

Clinical Policy: Asenapine (Saphris)

Reference Number: CP.PMN.15

Effective Date: 12.01.14

Last Review Date: 02.18

Line of Business: Commercial, Health Insurance Marketplace, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Asenapine (Saphris[®]) is an atypical antipsychotic.

FDA Approved Indication(s)

Saphris is indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder as acute monotherapy treatment of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age; as adjunctive treatment to lithium or valproate in adults; and as maintenance monotherapy treatment in adults

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] that Saphris is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Bipolar Disorder (must meet all):

1. Diagnosis of bipolar disorder;
2. Age \geq 10 years;
3. Failure of 2 preferred atypical antipsychotic (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) agents at up to maximally indicated doses, each trialed for \geq 4 weeks unless contraindicated or clinically significant adverse effects are experienced to ALL generic antipsychotics;
4. Dose does not exceed 20 mg per day (2 tablets/day).

Approval duration:

Medicaid/Health Insurance Marketplace – 12 months

Commercial – Length of Benefit

B. Schizophrenia (must meet all):

1. Diagnosis of schizophrenia;
2. Age \geq 18 years;
3. Failure of 2 preferred atypical antipsychotic (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) agents at up to maximally indicated doses, each trialed for \geq 4 weeks unless contraindicated or clinically significant adverse effects are experienced to ALL generic antipsychotics;

4. Dose does not exceed 20 mg per day (2 tablets/day).

Approval duration:

Medicaid/Health Insurance Marketplace – 12 months

Commercial – Length of Benefit

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Saphris for bipolar or schizophrenia and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg per day (2 tablets/day)

Approval duration:

Medicaid/Health Insurance Marketplace – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

Not applicable

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify [®])	10-30 mg by mouth daily	30 mg/day
ziprasidone (Geodon [®])	40-80 mg by mouth twice daily	160 mg/day
risperidone (Risperdal [®])	1-4 mg by mouth daily to twice daily	16 mg/day
Quetiapine (Seroquel [®])	400-800 mg/day by mouth twice daily to three times daily in divided doses	800 mg/day
olanzapine (Zyprexa [®])	10-20 mg by mouth daily	20 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: General Information

Saphris has a black box warning for increased mortality in elderly patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Saphris is not approved for the treatment of patients with dementia-related psychosis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	5 - 10 mg twice daily	10 mg twice daily
Bipolar in adults	5 - 10 mg twice daily	10 mg twice daily
Bipolar in pediatric members	2.5 mg twice daily	10 mg twice daily

VI. Product Availability

Sublingual tablets: 2.5 mg, 5 mg, and 10 mg

VII. References

1. Asenapine Drug Monograph. Clinical Pharmacology. Accessed November 2017. <http://www.clinicalpharmacology-ip.com>
2. Saphris Prescribing Information. Irvine, CA: Allergan USA, Inc.; February 2017. Available at: <http://www.saphris.com/>. Accessed November 1, 2017.
3. Lehman AF, Lieberman JA, Dixon LB et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.
4. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder. Am J Psychiatry. 2002 Apr;159(4 Suppl):1-50.
5. Argo TR, Crimson ML, Miller AL, et al. *Texas Medication Algorithm Project Procedural Manual: Schizophrenia Algorithm*. The Texas Department of State Health Services. 2007.
6. American Hospital Formulary Service Drug Information Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed online June 2017.
7. MicroMedex accessed at <http://www.micromedexsolutions.com/micromedex2/librarian/> Accessed June 2017.

8. American Psychiatric Association Practice Guideline for the Treatment of Patients with Major Depressive Disorder: Third Edition (2010). Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed online July 23, 2015.
9. American Psychiatric Association Practice Guideline for the Treatment of Patients with Bipolar Disorder: Second Edition (2010). Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed online July 23, 2015.
10. Crismon ML, Argo TR, Bendele SD et al. Texas Medication Algorithm Project Procedural Manual: Bipolar Disorder Algorithms. July 2007. Available at: <http://www.harding.edu/assets/druginfo/pdf/tmapalgorithmforbipolarorder.pdf>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: -Policies combined for commercial, HIM and Medicaid lines of business - No significant change from previous corporate approved policy - HIM: changed from failure of 1 atypical antipsychotic to failure of 2 for treatment of bipolar disorder. - References reviewed and updated.	11.14.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a 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 this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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