Clinical Policy: Asenapine (Saphris, Secuado)

Reference Number: CP.PMN.15
Effective Date: 12.01.14
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA*, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Asenapine (Saphris®, Secuado®) is an atypical antipsychotic.

FDA Approved Indication(s)

Saphris and Secuado are indicated for the treatment of schizophrenia in adults.

Saphris is also indicated for bipolar I disorder:

- Acute monotherapy treatment of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
- Adjunctive treatment to lithium or valproate in adults
- Maintenance monotherapy treatment in adults

**For Health Insurance Marketplace (HIM)/ICHRA, if request is through pharmacy benefit, Secuado is non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that asenapine, Saphris and Secuado are **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 ≥ 10 years;
3. Request is for Saphris;
4. Member meets one of the following (a or b):*
   ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix D*);
   b. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
5. For Saphris requests, member must use generic asenapine tablets, unless contraindicated or clinically significant adverse effects are experienced;

6. Dose does not exceed both of the following (a and b):
   a. 20 mg per day;
   b. 2 tablets per day.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 12 months or duration of request, whichever is less

B. Schizophrenia (must meet all)**:**
1. Diagnosis of schizophrenia;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b): *
   ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Request is for the treatment of a member in a State with limitations on step therapy in certain mental health settings (*see Appendix D*);
   b. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
4. For Saphris requests, member must use generic asenapine tablets, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed any of the following (a or b):
   a. Saphris (i and ii):
      i. 20 mg per day;
      ii. 2 tablets per day;
   b. Secuado (i and ii):
      i. 7.6 mg per day;
      ii. 1 patch per day.

Approval duration:
Medicaid – 12 months
HIM/ICHRA – 12 months for Saphris (*refer to HIM.PA.103 for Secuado)*
Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, 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 or Secuado for bipolar disorder 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 any of the following (a or b):
   a. Saphris (i and ii):
      i. 20 mg per day;
      ii. 2 tablets per day;
   b. Secuado (i and ii):
      i. 7.6 mg per day;
      ii. 1 patch per day.

Approval duration:
Medicaid – 12 months
HIM/ICHRA – 12 months for Saphris (*refer to HIM.PA.103 for Secuado)*
Commercial – 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, 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.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. Dementia-related psychosis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

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®)	**Bipolar Disorder and Schizophrenia** Adults: 10 to 15 mg PO QD	30 mg/day
olanzapine (Zyprexa®)	**Schizophrenia** Initial: 5 to 10 mg PO QD; target: 10 mg PO QD **Bipolar Disorder** Monotherapy: 10 to 15 mg PO QD; adjunct to lithium or valproate: 10 mg PO QD	20 mg/day
quetiapine (Seroquel®)	**Schizophrenia** Initial: 25 mg PO BID; target: 400 to 800 mg/day **Bipolar Disorder** Initial: 50 mg PO BID; target: 400 to 800 mg/day	800 mg/day
risperidone (Risperdal®)	**Schizophrenia** Initial: 1 mg PO BID or 2 mg PO QD; target: 4 to 8 mg PO QD **Bipolar Disorder** 2 to 3 mg PO QD	Schizophrenia: 16 mg/day Bipolar Disorder: 6 mg/day
ziprasidone (Geodon®)	**Schizophrenia** 20 mg PO BID **Bipolar Disorder** Initial: 40 mg PO BID; target: 40 to 80 mg PO BID	160 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: Contraindications/Boxed Warnings

- Contraindication(s):
  - Severe hepatic impairment (Child-Pugh C)
  - Known hypersensitivity to Saphris, Secuado, or to any components in the sublingual formulation or transdermal system

- Boxed warning(s): Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Saphris and Secuado are not approved for the treatment of patients with dementia-related psychosis.

Appendix D: States with Limitations against Redirections in Certain Mental Health Settings

State	Step Therapy Prohibited?	Notes
AR	Yes	For the treatment of psychosis and serious mental illness through antipsychotic prescription drugs, no step therapies allowed.
NV	No	Failure of ONE preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, used for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced.
TX	No	Failure of ONE preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, used for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Asenapine sublingual tablets (Saphris)	Schizophrenia	5 to 10 mg SL BID	20 mg/day
	Bipolar in adults		
	Bipolar in pediatric members	2.5 to 10 mg SL BID	
Asenapine transdermal system (Secuado)	Schizophrenia	3.8 to 7.6 mg TD QD	7.6 mg/day

VI. Product Availability

Drug Name	Availability
Asenapine sublingual tablets (Saphris)	Sublingual tablets: 2.5 mg, 5 mg, 10 mg
Asenapine transdermal system (Secuado)	Transdermal systems: 3.8 mg/day, 5.7 mg/day, 7.6 mg/day

VII. References

1. Saphris Prescribing Information. Irvine, CA: Allergan USA, Inc.; January 2025. Available at: https://www.rxabbvie.com/pdf/saphris_pi.pdf . Accessed April 20, 2026.
2. Secuado Prescribing Information. Miami, FL: Noven Therapeutics, LLC; January 2025. Available at: https://www.secuado.com/professional/. Accessed April 20, 2026.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 29, 2026.
   Schizophrenia
4. Keepers G, Fochtmann L, Anzia J, et al. APA Practice guideline for the treatment of patients with schizophrenia, third edition. Am J Psychiatry. 2020 Sept;177(9):868-872.

5. Moore TA, Buchanan RW, Buckley PF, et al. The Texas medication algorithm project antipsychotic algorithm for schizophrenia: 2006 Update. J Clin Psychiatry. 2007; 68:1751-1762.

Bipolar Disorder

6. Hirschfeld RMA, Bowden CL, Gitlin MJ, et al. Practice guideline for the treatment of patients with bipolar disorder, second edition. Arlington, VA: American Psychiatric Association; April 2002. Available online at: http://www.psychiatryonline.org/guidelines. Accessed April 23, 2025.
7. Suppes T, Swann AC, Dennehy EB, et al. Texas medication algorithm project: development and feasibility testing of a treatment algorithm for patients with bipolar disorder. J Clin Psychiatry. 2021;62(2):429-447.
8. Management of bipolar disorder work group. Clinical practice guideline for management of bipolar disorder Version 2.0 - 2023. Veterans Affairs/Department of Defense. Available at: https://www.healthquality.va.gov/guidelines/MH/bd/VA-DoD-CPG-BD-Full-CPGFinal508.pdf. Accessed May 29, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Template changes applied to other diagnoses/indications.	09.20.22	
1Q 2023 annual review: no significant changes; for Saphris, added must use generic asenapine tablet language; added dementia-related psychosis to section III; references reviewed and updated.	11.03.22	02.23
3Q 2023 annual review: no significant changes; added redirection bypass for members in a State with limitations on step therapy in certain mental health settings along with Appendix D, which includes Texas with requirements for single drug redirection for HIM requests; references reviewed and updated.	04.20.23	08.23
Added Nevada to Appendix D with requirements for single drug redirection for Medicaid requests.	08.31.23	
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.09.24	08.24
Added Arkansas to Appendix D with requirement for no step therapies allowed for HIM requests.	09.25.24	
3Q 2025 annual review: revised policy/criteria section to also include generic asenapine; added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	06.27.25	08.25
Removed “applies to HIM request only” from Appendix D for Arkansas per AR HB 1276.	02.13.26	
3Q 2026 annual review: added ICHRA line of business; removed all line of business-specific distinctions from Appendix D; references reviewed and updated.	04.20.26	08.26

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.