

Clinical Policy Title:	asenapine
Policy Number:	RxA.476
Drug(s) Applied:	Saphris®, Secuado®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

- Asenapine (Saphris®, Secuado®) is an atypical antipsychotic. 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
 - Adults and pediatric patients 10 to 17 years of age
 - Adjunctive treatment to lithium or valproate in adults
 - Maintenance monotherapy treatment in adults

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
asenapine (Saphris®)	Schizophrenia (acute and maintenance treatment)	5 to 10 mg sublingually twice daily	20 mg/day
	Bipolar in adults	5 to 10 mg sublingually twice daily	20 mg/day
	Bipolar in pediatric members	2.5 to 10 mg sublingually twice daily	20 mg/day
asenapine (Secuado®)	Schizophrenia	3.8/24 hours to 7.6 mg/24 hours transdermally once daily	7.6 mg/24 hours

Dosage Forms

- Sublingual tablets: 2.5 mg, 5 mg, 10 mg
- Transdermal system: 3.8 mg/24 hours, 5.7 mg/24hours, 7.6 mg/24 hours

Clinical Policy

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

I. Initial Approval Criteria

A. Bipolar Disorder (must meet all):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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

Approval duration

Commercial: 12 months

Medicaid: 12 months

B. Schizophrenia (must meet all):

1. Diagnosis of schizophrenia;
2. Age \geq 18 years;
3. Request is for Saphris or Secuado
4. Failure of two preferred atypical antipsychotic (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) agents at up to maximally indicated doses, each used for \geq 4 weeks, unless contraindicated or clinically significant adverse effects are experienced.
5. Dose does not exceed (a or b):
 - Saphris: 20 mg (2 tablets) per day;
 - Secuado: 7.6 mg per day;

Approval duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy

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

1. Member is currently receiving the medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy, 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 (a or b):
 - Saphris: 20 mg (2 tablets) per day;
 - Secuado: 7.6 mg per day;

Approval duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	Bipolar Disorder and Schizophrenia Adults: 10 to 15 mg PO once daily	30 mg/day
olanzapine (Zyprexa®)	Schizophrenia Initial: 5 to 10 mg PO once daily; target: 10 mg PO once daily Bipolar Disorder Monotherapy: 10 to 15 mg PO once daily; adjunct to lithium or valproate: 10 mg PO once daily	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 once daily; target: 4 to 8 mg PO once daily Bipolar Disorder 2 to 3 mg PO once daily	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 asenapine or to any components in the formulation.
- Boxed warning(s):
 - 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.

References

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2. 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.
3. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder.

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5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 30, 2018.
6. 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 September 17, 2020.
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8. 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/tmapalgorithmforbipolardisorder.pdf>. Accessed September 17, 2020.

Secuado (asenapine) transdermal system, Prescribing information. Miami, FL. Noven Therapeutics LLC.; October 2019. Available at <https://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid=685eaf44-5944-4f38-afba-0a4fc0b3462b>. Accessed on October 01, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical policy title was updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Dosing Regimen for Bipolar in adults updated and maximin dose updated for Bipolar in adults & pediatric members 4. Approval duration was updated for Commercial and deleted HIM 5. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance”. 6. Appendix B, Therapeutic alternatives language rephrased 7. Product information of Secuado was added to the policy. All relevant fields are updated to include Secuado 8. References were reviewed and updated. 	09/17/2020	12/07/2020