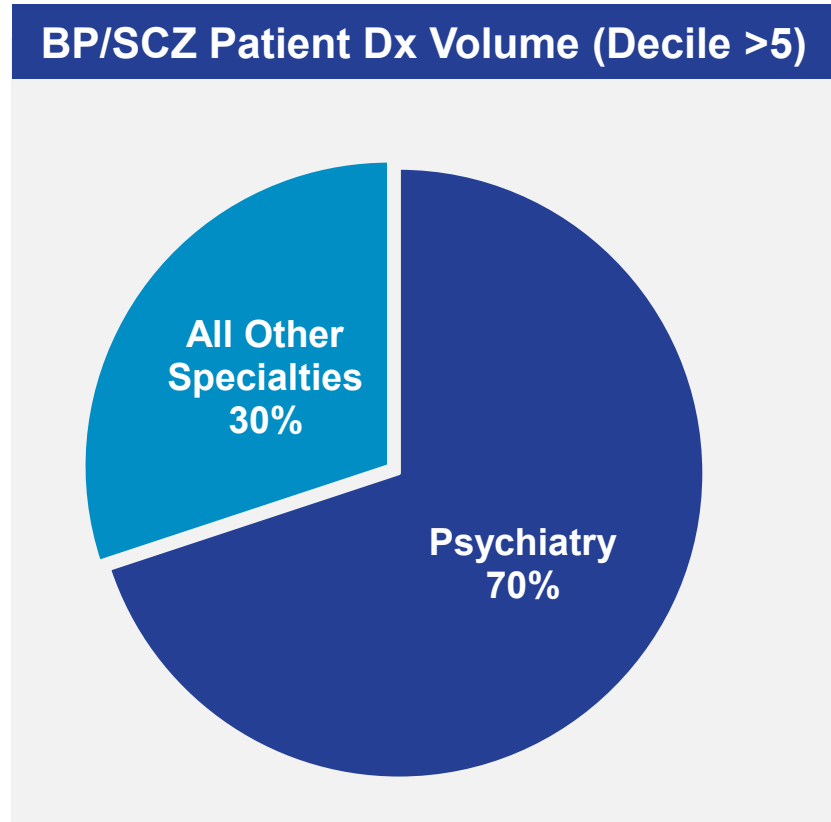
Retail Agitation Markets & Pricing Considerations

Current and development agitation products (chronic) cost over \$1400/month. These products have community psychiatry indications in Major Depressive Disorder as well, demonstrating pricing elasticity in psychiatric retail markets.



Provisional Targeting Model

Among the highest deciles of Bipolar & Schizophrenia patient Dx volume, 70% are managed by psychiatrists, with 8.1k total HCP targets. 50-70 discrete field FTEs can cover these targets



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