

## Clinical Policy: Asenapine (Saphris®)

Reference Number: NH.PMN.15

Effective Date: 08/15

Last Review Date: 07/17

[Revision Log](#)

### **IMPORTANT REMINDER**

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by the policy; and other indicia of medical necessity. Centene Corporation makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this policy.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based on the applicable contract provisions governing plan benefits (“Benefit Plan Contract”) and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This policy is current at the time of approval, may be updated and therefore is subject to change. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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### **Description**

The intent of the criteria is to ensure that patients follow selection elements established by Centene medical policy for asenapine (Saphris®).

### **Policy/Criteria**

It is the policy of health plans affiliated with Centene Corporation® that asenapine (Saphris®) is **medically necessary** for members meeting the following criteria:

#### **Initial Approval Criteria:**

##### **I. Bipolar Disorder** (must meet all)

- A. Diagnosis of bipolar disorder;
- B. Failure of two PDL generic atypical antipsychotics,  
OR  
Contraindication to two PDL generic antipsychotics FDA approved for bipolar disorder;
- C. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**II. Schizophrenia, Schizoaffective Disorder or other psychotic disorder:** (must meet all)

- A. Diagnosis of schizophrenia;
- B. Age  $\geq$ 10 years;
- C. Failure of two PDL generic atypical antipsychotics,  
OR  
Contraindication to two PDL generic antipsychotics FDA approved for schizophrenia;
- D. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**Continued Approval (must meet all as applicable):**

- A. Previously received medication via Centene benefit or member has previously met all initial approval criteria;
- B. If request is for a dose increase, new dose must not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**Background**

Asenapine is an atypical antipsychotic agent. The exact mechanism responsible for the therapeutic effects of antipsychotics is unknown. However, it has been theorized that the efficacy of asenapine in treating schizophrenia is mediated through dopamine (D2) and serotonin (5-HT2A) antagonism. It is FDA approved for bipolar disorder and schizophrenia.

**References (or Bibliography)**

1. Asenapine Monograph. Clinical Pharmacology. Accessed May 2016. <http://www.clinicalpharmacology-ip.com>
2. Saphris [Package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; March 2015. Available at: [http://www.allergan.com/assets/pdf/saphris\\_pi](http://www.allergan.com/assets/pdf/saphris_pi). Accessed May 2016.
3. Stroup ST, Marder S. Pharmacotherapy for schizophrenia: Acute and maintenance phase treatment. Stein MB. (Ed), UpToDate. Waltham MA. Accessed May 2016.
4. Stovall J. Bipolar disorder in adults: Pharmacotherapy for acute mania and hypomania. Keck P. (Ed), UpToDate. Waltham MA. Accessed May 2016.

Reviews, Revisions, and Approvals	Date	Approval Date
New guideline created – replaces CP.PMN.56	08/15	08/15
Updated template and references.	05/16	08/16
Removed age criteria for bipolar disorder	07/17	07/17

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