OBJECTIVE

The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for the treatment of bipolar disorder. The CPG discusses the importance of a Behavioral Health Action Plan and how to distinguish between episode types and when to seek medical care. Objectives and measurable health outcomes with respect to Care Management are included. Specific topics include pharmacology and non-pharmacology treatment options. In addition, the CPG outlines the organizations that WellCare aligns with regarding bipolar disorder and relevant Measureable Health Outcomes.

OVERVIEW

Bipolar affective disorder, or manic-depressive illness (MDI), is a common, severe, and persistent mental illness. This condition is a serious lifelong struggle and challenge. Other mental disorders and general medical conditions are more prevalent in patients with bipolar disorders than in patients in the general population. Among the general comorbid conditions, cardiometabolic conditions such as cardiovascular disease, diabetes, and obesity are a common source of morbidity and mortality for persons with bipolar disorder.1

The lifelong prevalence of bipolar affective disorder, or manic-depressive illness (MDI), including subsyndromal forms in the United States is almost 4%. However, the prevalence in patients who present with depression is higher in primary care (21-26%) and psychiatric clinic settings (28-49%). The age of onset of bipolar disorder varies greatly. For both BPI and BPII, the age range is from childhood to 50 years, with a mean age of approximately 21 years. Most cases of bipolar disorder commence when individuals are aged 15-19 years. The second most frequent age range of onset is 20-24 years. Some patients diagnosed with recurrent major depression may indeed have bipolar disorder and go on to develop their first manic episode when older than 50 years. These individuals may have a family history of bipolar disorder. However, the onset of mania in people ≥50 years should lead to an investigation for medical or neurologic disorders (e.g. cerebrovascular disease).1

Hierarchy of Support

GUIDELINE HIERARCHY

CPGs are updated annually or as necessary due to updates made to guidelines or recommendations by the American Psychiatric Association (APA). When there are differing opinions noted by national organizations, WellCare will default to the member’s benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to bipolar disorder, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- United States Preventive Services Task Force (USPSTF), National Quality Strategy (NQS), Agency for Healthcare Research and Quality (AHRQ);
- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).
Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with the APA on the topic of bipolar disorder. Highlights from their publications are noted below.

AMERICAN PSYCHIATRIC ASSOCIATION

WellCare adheres to the American Psychiatric Association’s Practice Guideline for the Treatment of Patients with Bipolar Disorder, Second Edition (2002). The guideline provides recommendations to help psychiatrists develop plans for the care of adult patients with bipolar disorder. Part A discusses the treatment recommendations for those with bipolar disorder. Sections focus on main treatment recommendations, a guide to the formulation and implementation of a treatment plan for the individual patient, and a range of clinical considerations that could alter the general recommendations discussed earlier in Part A. Part B provides background information and a review of available evidence; this details evidence underlying the treatment recommendations of Part A. Also included in Part A is an overview of DSM-IV bipolar disorder criteria, features of the disorder, and general information on its natural history, course, and epidemiology. Part B ends with a structured review and summary of published literature regarding available treatments. Future research needs conclude the Practice Guideline (Part C) with a summary of the previous sections with respect to helping providers improve clinical decisions.5

WellCare also adheres to the Guideline Watch (2005), an update of the 2002 guideline. The 2005 publication discusses controlled treatment studies of second-generation (atypical) antipsychotics as monotherapy and as adjunctive treatment (with more traditional mood stabilizers) for the acute treatment of mania, studies of antiepileptic agents for the acute treatment of mania, trials for three medications for the acute treatment of bipolar depression, four monotherapy and one combination therapy relapse prevention studies, and studies of psychosocial interventions for maintenance.3

Both the full Practice Guideline and the Guideline Watch can be accessed at http://psychiatryonline.org/guidelines.

Evidence Based Practice

MEASUREMENT OF COMPLIANCE

WellCare is committed to adhering to the measures and standards published by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please reference WellCare’s Clinical Policy Guiding Document titled Measures of Compliance.

NOTE: To access Clinical Policy Guiding Documents visit www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

Care Management

The goals for Care Management are to support the member’s ability to self-manage his or her disease/disorder, minimize risks of Bipolar Disorder, and remove barriers preventing the member from achieving those goals.

Member will be educated about primary symptoms and follow the Behavioral Health Care Plan and contact Behavioral Health Professional to report increased symptoms of:4

- Mania: A Manic Episode is characterized by having an abnormally and persistently elevated, expansive, or irritable mood and abnormally and persistently increased goal-directed activity or energy, lasting at least 1 week and present most of the day, nearly every day (or any duration if hospitalization is necessary).
  - Inflated self-esteem or grandiosity.
  - Decreased need for sleep (e.g., feels rested after only 3 hours of sleep).
  - More talkative than usual or pressure to keep talking.
  - Flight of ideas or subjective experience that thoughts are racing.
  - Distractibility (i.e., attention too easily drawn to unimportant or irrelevant external stimuli), as reported or observed.
  - Increase in goal-directed activity (either socially, at work or school, or sexually) or psychomotor agitation (i.e., engaging in unrestrained buying sprees, sexual indiscretion, or foolish business investments).
  - Episode is not attributable to physiological effects of a substance or another medical condition.
• Depression: A Major Depressive Episode (an episode of overwhelming feelings of sadness, isolation, and despair that lasts for a period of two weeks or longer.)
  o Depressed most of the day, nearly every day.
  o Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day.
  o Significant weight loss when not dieting or weight gain, or decrease or increase in appetite nearly every day.
  o Insomnia or hypersomnia nearly every day.
  o Fatigue or loss of energy nearly every day.
  o Feelings of worthlessness or excessive or inappropriate guilt nearly every day.
  o **Episode is not attributable to physiological effects of a substance or another medical condition.**

Member should seek immediate psychiatric and/or medical care for:
• Significant manic behavior leading to significantly destructive or potential life threatening situations
• Suicidal Ideation/behavior
• Homicidal ideation/behavior
• Any potential life threatening situations
• Medication issues or severe side effects

Member’s on Antipsychotic Medication should be screened for:
• Diabetes (HbA1c test annually)
• Cardiovascular disease (LDL-C test annually)
• Ongoing monitoring of Diabetes for People with Diabetes and Schizophrenia

**MEASURABLE HEALTH OUTCOMES**

Targeted Case Management outcomes (**Extended Program Goals**) result from successful self-management (see Case Management Objectives).

• **SYMPTOMS:** Decreased Member behavioral health symptoms. Compare Member response to assessment question (SF12), provider input and/or member narrative related to symptom changes pre- and post-engagement at 6-12 months.
• **ADHERENCE:** Improved Member adherence to medication and attendance of behavioral health and medical appointments. Compare pharmacy and office visit claims data pre-and post-engagement to validate adherence to timely refill of the prescribed medication(s) and provider visit(s). In absence of pharmacy and office visit claims data, the Member narrative and/or professional reporting of adherence to medication and attendance of behavioral health related appointments may be used. Member’s prescription refills demonstrate at least an 80% adherence rate (verified by claims or member/provider narrative) in the past 12 months.
• **ENGAGEMENT:** Improved Member social engagement with others through meaningful roles and relationships in his/her social life, educational and occupational settings. Compare member narrative pre- and post-engagement at 6-12 months.
• **UTILIZATION:** Decreased Member psychiatric episodes leading to emergency room visits and/or psychiatric hospitalization. Compare utilization data pre- and post-engagement at 6-12 months. In absence of these data sources, CM may use Provider and/or Member narrative.

**CASE MANAGEMENT GOALS**

Case Goals should target specific care gaps and/or adherence issues, and measure the member’s progress towards self-management and adherence which lead to the targeted health outcomes above.

• **SYMPTOMS:** Reduction of behavioral health symptoms by 10% using valid, reliable rating scales (e.g. BDRS, HAM-D, GAD, etc.).
• **SYMPTOMS:** Member describes a routine that includes checking and logging behavioral health symptoms per treatment recommendation over the last 30 days and shares data with treatment provider.
• **SYMPTOMS:** Member describes coping skills and support system over the last 30 days that demonstrates improved adherence to guideline and/or treatment recommendations.
• **ADHERENCE:** Attendance of >75% of behavioral health and medical appointments during a 90-day period
• **ADHERENCE:** Member’s prescription refills demonstrate at least an 80% adherence rate (verified by claims or member/provider narrative) over last 30 days.

• **ADHERENCE:** Monitoring of medication adherence (member self-report).

• **ENGAGEMENT:** Increased frequency of social engagement by ≥25% over previous period as measured by number of social interactions (self-report).

• **UTILIZATION:** Documentation of use of Therapist visit, Case Management intervention, Crisis Line call, Primary Care Physician call or visit, or Urgent Care visit prior to emergency department visit or BH Inpatient Admission ≥75% of the time.

### CASE MANAGEMENT OBJECTIVES

Case Management Objectives should focus on improving the member’s self-management skills and mental health through:

- Assist with implementation of the Care Plan
- Provide Psychoeducation
- Identify community resources
- Refer to professional resources including: medical, psychiatry, counseling, etc.
- Screen to determine substance use/abuse needs
- Encourage and monitor attendance of scheduled appointments
- Encourage maintenance of social contact and interaction within social groups and social supports
- Encourage medication adherence (utilizing pill taking strategies including pill boxes, bubble packs, etc.)
- Promote the use of mood chart/Mood tracking
- Assist with identification of support system
- Assist with development of Safety Plan

### OTHER CONSIDERATIONS

**Diabetes Risk.** Those members treated with antipsychotic medications are at higher risk of diabetes. Fasting plasma glucose is the screening recommended by the American Diabetes Association for this population. Fasting plasma glucose, lipid levels, BMI and blood pressure should be assessed baseline (before starting antipsychotic medication) and 3 months after initiation of antipsychotic medications. At a minimum thereafter, these members should be screened annually, more frequently if a member’s risk factors increase or there are medication dosage changes.5

**Nonpharmacotherapy.** Psychotherapy may help to decrease relapse rates, improve quality of life, and/or increase functioning, or more favorable symptom improvement. Electroconvulsive therapy may be useful in selected patients with bipolar disorder.

### MEMBER EDUCATIONAL RESOURCES

WellCare contracts with Krames/StayWell for Member educational materials utilized by Case Managers. Items are available to review with Members to address knowledge gaps. Case Managers verbally educate Members on the topics below related to asthma.

- Treating Affective (Mood) Disorders
- Treating Bipolar Disorder
- Understanding Affective (Mood) Disorders
- Understanding Bipolar Disorder
- Understanding Schizoaffective Disorder

These materials are in the approval process and will be available for member educational mailing in the future. Providers may wish to research the titles above related to bipolar disorder that Case Managers utilize with Members.

### PHARMACOLOGY

Medications used to manage patients with bipolar disorder include the following:

- Benzodiazepines (e.g., lorazepam, clonazepam)
- Antimanic agents (e.g., lithium)
- Anticonvulsants (e.g., carbamazepine, valproate sodium, valproic acid, divalproex sodium, lamotrigine, topiramate)
- First-generation antipsychotics (e.g., inhaled loxapine, haloperidol)
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HS-1017

- Second-generation antipsychotics (e.g., asenapine, ziprasidone, quetiapine, risperidone, aripiprazole, olanzapine, olanzapine and fluoxetine, clozapine, paliperidone)
- Phenothiazine antipsychotics (e.g., chlorpromazine)
- Dopamine agonists (e.g., pramipexole)

Related WellCare Guidelines

In addition to the information contained in this document, please reference the following CPG: Persons with Serious Mental Illness and Medical Co-Morbidities (HS-1044). NOTE: Clinical Policies can be accessed by going to www.wellcare.com – select the Provider tab, then “Tools” and “Clinical Guidelines”.

References

1. WellCare. Internal Care Management Training. 2015.

Disclaimer

Clinical Practice Guidelines (CPGs) made available by WellCare are informational in nature and are not a substitute for the professional medical judgment of treating physicians or other health care practitioners. CPGs are based on information available at the time and may not be updated with the most current information available at subsequent times. Individuals should consult with their physician(s) regarding the appropriateness of care or treatment options to meet their specific needs or medical condition. Disclosure of a CPG is not a guarantee of coverage. Members of WellCare health plans should consult their individual coverage documents for information regarding covered benefits. WellCare does not offer medical advice or provide medical care, and therefore cannot guarantee any results or outcomes. WellCare does not offer medical advice or provide medical care, and therefore cannot guarantee any results or outcomes. WellCare does not warrant or guarantee, and shall not be liable for any deficiencies or medical condition. Disclaimers.

Medical Policy Committee Approval History

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<tr>
<th>Date</th>
<th>History and Revisions by the Medical Policy Committee</th>
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<tr>
<td>10/10/2017</td>
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Addendum

Signs and Symptoms. Bipolar affective disorder is characterized by periods of deep, prolonged, and profound depression that alternate with periods of an excessively elevated or irritable mood known as mania.

Manic episodes are feature at least 1 week of profound mood disturbance, characterized by elation, irritability, or expansiveness (referred to as gateway criteria). At least 3 of the following symptoms must also be present:

- Grandiosity
- Diminished need for sleep
- Excessive talking or pressured speech
- Racing thoughts or flight of ideas

- Clear evidence of distractibility
- Increased level of goal-focused activity (home, work, sex)
- Excessive pleasurable activities, often with painful consequences
### Hypomanic episodes

Hypomanic episodes are characterized by an elevated, expansive, or irritable mood of at least 4 consecutive days' duration. At least 3 of the symptoms above must also be present.

### Major depressive episodes

Major depressive episodes are characterized as lasting for the same 2 weeks when the person experiences ≥5 of the following symptoms (each with at least 1 of the symptoms being either a depressed mood or characterized by loss of pleasure or interest):

- Markedly diminished pleasure or interest in nearly all activities
- Significant weight loss or gain or significant loss or increase in appetite
- Hypersomnia or insomnia
- Psychomotor retardation or agitation
- Loss of energy or fatigue
- Feelings of worthlessness or excessive guilt
- Decreased concentration ability or marked indecisiveness
- Preoccupation with death or suicide; patient has a plan or has attempted suicide

### Diagnosis

Diagnosis. Examination of patients with suspected bipolar affective disorder includes evaluation using the Mental Status Examination as well as assessment of the following:

| Appearance | Homicide/violence/aggression |
| Affect/mood | Judgment/insight |
| Thought content | Cognition |
| Perception | Physical health |
| Suicide/self-destruction | |

### Testing

Testing. Although bipolar disorder is diagnosed based on the patient’s history and clinical course, laboratory studies may be necessary to rule out other potential causes of the patient’s signs and symptoms as well as to have baseline results before administering certain medications. Laboratory tests that may be helpful include the following:

| CBC count | Thyroid hormone levels |
| ESR levels | Creatinine and blood urea nitrogen levels |
| Fasting glucose levels | Liver and lipid panel |
| Electrolyte levels | Substance and alcohol screening |
| Protein levels | |

Depending on patient’s presentation, other laboratory tests may be indicated, which may include urinary copper levels, antinuclear antibody testing, HIV testing and/or VDRL testing. Electrocardiography is important in elderly patients and before antidepressant therapy. Electroencephalography and/or MRI may be appropriate for selected patients.

### Management

Management. The treatment of bipolar affective disorder is directly related to the phase of the episode (e.g., depression or mania) and the severity of that phase, and it may involve a combination of psychotherapy and medication. Members should be evaluated with mania, hypomania, or mixed episode, and those with bipolar depression, for suicidality, acute or chronic psychosis, or other unstable or dangerous conditions.