Clinical Policy: Asenapine (Saphris®)
Reference Number: NE.PMN.15
Effective Date: 01/01/2017

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. Age ≥10 years;
   C. Failure of two formulary generic atypical antipsychotics, each used for ≥ 4 weeks;
      OR contraindication to ALL formulary generic antipsychotics FDA approved for bipolar disorder;
   D. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.
II. Schizophrenia (must meet all)
   A. Diagnosis of schizophrenia;
   B. Age ≥18 years;
   C. Failure of two formulary generic atypical antipsychotics, each used for ≥ 4 weeks;
      OR
      Contraindication to ALL formulary 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

Workflow Document

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)
      http://www.clinicalpharmacology-ip.com
   3. Stroup ST, Marder S. Pharmacotherapy for schizophrenia: Acute and maintenance phase
treatment. Stein MB. (Ed), UpToDate. Waltham MA. Accessed May 2016.
      Keck P. (Ed), UpToDate. Waltham MA. Accessed May 2016.