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Patient Treatment Preferences In Bipolar-I Disorder:

Are We Really Listening?

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Our Featured Speakers

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Objectives

Examine WHEN And WHY

we should listen to patients living with BP-I disorder regarding treatment preferences

Review WHAT

to listen for when discussing treatment preferences and options

Discuss HOW

to translate our listening into effective patient care

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WHEN And WHY

Bipolar-I Disorder Overview And Reasons To Listen To Patients

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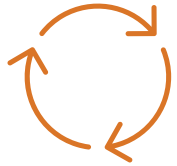
BP-I Disorder Is A Chronic And Severe Condition

BP-I is a chronic and severe mental health disorder with high rates of mood episode recurrence[1]



Over 90% of patients with BP-I experience recurrent mood episodes, with ~50% experiencing recurrence within the first year following their first manic episode[2,3]

Mood episode recurrence in BP-I impacts short- and long-term clinical outcomes and cognitive functioning[4]

BP-I, bipolar I disorder

1. Oswald P, et al. *Eur Neuropsychopharmacol*. 2017;17(11):687-695.
2. Perlis RH, et al. *Am J Psychiatry*. 2006;163:217-224.
3. Yatham LN, et al. *Can J Psychiatry*. 2009;54(2):105-112.
4. Bridges JFP, et al. *Patient Prefer Adherence*. 2023;17:2545-2555.

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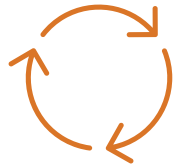
Patients Living With BP-I Are At Risk Of Increased Morbidity and Mortality

BP-I is associated with increased morbidity and mortality, as the presence of comorbid physical health complications and psychosocial burden lead to increased rates of hospitalizations and suicidal ideation compared with healthy individuals[1]



The mortality gap between the general population and patients with severe mental disorders, including BP-I, has been described as a public health crisis that requires urgent action from health care professionals[2]

BP-I, bipolar I disorder.

1. Peters AT, et al. *J Nerv Ment Dis*. 2016;204(2):87-94.
2. Fiorillo A, Sartorius N. *Ann Gen Psychiatry*. 2021;20(1):52.

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Comorbidities Contribute To The Burden Of BP-I

- Bipolar disorder commonly manifests with other associated neuropsychiatric disorders. Comorbidity rates indicate elevated lifetime risk of co-occurring symptomologies, including SUD.[1,2]
- As observed in one study, in ~40% of patients (n=85) hospitalized for SUD, comorbid bipolar disorder was misdiagnosed prior to hospitalization, most commonly (80%) as unipolar depression by mental health clinicians.[3]

- BP-I and PTSD commonly co-occur and result in increased symptom burden and low QoL.[4]
- In patients living with BP-I, lifetime trauma exposure emerged in 72.3%, with a DSM-5 PTSD diagnosis reported by 35.6%. Patients with PTSD showed more frequently a (hypo)manic episode at onset, SUD, and psychotic features.[5]

- Studies suggest that neuropsychiatric comorbidities contribute differently to the burden of BP-I for female and male patients.
- Male patients living with BP-I have a history of more frequent manic episodes and more associated co-occurring SUD.[6]
- Women have later onset of BP-I, often initially present with a major depressive episode, and have a 2-fold higher likelihood of co-occurring PTSD[7,8]

BP-I, bipolar I disorder; DSM, Diagnostic and Statistical Manual of Mental Disorders, 5th ed; PTSD, post-traumatic stress disorder; QoL, quality of life; SUD, substance use disorder.

1. Goes FS. *BMJ*. 2023;381:e073591.
2. Grant BF, et al. *J Clin Psychiatry*. 2005;66(10):1205-1215.
3. Albanese MJ, et al. *J Psychiatr Pract*. 2006;12(2):124-127.
4. Bajor LA, et al. *J Affect Disord*. 2013;145(2):232-239.
5. Carmassi C, et al. *J Affect Disord*. 2020;262:267-272.
6. Messer T, et al. *Psychiatry Res*. 2017;253:338-350.
7. Vega P, et al. *Women's Health (Lond)*. 2011;7(6):663-674.
8. Patel RS, et al. *Brain Sci*. 2018;8(9):168.

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Beliefs Of Patient Living With BP-I Disorder Impact Acceptance And Adherence To Treatments

In a qualitative study that incorporated analytical discourse analysis, patients (N=36) diagnosed with BD were interviewed individually to explore perceived factors that facilitated or hindered their adherence to a pharmacological treatment

Beliefs That May Contribute To Better Adherence

- Recognition of illness
- Perceived need for treatment
- Attributing symptoms to underlying biological cause of illness
- Shared clinical decision-making

Beliefs That May Contribute To Worse Adherence

- Belief in lack of effective treatments
- Side effects
- Social control factors

BD, bipolar disorder; BP-I, bipolar I disorder.

Alcalá JÁ, et al. *Int J Environ Res Public Health*. 2022;19(13):7633.

Patient And Family/Significant Other/Caregiver Involvement In Treatment Decisions

In several studies, more than half of people living with BP-I reported being less involved in decision-making than they would prefer. Across these studies, patients who experienced their preferred involvement level reported more positive outcomes.[1]

These findings suggest that patients living with BP-I tend to desire greater levels of decision-making involvement than they currently experience, which in turn may lead to more positive outcomes.[1,2]

Patients rely on family/significant other/caregivers as allies or "sounding boards" in the decision-making process[3]

BP-I, bipolar I disorder.

1. Fisher A, et al. *Patient Educ Couns*. 2016;99(7):1106-1120.
2. Bridges JFP, et al. *Patient Prefer Adherence*. 2023;17:2545-2555.
3. Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.

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WHAT

Provider Approaches To Patient Listening When Discussing Treatment Preferences And Options With Patients

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Patients Living With BP-I Disorder Ranked The Relative Importance Of Treatment Goals

US-based patients (N=255) with self-reported diagnosis of BP-I were administered a survey to prioritize the importance of 16 treatment goals using a best-worst scaling system

Goal	Relative Importance	95% CI
Being less impulsive, angry, or irritable	9.73	9.06-10.40
Able to feel pleasure/happiness	9.54	8.88-10.21
Reduce frequency of mania, depression, and mixed episodes	9.48	8.82-10.15
Stay focused/think clearly	8.41	7.78-9.06
Decrease the severity of the symptoms once they start	8.01	7.39-8.64
Decrease the duration of the severity of symptoms once they start	7.99	7.37-8.63
Have increased confidence in managing daily life and stressors	7.39	6.80-8.01
Feel increased motivation/ energy levels	6.99	6.41-7.59

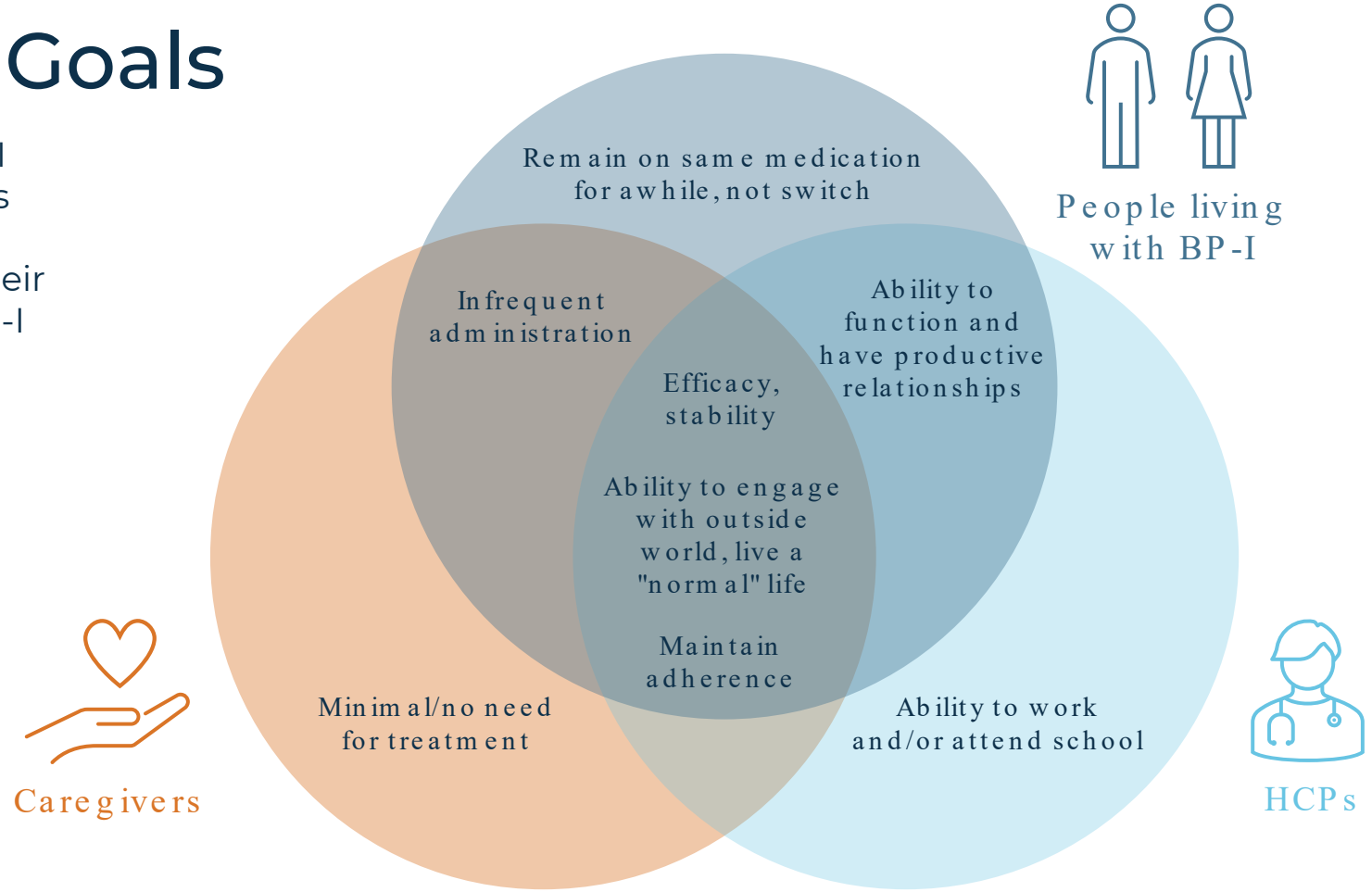
Goals	Relative Importance	95% CI
Begin or maintain relationships with family and/or friends	5.92	5.40-6.47
Begin or maintain a relationship with a partner/significant other	5.54	5.04-6.07
Reduced risk of insomnia, restlessness or moving around too much during sleep	4.51	4.08-4.97
Reduced risk of excessive sleepiness, drowsiness, or being slowed down	4.34	3.92-4.78
Able to work or go to school	3.25	2.91-3.61
Reduced dependence on others	3.04	2.72-3.39
Reduced risk of weight gain	2.96	2.65-3.29
Reduce number of visits to the hospital or emergency department	2.91	2.61-3.24

BP-I, bipolar I disorder; CI, confidence interval.

Bridges JFP, et al. *Patient Prefer Adherence*. 2023;17:2545-2555.

Stakeholders And Their Treatment Goals

In a US-based study, patients with BP-I (n=10), caregivers (n=5), and prescribers (n=5) were administered qualitative telephone interviews to understand their preferences for LAI medications for BP-I



BP-I, bipolar I disorder; HCP, healthcare provider; LAI, long-acting injectables.

Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.

Prescriber Preferences And Goals

In a US-based study, patients with BP-I (n=10), caregivers (n=5), and prescribers (n=5) were administered qualitative telephone interviews to understand their preferences for LAI medications for BP-I

Factors important to prescribers when selecting a medication include:

- Patient age
- Dosing schedule/frequency
- Patient allergies
- Caregiver/family involvement
- Patient preference
- Previous treatment responses
- Patient access to medication
- History of treatment adherence
- Past prescriber experience with the medication
- Cost/insurance coverage

Prescriber treatment goals overlap with those of patients living with BP-I, as both cohorts value treatment efficacy and stability as well as affording patients the ability to effectively engage with the outside world, have functional and productive relationships, and live life with a sense of normalcy

BP-I, bipolar I disorder; LAI, long-acting injectables.

Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.

Most Important Outcomes For Patients[1]

Interviewed patients living with BP-I reported treatment effectiveness and duration of efficacy as critical factors in medication selection[2]

Additional features of an ideal treatment include[2]:

- Mild adverse event profile
- Reduced need for comedications

Providers may overlook or misunderstand the potential impact of treatment on QoL and function[3]

It is imperative that providers address the unmet psychosocial impacts of bipolar disorder, including the struggle to maintain identity, the unpredictable nature of the disorder, and social stigma associated with the condition[3]

BP-I, bipolar I disorder; QoL, quality of life.

1. Eiring Ø, et al. *Patient*. 2016;9(2):91-102;
2. Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.
3. Siegel-Ramsay JE, et al. *Int J Bipolar Disord*. 2023;11(1):13.

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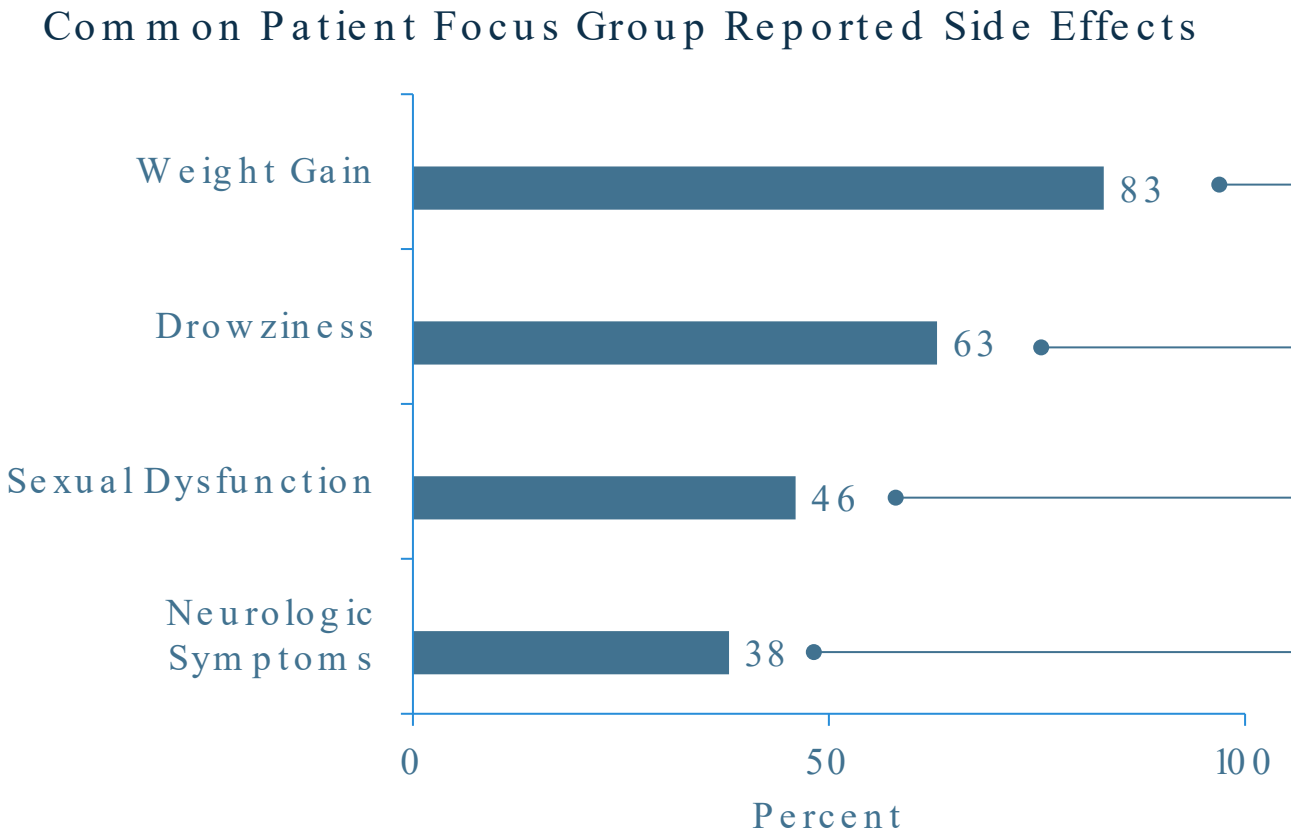
Patient Concerns About Side Effects Of Antipsychotics



"Then you gain the weight and then you bring yourself back into a tailspin because you're gaining weight"

"My medicine just knocks me out, and I'm tired all the time."

"Mine was low libido. And it's causing issues in my marriage."

"My hands will shake and I – especially like my diaphragm will just go into spasms."

Doane MJ, et al. *BMC Psychiatry*. 2023;23(1):245.

Pharmacological Maintenance Therapy In BP-I

Pharmacological treatment is recommended to achieve and maintain symptom control[1,2]

Almost all individuals living with BP-I require maintenance treatment to prevent relapse and to restore functioning and QoL[3]

Maintenance therapy options include[3]	
Lithium, Mood Stabilizers/Anticonvulsants	Lithium, divalproex, lamotrigine, and carbamazepine
SGAs	aripiprazole, asenapine, clozapine (adj), olanzapine, paliperidone, quetiapine, risperidone
Combinations	aripiprazole + lamotrigine, aripiprazole + Li/DVP, ziprasidone + Li/DVP, lurasidone + Li/DVP, olanzapine + fluoxetine, quetiapine + Li/DVP
Others	gabapentin (adj)

Adj, adjunctive therapy; BP-I, bipolar I disorder; DVP, divalproex; Li, lithium; QoL, quality of life; SGA, second-generation antipsychotic.

1. Lazary J, et al. *Neuropsychopharmacol Hung*. 2021;23(4):363-373.
2. Greene M, et al. *Neuropsychiatr Dis Treat*. 2018;14:1545-1559.
3. Keramatian K, et al. *Focus (Am Psychiatr Publ)*. 2023;21(4):344-353.

Treatment Guidelines: SGAs

2023 CANMAT And ISBD Guidelines Summary And Update[1]

- Recommend SGAs as first- and second-line monotherapies
- Recommend certain combinations of SGAs and mood stabilizers as first- and second-line combination therapies
- Recommend SGA LAIs with “level 2 evidence”

2023-2024 Florida Best Practice Guidelines[2]

- Recommend SGAs as first-line monotherapies or as first-line treatments adjunctive to mood stabilizers
- Recommend SGA LAIs with “level 1A established efficacy”

2017 CINP Guidelines[3]

- Recommend SGA monotherapy as the first-line treatment choice
- SGA combination therapy with additional adjunctive agents recommended for second-line and beyond treatment
- Recommend SGA LAIs with “level 1 evidence”

CANMAT, Canadian Network for Mood and Anxiety Treatments; CINP, International College of Neuro-Psychopharmacology; ISBD, International Society for Bipolar Disorders; LAI, long-acting injectable; SGA, second-generation antipsychotic.

1. Keramatian K, et al. *Focus (Am Psychiatr Publ).* 2023;21(4):344-353.
2. Florida Best Practice Psychotherapeutic Medication Guidelines for Adults. Accessed August 7, 2024: https://floridabhcenter.org/wp-content/uploads/2023/07/2023-06-Medication-Guidelines-%E2%80%93-Adults-Final_06.30.2023.pdf.
3. Fountoulakis KN, et al. *Intl J Neuropsychopharmacol.* 2017;20(2):180-195.

Prescribers Must Bridge Differences Between Patient Preferences And Treatment Guidelines

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HOW

Aligning Patient Listening With Prescriber Treatment Goals Into Effective Care

Shared Decision-Making Best Practices For Patients Living With BP-I

How to translate listening to effective treatment

- Develop a relationship of trust and confidence with patients
- Inform the patient and/or family/significant other/caregiver of all available treatment options with open communication about potential side-effects
- Align on treatment goals with patients to ensure optimal treatment compliance
- Topics discussed and information relayed during initial patient visits should be reiterated often once the patient has stabilized

BP-I, bipolar I disorder.

Faiman B, Tariman JD. *Clin J Oncol Nurs.* 2019;23(5):540-542.

Treatment Options: Potential Advantages And Disadvantages Of Oral And LAI Formulations

Oral: Potential **Advantages**

- Effective[1]
- Many generics available[2]
- Extensive clinical experience[1]
- Flexibility[3]
- Short duration of action[3]

Oral: Potential **Disadvantages**

- Daily administration[4]
- Potential for misuse[3]
- Influenced by first-pass metabolism[5]
- Adherence rates can be inaccurate[6]

LAI: Potential **Advantages**

- Transparency of adherence[7]
- Ease of administration[8]
- Reduced peak-trough plasma levels[7]
- Improved patient outcomes[7]
- Improved patient and physician satisfaction[7]
- Lowered relapse rate[5,7]
- Decreased rehospitalizations[9]

LAI: Potential **Disadvantages**

- Concerns regarding potential pain of injection[10]
- Slow dose titration and longer time to reach steady state[8]
- May prolong side effects[8]
- Difficult to adjust small doses[10]
- Potential for small amount to leak into subcutaneous tissue[8]
- Association with involuntary hospitalization and related trauma[11]
- Perception that treatment is punitive or forced by clinicians without consideration of patient feelings or rights[12]

LAI, long-acting injectable.

1. Citrome L. *Expert Opin Pharmacother*. 2012;13(11):1545-1573.
2. Albright B. *Behav Healthc*. 2012;32(2):44-45.
3. Burton N. *Psychiatry*. 2nd ed. Wiley-Blackwell; 2010.
4. Bera RB. *J Clin Psychiatry*. 2014;75(suppl 2):30-33.
5. Zhornitsky S, et al. *Schizophr Res Treatment*. 2012;2012:407171.
6. Velligan DI, et al. *Schizophr Res*. 2020;215:17-24.
7. Geerts P, et al. *BMC Psychiatry*. 2013;13:58.
8. Agid O, et al. *Expert Opin Pharmacother*. 2010;11(14):2301-2317.
9. Lafeuille MH, et al. *BMC Psychiatry*. 2013;13:221.
10. Jeong HG, et al. *Clin Psychopharmacol Neurosci*. 2013;11(1):1-6.
11. Iyer S, et al. *Can J Psychiatry*. 2013;58(5 suppl 1):14S-22S.
12. Brissos S, et al. *Ther Adv Psychopharmacol*. 2014;4(5):198-219.

Additional Considerations For Antipsychotic Formulations

LAI antipsychotics were developed to support drug plasma concentration stability to reduce relapse and AE risks[1,2] Nonetheless, it is important for clinicians to consider pharmacokinetic characteristics of both oral and LAI antipsychotics when prescribing LAIs[3]

One component of optimal clinical management with pharmacological intervention involves continuous drug therapy by adherence to dosing regimen that achieves pharmacokinetic steady state[2]

At steady-state, lower fluctuation in drug plasma concentrations (ie, lower peak-to-trough plasma concentration variation at steady state) is considered advantageous[3,4]

AE, adverse event; LAI, long-acting injectable.

1. Correll CU, et al. *CNS Drugs*. 2021;35(1):39-59.
2. Ma N, et al. *Neuropsychiatr Dis Treat*. 2023;19:1987-2006.
3. Sheehan JJ, et al. *Innov Clin Neurosci*. 2012;9(7-8):17-23.
4. Wakamatsu A, et al. *Innov Clin Neurosci*. 2013;10(3):23-30.

Patient Preference Research Findings: Antipsychotic Formulations

Patients with BP-I report several factors impacting treatment preference, including:

- Rapid symptom improvement[1]
- Symptom relapse/ recurrence prevention[1]
- Safety/tolerability, including side effects affecting QoL and serious health problems[2]

Patients with BP-I reported attributes that inform oral antipsychotic preference[3]:

- Treatment efficacy (ie, symptom severity improvements)
- Specific side effect attributes (ie, weight gain, sexual dysfunction, akathisia, sedation risk)

Patients (n=10) living with BP-I who were taking a once-monthly LAI[4]:

Reported greater adherence to an LAI-based treatment regimen over that for oral medications

Valued the convenience of decreased administration frequency of LAIs over oral medications and wished to further reduce the frequency of administration

Highly preferred to remain on the same medication as opposed to switching medications frequently

BP-I, bipolar I disorder; LAI, long-acting injectable; QoL, quality of life.

1. Nozaki K, et al. Poster presented at: CINP World Congress of Neuropsychopharmacology. June 22-26, 2014; Vancouver, Canada. Abstract P-22-002.
2. Doane MJ, et al. *BMC Psychiatry*. 2023;23(1):245.
3. Doane MJ, et al. *BMJ Psychiatry*. 2024;24:605.
4. Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.

Perceived Advantages And Disadvantages of LAIs

In a US-based study, patients (n=10) currently treated with a once-monthly LAI, living with BP-I, caregivers (n=5) living with and providing care for BP-I patients, and prescribers (n=5) managing at least 10 patients with BP-I, were administered qualitative telephone interviews to understand their preferences for LAI medications

	Perceived Advantages	Perceived Disadvantages
Individuals Living with BP-I	✓ **Convenience:** less time attending appointments and associated travel ✓ **Personal impact**: fewer injections; less responsibility and pressure; improved relationships; ability to travel for long periods ✓ **Decreased burden:** feel "normal" due to receiving fewer treatment	× **Duration of effect:** medication wearing off before the next dose[a] × **Organization:** difficulty in remembering when an injection is scheduled; forgetting appointments × **Tolerability:** potential for additional side effects and increased pain of injection × **Duration of side effects:** may prolong side effects or require treatment to mitigate
Prescribers	✓ **Physician benefits:** fewer appointments for patients with stabilized disease, freeing up time for patients who may need more support ✓ **Patient benefits:** fewer appointments and injections, leading to patients feeling less burdened by treatment and having more freedom ✓ **Clinical benefits:** patients may be stable for longer with gradual release of medication ✓ **Overall:** patients feeling positive due to fewer visits, fewer injections (less pain), and feeling more normal due to less treatment	× **Q2M LAI need:** may be no need for an extended formulation given availability of other medication frequencies, with patients doing well on once-monthly LAIs × **Control:** Inability to "tweak" dosing if the patient experiences side effects; linking patient visits to injection administration may lead to fewer patient visits × **Efficacy:** potential lack of duration of efficacy, and thus a need for oral supplementation

[a]Some people living with BP-I reported experiencing this with a once-monthly LAI.

BP-I, bipolar I disorder; LAI, long-acting injectable; Q2M, every 2 months.

Loomer S, et al. Poster presented at: ASCP 2024 Annual Meeting. May 28–31, 2024, Miami Beach, FL.

Initiating Discussion On LAIs With Patients + Family/Significant Other/Caregiver: What To Listen For

Multiple studies* have used a checklist/questionnaire-based approach to understand barriers leading to underutilization of LAIs and provided checklists to facilitate conversation among prescribers and patients/caregivers. Below is a compilation of questions from such checklists:

1	The patient has missed doses since the last visit	☐ Yes	☐ No
2	Patient is currently on more than 1 antipsychotic	☐ Yes	☐ No
3	Patient has tried more than 2 antipsychotics in the past 12 months	☐ Yes	☐ No
4	Patient has been hospitalized or had a crisis visit in the past 12 months	☐ Yes	☐ No
5	Patient is experiencing diurnal exacerbation of intolerable side effects	☐ Yes	☐ No
6	Patient is not satisfied with current level of symptom control	☐ Yes	☐ No
7	Patient values predictable mood stability	☐ Yes	☐ No
8	Patient has tried more than 2 antipsychotics in the past 12 months	☐ Yes	☐ No
9	Patient has concerns about discretion among friends	☐ Yes	☐ No
10	Patient worries about taking medication while traveling	☐ Yes	☐ No

LAI, long-acting injectable.

*Velligan et al included patients from community mental health clinics within one healthcare system in Texas and Ohio. Mace et al included patients from 4 community mental health groups from "promoting recovery" teams.

1. Derived from: Velligan DI, et al. *Psychiatr Serv.* 2021;72(9):1012-1017.
2. Derived from: Mace S, et al. *Ther Adv Psychopharmacol.* 2019;9:2045125319860977.

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Treatment Discussions With Patients And Family/Significant Others/Caregivers: When And How Often?

RAISE
the discussion of treatment options early

- At diagnosis
- During hospital admission when preparing for discharge
- First clinic/office visit

REPEAT
treatment options often

- At each visit
  - To repeat options and/or discuss progress
  - When patient is stabilized and able to comprehend/ focus on detailed information

REVIEW
treatment pros and cons

- At each visit
  - To address questions, concerns, and side effects

REINFORCE
treatment choice with patients and family/ significant other/caregiver

- At each visit
  - To remind patients of their commitment to achieve stability
  - To highlight progress made on treatment

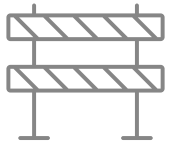
Summary recommendations are based on 2024 KOL faculty discussions and a 2-day medical affairs advisory board involving 5 patients, 1 caregiver, and 8 HCPs.

Key Points

BP-I is a chronic and severe mental health disorder in which 90% of patients experience recurrent mood episodes that impact short- and long-term clinical outcomes and cognitive functioning[1-4]

Pharmacological treatment is recommended to achieve symptom control, and almost all patients require maintenance treatment to prevent relapse and restore functioning and QOL[5-7]

Guidelines support the use of both oral and LAIs as first, second, and adjunctive therapy for patients living with BP-I[7-9]



LAIs may be underutilized in the treatment of BP-I, likely due to lack of awareness and overestimation of patient adherence to oral medications[10]

Prescriber treatment goals overlap with those of patients living with BP-I, as both cohorts value treatment efficacy and stability and affording the patient the ability to effectively engage with the outside world, have functional and productive relationships, and live life with a sense of normalcy[11]

BP-I, bipolar I disorder; LAI, long-acting injectable; QOL, quality of life.

1. Oswald P, et al. *Eur Neuropsychopharmacol*. 2017;17(11):687-695.
2. Perlis RH, et al. *Am J Psychiatry*. 2006;163:217-224.
3. Yatham LN, et al. *Can J Psychiatry*. 2009;54(2):105-112.
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5. Lazary J, et al. *Neuropsychopharmacol Hung*. 2021;23(4):363-373.
6. Greene M, et al. *Neuropsychiatr Dis Treat*. 2018;14:1545-1559.
7. Keramatian K, et al. *Focus (Am Psychiatr Publ)*. 2023;21(4):344-353.
8. Florida Best Practice Psychotherapeutic Medication Guidelines for Adults. Accessed August 7, 2024: https://floridabhcenter.org/wp-content/uploads/2023/07/2023-06-Medication-Guidelines-%E2%80%93-Adults-Final_06.30.2023.pdf.
9. Fountoulakis KN, et al. *Intl J Neuropsychopharmacol*. 2017;20(2):180-195.
10. Tohen M. *J Clin Psychiatry*. 2020;81(4):OT19046AH1.
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Patient Treatment Preferences In Bipolar-I Disorder:

Are We Really Listening?

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