West Virginia Medicaid
Bipolar Disorder Management

Educational RetroDUR Mailing	☑Initial Study ❑Follow – up /Restudy

Executive Summary

Purpose:	To promote safe and effective drug therapy in patients with Bipolar Disorder (BD). The Veterans Affairs Guidelines, the Canadian Network for Mood and Anxiety Treatments (CANMAT) guidelines, and the British Association for Psychopharmacology (BAP) guideline for the management of bipolar disorder provide the foundation for this proposal.[1-3] These guidelines, along with recently published major studies, provide performance indicators to evaluate the medication management of BD.	
Why Issue was Selected:	BD is a complex, long-term illness characterized by a repeating course of relapse and remission. It has a lifetime prevalence of 1% to 2% and has been estimated to lead to 2% of all disability-adjusted life-years associated with non-communicable diseases.[4,5] Pharmacotherapy is the mainstay of treatment for BD, and treatment guidelines recommend such regimens be built around adequate dosing of a mood stabilizer.[1-3] Additional medication classes commonly employed include antipsychotic agents, antidepressants, and stimulants. The principles to effectively employ and combine these different medication groups to obtain optimal outcomes with minimal risks are the focus of this intervention.	
Program Specific Information:	Performance Indicators	Candidates
	• Use of an antidepressant in the absence of a mood stabilizer/atypical antipsychotic	*TBD*
	• Extended use of an antidepressant medication	*TBD*
	• Use of multiple atypical antipsychotics simultaneously as mood stabilizers	*TBD*
	• Use of a stimulant medication resulting in increased risk	1,416
	• Lithium monitoring: serum levels, renal function, and thyroid function	660
	• Atypical antipsychotic monitoring: blood glucose levels and lipid panel	3,675
	• Monitoring for potential toxicities of valproic acid products and/or carbamazepine	*TBD*
Setting & Population:	All patients with a diagnosis of bipolar disorder in the past two years and have pharmacy claims in the past 90 days.	
Types of Intervention:	Cover letter and individual patient profiles	
Main Outcome Measures:	The performance indicators will be remeasured when six months of outcome data are available.	

Anticipated Results:	• Increased use of mood stabilizers in patients with BD. • Decreased risk of antidepressant and/or stimulant induced mania. • Improved safety through increased monitoring of BD therapies.

Performance Indicator #1: Antidepressants without a Mood Stabilizer

Why has this indicator been selected?	Depression is a common feature of BD and many bipolar patients have more frequent depressive episodes than manic episodes. Antidepressants have long been used in this patient population, despite ongoing controversy regarding their safety and efficacy.[17] No antidepressants are specifically FDA approved for use in the treatment of depression associated with BD. Unfortunately, antidepressants may destabilize patients with BD and result in a switch into mania. The risk for destabilization appears to vary slightly among available antidepressants, but has been estimated at 20% to 40%.[18] Treatment guidelines recommend antidepressant use only in combination with a mood stabilizer.[1-3] A recent study funded by the National Institutes of Mental Health (NIMH) has only added to the controversy surrounding antidepressant use in BD.[19] It found that adding an antidepressant to a mood stabilizer to treat depression in BD was no more effective than adding a placebo.
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with an antidepressant in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who do not also have therapy with a mood stabilizer/atypical antipsychotic in the last 30 days.

Performance Indicator #2: Extended use of Antidepressant Medications

Why has this indicator been selected?	No antidepressants are specifically FDA approved for use in the treatment of depression associated with BD. Unfortunately, antidepressants may destabilize patients with BD and result in a switch into mania. The risk for destabilization appears to vary slightly among available antidepressants, but has been estimated at 20% to 40%.[18] Treatment guidelines recommend advise caution regarding long-term use of antidepressants in BD, with use generally recommended to last only until patient is stable.
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with an antidepressant in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who have been on an antidepressant for longer than 365days.

Performance Indicator #3: Use of an Atypical Antipsychotic as the Sole Mood Stabilizer

Why has this indicator been selected?	Psychosis is a common feature in BD patients and antipsychotic agents have always been used as adjunctive therapy to manage it, although until recently there was limited published evidence to support such use.[15] In the past several years, many atypical antipsychotics have received FDA approved indications for the management of BD. These indications are primarily for acute use in the

	management of manic or mixed episodes. Only four have approved indications for maintenance use, and two of those only as an adjunct to another mood stabilizer. The use of multiple atypical antipsychotics should not occur in bipolar patients. If the response to an atypical antipsychotic in inadequate, a different type of mood stabilizer should be added[1-3]
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with an atypical antipsychotic for the past 90 days with a diagnosis of BD in the past 2 years and who do not have a diagnosis of schizophrenia in the past 2 years.
Exception criteria (numerator):	Candidates who received therapy with more than one atypical antipsychotic in the past 30 days.

Performance Indicator #4: Use of Stimulants

Why has this indicator been selected?	The problems associated with antidepressant use in BD patients have led clinicians to attempt to manage bipolar depression with alternative agents. Stimulants, such as methylphenidate, have been reported to be one such alternative.[20] In addition, BD is being diagnosed with increasing frequency in the pediatric population, resulting in clinicians more frequently attempting to manage ADHD and BD simultaneously[8] Unfortunately, empiric evidence to support and guide the use of stimulants in a BD population is limited and they do not appear to be any safer than antidepressants in terms of the risk of destabilization.[21] Available treatment guidelines for BD do not adequately address the appropriate use of stimulants, but available research indicates such use should be limited to those with co-morbid ADHD and BD, be in conjunction with a mood stabilizer, and combinations of a stimulant and an antidepressant should be avoided to minimize the risk of manic switch.[22]
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with a stimulant in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who do not have a diagnosis of ADHD in the past 2 years or do not also have therapy with a mood stabilizer in the last 30 days or who also have therapy with an antidepressant in the past 30 days.

Performance Indicator #5: Monitoring of Lithium: Serum Lithium Level, Renal Function, Thyroid Function

Why has this indicator been selected?	Lithium is a very effective mood stabilizer but it has a narrow therapeutic index and serum lithium levels must be monitored for patient safety. In addition, it is associated with potential adverse effects on renal and thyroid function that require periodic monitoring.[10]
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with lithium in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who do not have: 1) a documented serum lithium level in the past year 2) evaluation of renal function in the past year 3) evaluation of thyroid function in the past year.

Performance Indicator #6: Monitoring of Atypical Antipsychotics: Blood Glucose and Lipid Levels

Why has this indicator been selected?	Atypical antipsychotics may be effective when used appropriately in the management of BD but their long-term use may result in metabolic adverse effects.[16]
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with an atypical antipsychotic in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who do not have: 1) a documented hemoglobin A1C in the past year 2) a documented lipid panel in the past two years

Performance Indicator #7: Monitoring of Anticonvulsants Used as Mood Stabilizers

Why has this indicator been selected?	Selected anticonvulsants are associated with black box warnings relating to potential complications associated with their use. Official prescribing information for these agents suggests monitoring that should be employed to minimize the risk for complications.
How will the patients be selected ?	
Candidates (denominator):	Patients who have therapy with a anticonvulsant mood stabilizer in the past 30 days with a history of a BD diagnosis in the past 2 years.
Exception criteria (numerator):	Candidates who do not have the recommended monitoring documented in the past 365 days (see Appendix A).

Appendix A: Anticonvulsant Monitoring[%,*]

ANTICONVULSANT	RECOMMENDED MONITORING
Carbamazepine	Hepatic Function and Urinalysis
Valproic Acid Analogs	Hepatic Function and Platelet Count

[%] Official Prescribing Information. Available at: http://www.fda.gov/cder/ [last accessed 3/15/08].

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