Box 2. Assessment Scales for Adult Acute Bipolar Depression

- Beck Depression Inventory (BDI)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- Patient Health Questionairre-9 (PHQ-9)
- Quick Inventory of Depression Symptomotology (QIDS)
- Young Mania Rating Scale (YMRS)

**Notes: The recommendations are based on the evidence-base and clinical consensus. The Montgomery-Asberg Depression Rating Scale (MADRS) and Hamilton Rating Scale for Depression (HAM-D) can also be used to assess symptoms of depression in major depressive disorder.*

Note: Treatment recommendations are based on levels of evidence and expert opinion. For a description of the criteria for each level, see pages 2-3.

Conduct comprehensive assessment and use measurement-based care. Refer to Principles of Practice on pages 4-9.

The primary therapeutic objectives of bipolar disorder care are to achieve symptomatic remission, promote syndromal recovery, prevent recurrence, and facilitate full functional recovery.

- Selection of acute treatment should take maintenance treatment goals into account.
- Be aware of safety and tolerability concerns, evidence for maintenance use, and acute efficacy.
- Revisit the appropriateness of current regimen (e.g. inappropriate polypharmacy)

Strongly recommend psychiatric consultation prior to initiation of therapy + psychotherapeutic medication using a multi-disciplinary approach if treated by a non-psychiatrist.

Level 1 Options for initial treatment:

- More than one Level 1 trial is recommended before moving to Level 2. (See tables 2 - 4.)

Note: Only quetiapine and lumateperone are FDA approved in bipolar disorder II (BD-II) depression. Both are efficacious in BD-II but inferior tolerability with quetiapine largely due to sedation and weight/metabolic adverse events.

- Lurasidone or cariprazine monotherapy*

**Note: Lurasidone, lumetaperone, and cariprazine have better metabolic profiles than quetiapine.*

- Lumateperone as monotherapy or adjunctive in bipolar disorder I (BD-I) or bipolar disorder II (BD-II) depression
- Lamotrigine monotherapy
- Quetiapine or quetiapine XR monotherapy if the patient has bipolar I or bipolar II depression
- Lithium monotherapy
- Lurasidone or lamotrigine, like lumetaperone, can be considered adjunctive to lithium or divalproex if index agent (lithium or divalproex) has been previously prescribed and optimized. Adjunctive data for cariprazine not available, but cariprazine could be considered as alternative adjunct.

***Caution: There is a drug-drug interaction with use of lamotrigine and divalproex together that requires reducing the lamotrigine dose by 50% of the typical lamotrigine dose. For dosing recommendations, refer to Table 3 on pages 22-23.*

- Do not utilize conventional antidepressants (e.g., SSRIs, SNRIs, TCAs, MAOIs) as a first-line therapy.

Table 2. Second Generation Antipsychotic Drugs in Bipolar Depression

	Monotherapy		Adjunctive (to lithium or valproate)	
	Bipolar I	Bipolar II	Bipolar I	Bipolar II
Lumateperone	X	X	X	X
Quetiapine	X	X		
Olanzapine/Fluoxetine	X			
Lurasidone	X		X	
Cariprazine	X			

Level 2 If multiple Level 1 trials are ineffective and/or not well tolerated:

- Divalproex + lurasidone
- Olanzapine + fluoxetine (bipolar I disorder)

**Note: Tolerability limitations include weight gain and metabolic concerns.*

- Two (2) drug combination of Level 1 medications but NOT TWO antipsychotic medications.

**Note: Efficacy limitations, relatively few positive randomized controlled trials.*

Level 3 If Levels 1 and 2 are ineffective and/or not well tolerated:

- Electroconvulsive therapy (ECT)

**Note: Consideration is merited due to clinical need, despite even greater efficacy/tolerability limitations than Level 1 and 2 treatments.*

- Repetitive transcranial magnetic stimulation (rTMS) [Less robust evidence for efficacy compared to ECT; accumulating evidence for use in bipolar depression.]

Level 4 If Levels 1 – 3 are ineffective and/or not well tolerated:

- Intravenous racemic ketamine and/or esketamine
- FDA-approved agent for bipolar disorder + conventional antidepressant (e.g., SSRI)*
- Pramipexole
- Adjunctive: Armodafinil or modafanil, thyroid hormone (T3), or stimulants
- Three (3) drug combination

**Notes:*

- *Antidepressant monotherapy is not recommended in bipolar I depression; recommendation is for adjunctive mood stabilizer with antidepressant.*
- *The safety and efficacy of antidepressant monotherapy in bipolar II depression is uncertain but may be appropriate in select circumstances.*

Treatment of Acute Bipolar Disorder – Mania

Box 3. Assessment Scales for Adult Acute Bipolar Mania

- Hamilton Rating Scale for Depression (HAM-D)
- Montgomery-Asbergy Depression Rating Scale (MADRS)
- Young Mania Rating Scale (YMRS)

**Notes: The recommendations are based on the evidence-base and clinical consensus. Although the MADRS and HAM-D do not assess manic symptoms, these scales are recommended to evaluate depression symptoms in individuals presenting with bipolar mania (e.g., to rule out bipolar disorder – mixed features) and to assess for depressive symptoms among individuals on maintenance treatment for bipolar disorder.*

Note: Treatment recommendations are based on levels of evidence and expert opinion. For a description of the criteria for each level, see pages 2-3.

Conduct comprehensive assessment and use measurement-based care. Refer to Principles of Practice on pages 4-9.

The primary therapeutic objectives of bipolar disorder care are safety, symptomatic improvement, and patient psychoeducation.

- Selection of acute treatment should take maintenance treatment goals into account.
- Be aware of safety and tolerability concern, evidence for maintenance use, and acute efficacy.

Strongly recommend psychiatric consultation prior to initiation of therapy + psychotherapeutic medication using a multi-disciplinary approach if treated by a non-psychiatrist.

Level 1A Options for initial treatment:

Mild to moderate severity and/or not requiring hospitalization

- Lithium* monotherapy
- Monotherapy with aripiprazole, asenapine, divalproex*, quetiapine, risperidone, ziprasidone, or cariprazine
- Lithium* or divalproex* + aripiprazole, asenapine, quetiapine, risperidone, or cariprazine
- Electroconvulsive therapy (ECT) is recommended if medical emergency/patient welfare at risk and pharmacotherapy is insufficient
- Olanzapine/samidorphan monotherapy or adjunct to lithium or valproate

Level 1B If multiple Level 1A trials are ineffective and/or not well tolerated:

Mild to moderate severity

- Monotherapy with either haloperidol or olanzapine

Level 2 If Levels 1A and 1B are ineffective and/or not well tolerated:

- Combination treatment with lithium* + divalproex*
- Combination with lithium* and/or divalproex* + second generation antipsychotic (SGA) other than clozapine
- Carbamazepine* monotherapy

Level 3 If Levels 1 and 2 are ineffective and/or not well tolerated:

- Electroconvulsive therapy (ECT)
- Clozapine + lithium* or divalproex*
- Lithium* + carbamazepine*
- Divalproex* + carbamazepine*

Level 4 If Levels 1 – 3 are ineffective and/or not well tolerated:

- A three (3)-drug combination of Level 1, 2, and 3. Drugs may include first generation antipsychotic (FGA) or second-generation antipsychotic (SGA) but NOT TWO antipsychotic medications.

Example: Lithium* + (divalproex* or carbamazepine*) + antipsychotic

Notes:

**Caution should be used when prescribing lithium, lamotrigine, divalproex or carbamazepine to women of reproductive age due to increased risk to the fetus with use during pregnancy, including neural tube and other major birth defects. The risk of divalproex use during pregnancy may be higher in reference to pregnancy-associated safety risk. Please see Florida Best Practice Recommendations for Women of Reproductive Age with Serious Mental Illness and Comorbid Substance Use Disorders and online guideline on the Pharmacological Treatment of Mood Disorders During Pregnancy available at https://floridabhcenter.org.*

***Side-effect concerns with these agents include weight gain, metabolic syndrome, and extrapyramidal symptoms (EPS). Side-effects warrant vigilance and close monitoring on the part of the clinicians.*

Data for use of paliperidone to treat bipolar mania are mixed. Paliperidone greater than 6mg has some data supporting efficacy.

Benzodiazepines may be used as an adjunct treatment for acute treatment of bipolar mania.

Box 4. Assessment Scales for Adult Bipolar I Disorder Continuation/ Maintenance Therapy

- Montgomery-Asberg Depression Rating Scale (MADRS)
- Patient Health Questionairre-9 (PHQ-9)
- Quick Inventory of Depression Symptomatology (QIDS)
- Young Mania Rating Scale (YMRS)

**Notes: The recommendations are based on the evidence-base and clinical consensus. Although the MADRS and HAM-D do not assess manic symptoms, these scales are recommended to evaluate depression symptoms in individuals presenting with bipolar mania (e.g., to rule out bipolar disorder – mixed features) and to assess for depressive symptoms among individuals on maintenance treatment for bipolar disorder.*

Note: Treatment recommendations are based on levels of evidence and expert opinion. For a description of the criteria for each level, see pages 2-3.

Conduct comprehensive assessment and use measurement-based care. Refer to Principles of Practice on pages 4-9.

The list of possible treatments in the prevention of bipolar disorder is comprised of many treatment options; therefore, the regimen that stabilizes a patient should be strongly considered for continuation and maintenance (monitoring for efficacy and adverse events).

Strongly recommend psychiatric consultation prior to initiation of therapy + psychotherapeutic medication using a multi-disciplinary approach if treat by a non-psychiatrist.

Level 1 Options for initial treatment:

- Periodic evaluation: frequency based on clinical needs
- Continue with effective and well-tolerated treatment
- Lithium* monotherapy
- Quetiapine monotherapy
- Lamotrigine* (evidence strongest for prevention of depression)
- If initially stabilized on divalproex*†, maintain.
- Oral aripiprazole or aripiprazole long-acting injectable, long-acting risperidone monotherapy
- Quetiapine (for recurrence prevention) or ziprasidone (for relapse prevention) adjunctive to (lithium* or divalproex*†)
- Asenapine monotherapy
- Olanzapine/samidorphan monotherapy
- Manual-based psychotherapy (e.g., interpersonal social rhythm therapy, CBT, mindfulness best evidence along with psychoeducation during the maintenance phase)

†Note: Be aware that there are limited data on long-term efficacy of divalproex.

Level 2A If multiple Level 1 trials are ineffective and/or not well tolerated:

- Olanzapine monotherapy
- Olanzapine adjunctive to lithium* or divalproex*†

Level 2B If Levels 1 and 2A are ineffective and/or not well tolerated:

- Continue effective and well-tolerated acute treatment(s) if not listed in Level 1
- Lithium* and divalproex*† combination
- Follow acute mania/bipolar depression guidelines to achieve remission or partial remission

Level 3 If Levels 1 and 2 are ineffective and/or not well tolerated:

- Adjunctive clozapine (avoid combining with another antipsychotic)
- Electroconvulsive therapy (ECT)†

Notes:

** Caution should be used when prescribing lithium, lamotrigine, divalproex or carbamazepine to women of reproductive age due to increased risks to the fetus with use during pregnancy, including neural tube and other major birth defects. Please see Florida Best Practice Recommendations for Women of Reproductive Age with Serious Mental Illness and Comorbid Substance Use Disorders available at https://floridabhcenter.org.*

***Side-effect concerns with these agents include weight gain, metabolic syndrome, and extrapyramidal symptoms (EPS). Side-effects warrant vigilance and close monitoring on the part of the clinician.*

†Long-term efficacy data are limited for the following: divalproex monotherapy, carbamazepine (drug interaction risk), antidepressants, and electroconvulsive therapy (inconvenience/expense).

Table 3. Recommended Medications for the Treatment of Bipolar Disorder – Mood Stabilizers

Medication	Dosage	Comments
Lithium	In acute mania: 1,200–2,400 mg/day (serum level 0.8–1.2 mEq/L)	▶ Initial titration for tolerability: » Start 600–900 mg/day, increase 300 mg/day every 5 days. » Check levels 5 days after initiation/dose change (ideally, trough lithium levels 12 hours after last dose). ▶ Check blood levels more frequently if signs or suspicion of clinical toxicity. ▶ Lower doses/levels may be necessary in non-manic compared to manic patients. ▶ Monitor renal and thyroid functions. ▶ For maintenance, some patients require serum levels of 0.8 to 1.2 mEq/L, others can be maintained with lower levels, but not below 0.6 mEq/L. ▶ In older individuals, start with lower lithium dose, titrate more slowly, and target lower serum lithium levels.
Divalproex	In acute mania: 5–60 mg/kg/day; 1,000–2,500 mg/day (serum level 85–125 µg/mL)	▶ Initial dosing: » Initial loading may be tolerated, but some patients need initial titration for tolerability. » Lower doses/levels may be necessary in non-manic compared to manic patients. » Check levels 48 hours after initiation and adjust dose accordingly. ▶ Side-effects (especially gastrointestinal) are more evident above 100 µg/ml. ▶ More teratogenic than other mood stabilizers. ▶ Serious side effects include hepatotoxicity, thrombocytopenia, pancreatitis, and hyperammonemic encephalopathy.
Carbamazepine	In acute mania: 200–1,600 mg/day (serum level 6–12 µg/mL)	▶ Initial titration for tolerability due to hepatic auto-induction: » Start 200–400 mg/day and increase 200 mg/day every 3 days. Lower doses/ levels may be necessary in non-manic compared to manic patients. » Monitor for blood dyscrasias and serious rash. » Screen individuals of Asian descent for HLA-B*1502 (serious rash risk indicator) due to high risk for Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). » Patients testing positive for the HLA-B*1502 allele should not be treated with carbamazepine unless benefits clearly outweigh risks. ▶ Carbamazepine decreases serum levels of multiple other CYP450-metabolized drugs due to induction of CYP450 enzymes 3A4, 1A2, 2C9, and 2C19.

Medication	Dosage	Comments
Lamotrigine	In bipolar maintenance: 100–400 mg/day	▶ Initial titration to reduce risk of Stevens-Johnson syndrome and Toxic Epidermal Necrolysis (TEN) [serious rash]: » Start 25 mg/day (12.5 mg/day if taken with divalproex). » Increase by 25 mg/day (12.5 mg/day if taken with divalproex) after 2 and 4 weeks and weekly thereafter. Initial target dose 200 mg/day, but final doses may be 100–400 mg/day. ▶ May be used in some patients with acute bipolar depression (despite acute efficacy limitation) due to good tolerability and depression prevention efficacy.

**mg/day= milligrams per day; mEq/L = milliequivalents per Liter; mg/kg/day = milligram per kilogram per day; µg/ml = microgram per millimeter*

Table 4. Recommended Medications for the Treatment of Bipolar Disorder—Second Generation Antipsychotics (SGAs) and Antidepressants

Medication	Dosage	Comments
Second Generation Antipsychotics (SGA)	**In acute mania:** ▶ Aripiprazole: 15–30 mg/day ▶ Asenapine: 10–20 mg/day ▶ Olanzapine: 6–20 mg/day ▶ Olanzapine/samidorphan: 5mg/10mg–20mg/10mg per day; 10mg/10mg–20mg/10mg if adjunct to lithium or valproate. ▶ Paliperidone: 3–12 mg/day ▶ Quetiapine: 400–800 mg/day ▶ Risperidone: 2–6 mg/day ▶ Ziprasidone: 80–160 mg/day **In acute bipolar depression:** ▶ Quetiapine: 200–600 mg/day ▶ Olanzapine/Fluoxetine: 3 mg/12.5 mg–12 mg/50 mg per day ▶ Lurasidone: 40–120 mg/day ▶ Clozapine: 50–400 mg/day (if treatment resistant)	▶ Initial titration may be necessary for tolerability. Lower doses may be necessary in depressed patients (e.g. quetiapine 300 mg/day). Ziprasidone should be taken with food. Asenapine is sublingual. ▶ Monitor for side effects, including sedation (especially with quetiapine and clozapine), weight gain (especially with olanzapine and clozapine), akathisia (especially with aripiprazole and ziprasidone) and extrapyramidal symptoms (EPS), especially with risperidone. Monitor weight and body mass index (BMI) at each visit and laboratory metabolic indices at baseline, 3 months, and yearly thereafter.
Antidepressants	**In acute bipolar depression:** As dosed for major depression. (No specific dosing recommendations can be given for bipolar depression.)	▶ Larger trials have not found a benefit of antidepressant when added to mood stabilizers/antimanics for bipolar depression (other than olanzapine/ fluoxetine combination). May be used in combination with antimanic drugs in some patients with acute bipolar depression, but should not be prescribed as monotherapy in patients with bipolar I disorder due to manic switch risk. ▶ Serotonin-norepinephrine reuptake inhibitors (SNRIs) and tricyclic antidepressants (TCAs) may have greater manic switch risk. ▶ Antidepressant carry an FDA boxed warning for increased suicidality risk in pediatric and young adult patients (under age 25). May be continued in patients who are on antidepressants and have stable mood.

**mg/day = milligrams per day*

Note: Samidorphan is an opioid receptor antagonist approved for use in combination with olanzapine to mitigate olanzapine-associated metabolic side effects.

Summary: Treatment of Bipolar Disorder

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Introduction

Bipolar disorders (BD) are a group of severe lifelong disorders that are associated with staggering loss of human capital, loss of healthy living years as well as lifespan. Although mania is the defining feature of bipolar I disorder, and hypomania with at least one depressive episode defining bipolar II disorder, it is well-established that depressive symptoms and episodes are the predominant illness presentation. The predominance of depressive symptoms across bipolar subtypes is apparent not only at the first illness presentation but also along the longitudinal course.

An unmet need in bipolar disorder remains the staggering misdiagnosis rate and the delay in determining that the diagnosis is present. This prolongs human suffering, increases morbidity and mortality, service utilization, healthcare costs and necessarily fosters progression of the illness. As most individuals with bipolar disorder are initially incorrectly diagnosed, treatment selection is often inappropriate, further promoting negative health outcomes.

The predominance of depression in bipolar disorder and high misdiagnosis rate provides the impetus for routine screening for bipolar disorders in all persons initially presenting with depression and for subsequent visits if characteristics of bipolar disorder become manifest and/or response to treatment is inadequate. A quantity of screening tools for bipolar disorder exist which differ in their items, psychometrics, time to completion and feasibility in busy clinical practice. The Rapid Mood Screener (RMS; https://www.rapidmoodscreener.com/) has been recently validated as a brief, validated screening tool with validation completed and satisfactory psychometrics in adults with bipolar I and bipolar II disorder. The RMS has improvements in psychometrics in time to administration as well as end-user satisfaction relative to other screening tools for bipolar disorder.

Principles of Treatment

The use of measurement to track symptoms (e.g., mood diaries) is encouraged and attempts to prevent comorbidities should be a clinical focus at initial presentations. Recognition that BD is an independent risk factor for cardiovascular disease further underscores the importance of holistic approaches to the assessment, prevention, and management of BD. Individuals with BD report much higher rates of physical and sexual trauma in the recent or distant past as well as describe psychosocial stressors as associated with episode recurrence. In addition to targeting key features of BD, the management of BD also needs to include psychoeducation, improvement of diagnosis and treatment literacy, conflict and stress management skills, as well as lifestyle improvement with focus on diet as well as sleep hygiene.

Pharmacologic Treatment of Acute Bipolar Mania/Mixed States

The pharmacologic treatment of acute bipolar mania/mixed states has been augmented with the combination of olanzapine-samidorphan. Olanzapine-samidorphan combination is FDA-approved for the treatment of acute mania/mixed states in adults with bipolar I disorder as monotherapy or adjunct to lithium or valproate. It was the panel's view that olanzapine-samidorphan would be prioritized ahead of olanzapine in the treatment of acute mania or mixed states as monotherapy or adjunct to lithium or valproate due to a lower

weight gain liability of olanzapine-samidorphan relative to olanzapine. Moreover, available evidence indicates that although samidorphan mitigates weight gain liability attributable to olanzapine, it does not mitigate olanzapine's efficacy.

Pharmacologic Treatment of Acute Bipolar Depression

The panel recommends cariprazine, lumateperone and lurasidone monotherapy as initial treatment for bipolar I depression. Lumateperone and lurasidone are also approved as adjuncts to lithium or valproate in bipolar I depression. Lumateperone is additionally approved as monotherapy or adjunct to lithium or valproate in the treatment of bipolar II depression. Quetiapine is approved as monotherapy in bipolar II depression but not as adjunctive treatment. The panel recognizes that cariprazine, lumateperone and lurasidone have lower propensity to weight gain and are metabolically similar to placebo in the treatment of adults with BD. These observations differentiate these second-generation antipsychotics (SGAs) from quetiapine and olanzapine-fluoxetine combination which have greater susceptibility to clinically significant weight gain and/or metabolic shift. It was the view of the panel that consideration of weight gain and metabolics is paramount in selecting treatments for bipolar depression. The panel also recommends lithium or lamotrigine as possible first-line treatments for bipolar depression. The anti-suicide effects of lithium, not seen with other FDA-approved treatments for BD, are an important attribute of lithium.

The panel recognizes that antidepressant monotherapy in bipolar I disorder is to be discouraged. Conventional antidepressants are not recommended in bipolar I disorder for adults manifesting mixed features, rapid cycling, and/or histories of previous antidepressant-associated emergence of hypo/mania. For adults with bipolar II disorder, preliminary evidence suggests that some adults may be safely and effectively treated with antidepressant monotherapy. Antidepressant monotherapy however would not be recommended for persons with bipolar II disorder presenting with mixed features, rapid-cycling and/or history of antidepressant-associated affective switching/cycle acceleration/dysphoria. The lack of empirically supported response predictors to antidepressant monotherapy in BD implies that it is unknown *a priori* which individuals with bipolar II disorder may be safely treated with antidepressant monotherapy. The panel also recognizes that there is a paucity of long-term treatments with antidepressants in BD. The recommendation to continue antidepressants will be determined on an individual basis.

The ***2023-2024 Florida Best Practice Psychotherapeutic Medication Guidelines for Adults*** has retained similar guidance with respect to pharmacologic treatments of bipolar mania. Bipolar mania is recognized as a medical emergency requiring, in many cases, a higher intensity of treatment. Safety is of paramount importance of mania and, where applicable, inpatient stay and specialist consultation is encouraged. The panel also recognizes that for many adults with bipolar mania, the predominant presentation is dysphoric and mixed with many adults manifesting non-specific symptoms (e.g., anxiety, agitation, irritability, anger) that often obscure the underlying diagnosis of mania. SGA monotherapy as well as lithium or divalproex are recommended in cases of mania of milder severity (e.g., non-psychotic mania). In situations where patients have severe mania (e.g., psychosis, need for hospitalization), combination SGA and additional mood stabilizing agent (e.g., lithium) is recommended.

Maintenance Pharmacological Treatment of Bipolar Disorder

More than 90% of individuals with BD will experience recurrence of illness. Episode recurrence in BD is highly associated with progressive changes to brain structure and function, as well as the accumulation of multiple comorbidities. Further evidence also suggests that greater episode frequency is associated with more pronounced cognitive deficits in BD. Moreover, it is not frequent in BD to witness a phenomenological shift across time where patients manifest increasing depressive symptom burden. A clinical impression awaiting cogent empirical confirmation is that, increasingly, clinicians are encountering a higher percentage of individuals with BD presenting with mixed features during the acute or maintenance phase. It is uncertain what is causing this, but, certainly, antidepressant utilization, drug and alcohol misuse and obesity are contributing causes.

The combination of olanzapine-samidorphan has been approved as a maintenance monotherapy in adults with bipolar I disorder. The approval of olanzapine-samidorphan was based on legacy studies in maintenance treatment of bipolar disorder with olanzapine. The combination of olanzapine-samidorphan exhibits a lower propensity to weight gain and waist circumference enlargement when compared to olanzapine when studied in adults with schizophrenia. It was the panel's view that a lower weight gain liability with olanzapine-samidorphan relative to olanzapine would prioritize olanzapine-samidorphan over olanzapine in the selection sequencing of maintenance treatments in bipolar disorder.

For most adults with BD, multi-year/lifetime pharmacotherapy is recommended, integrated with lifestyle interventions targeting healthful living, diet, exercise, and sleep hygiene. For many adults, manual-based psychosocial treatments (e.g., cognitive therapy), interpersonal social rhythm therapy and psychoeducation, are critical adjuncts to pharmacotherapy to improve overall psychosocial function and wellbeing. During the acute and maintenance phase of BD, careful attention to suicidality is paramount.

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