



## POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.028.E*

REVISION DATE: *4/13*

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**POLICY TITLE:** **Symbyax (Olanzapine/fluoxetine) Step Therapy**  
**DEPARTMENT:** **Clinical Pharmacy Services- Utilization Management**  
**ORIGINAL DATE:** **April 2004**

**Last P & T Committee Approval Date:** *February 2018*

**Product Applicability:** *mark all applicable products below:*

<b>COMMERCIAL</b>	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<i>Products:</i> <input type="checkbox"/> Small	<i>Exchange:</i> <input type="checkbox"/> Shop	<input checked="" type="checkbox"/> All
			<input type="checkbox"/> Indiv.	<input type="checkbox"/> Indiv.	
			<input type="checkbox"/> Large		
<b>OTHER</b>	<input checked="" type="checkbox"/> Self-funded/ASO				

### PURPOSE

The purpose of this policy is to define the prior authorization process for Symbyax (Olanzapine/fluoxetine).

Symbyax (Olanzapine/fluoxetine) is indicated for the treatment of depressive episodes associated with bipolar disorder and for the acute treatment of treatment resistant depression (Major Depressive Disorder in adults who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode).

### DEFINITIONS

N/A

### POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Symbyax (Olanzapine/fluoxetine), is subject to the prior authorization process.



## PROCEDURE

### Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

#### 1. For Bipolar Depression:

- Must have a documented pharmacy claim history of olanzapine (Zyprexa)
- For members without a documented claim history of olanzapine (Zyprexa), a medical necessity review is completed and the following criteria must be met:
  - Must have a diagnosis of Bipolar depression
  - Must be prescribed by a psychiatrist
  - Must have a trial of olanzapine (Zyprexa) in the past year

#### 2. For Major Depressive Disorder:

- Must have a diagnosis of treatment resistant Major Depressive Disorder
- Must have failure of both monotherapy and combination antidepressant therapy which includes both of the following:
  - An adequate trial and failure, an inadequate response (duration of at least 4 weeks), or intolerance to monotherapy with 2 different antidepressant therapies
  - A trial and failure, an inadequate response (duration of at least 4 weeks), or intolerance to one of the following:
    - A single trial of combination antidepressant therapy such as a Selective Serotonin Reuptake Inhibitor (SSRI) and bupropion or a Selective Norepinephrine Reuptake Inhibitor (SNRI) and bupropion
    - A single trial of an antidepressant with augmentation therapy (such as lithium)

### Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Limits	
All	30 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

## REFERENCES

1. Symbyax [package literature]. Eli Lilly; December 2003.
2. Weissman MM, et al. Cross-National Epidemiology of Major depression and Bipolar disorder. *JAMA* 1996;276: 293-299
3. Kessler RC, et al. Lifetime and 12-Month Prevalence of DSM-III-R Psychiatric Disorders in the United States. *Arch Gen Psychiatry* 1994;51:8-19.
4. Diagnostic and Statistical Manual of Mental Disorders. Fourth Edition, Text Revision. DSM-IV-TR. American Psychiatric Association 2000.
5. Tondo L, et al. Suicidal Behavior in Bipolar Disorder: Risk and Prevention. *CNS Drugs* 2003;17(7):491-511



**Symbyax (Olanzapine/fluoxetine)**

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6. Bryant-Comstock L, et al. Health care utilization and costs among privately insured members with bipolar I disorder. *Bipolar Disorders* 2002;4:398-405
7. Hilty DH, et al. A review of bipolar disorder among adults. *Psychiatric Services* 199;50(2):201-213
8. Hirschfield RM, et al. Perceptions and impact of bipolar disorder: How far have we really come? Results of the national depressive and manic-depressive association 2000 survey of individuals with bipolar depression. *J Clin Psych* 2003;64(2):161-167

**RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/17, 02/18</i>

