Asenapine (Saphris)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Asenapine (Saphris) is a second generation antipsychotic, also referred to as an atypical antipsychotic. It is FDA-approved for the treatment of:

1. Schizophrenia in adults.
2. Bipolar I disorder in those 10 years of age and older:
    a. Acute monotherapy treatment of manic or mixed episodes, in adults and pediatric individuals 10 to 17 years of age
    b. Adjunctive treatment to lithium or valproate in adults
    c. Maintenance monotherapy treatment in adults

Bipolar disorder, schizophrenia, and other serious mental health conditions require comprehensive treatment approaches. Treatment plans usually include both medication and non-medication approaches. Medicines, such as asenapine (Saphris), are often a part of treatment. Other medications in the group of second generation antipsychotics include, but are not limited to aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperidal), and ziprasidone (Geodon). Tolerance and response to antipsychotic agents vary, and patients who do not tolerate or respond to a specific agent may be treated with a different agent and expect a different response or adverse effect(s). The choice of an antipsychotic agent depends on a multitude of factors, including but not limited to

response (or lack thereof) to previously used medications, safety and tolerability of each agent, and patient-specific considerations.

Definitions

"Bipolar disorder" is a mental health condition which includes episodes of emotional highs (mania) and lows (depression). It may cause extreme changes in behavior and mood, such as feeling much happier or sadder than normal.

"Postpartum Psychosis" is a rare but serious mental health emergency characterized by sudden onset of psychotic symptoms shortly after childbirth. It is often characterized by acute onset of delusions, disorganized thoughts, hallucinations, and/or agitation. While it may occur as a manifestation of bipolar disorder, it can also present in patients without prior psychiatric history. Early recognition and treatment is critical due to risks to both mother and infant.

"Schizophrenia" is a psychiatric disorder involving chronic or recurrent psychosis and is commonly associated with impairments in social and occupational functioning.

"Schizoaffective disorder (ScAD)" is a mental health condition which has both psychotic symptoms and mood (affective) disorder symptoms. People with ScAD may have symptoms of depression (e.g., feeling sad, empty) or mania (e.g., raised mood, feel powerful and can do anything).

Clinical Indications

The Plan considers asenapine (Saphris) medically necessary when ALL the following criteria are met for the applicable indication listed below:

Medical Necessity Criteria for Initial Authorization

Bipolar Disorder:

1. The requested medication is prescribed by or in consultation with a psychiatrist; *AND*
2. The member is 10 years of age or older; *AND*
3. The member has a diagnosis of bipolar disorder; *AND*
4. The member is unable to use or has tried and failed at least a one-month trial to ONE (1) of the following:
    a. Aripiprazole (Abilify); *and/or*
    b. Lurasidone (Latuda); *and/or*
    c. Olanzapine (Zyprexa); *and/or*
    d. Risperidone (Risperdal); *and/or*
    e. Paliperidone (Invega); *and/or*
    f. Quetiapine (Seroquel); *and/or*
    g. Ziprasidone (Geodon); *AND*

Postpartum Psychosis:

1. The requested medication is prescribed by or in consultation with a psychiatrist; *AND*
2. The member has postpartum psychosis as evidenced by ONE (1) of the following:
    a. New onset psychotic symptoms (e.g., delusions, disorganized thoughts, hallucinations, agitation, bizarre behavior) in the postpartum period; *or*
    b. Bipolar disorder with postpartum psychotic features (e.g., delusions, disorganized thoughts, hallucinations, agitation, bizarre behavior); *or*
    c. Primary mental disorder with psychotic symptoms during the peripartum period.

Schizophrenia:

1. The requested medication is prescribed by or in consultation with a psychiatrist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of schizophrenia; *AND*
4. The member is unable to use or has tried and failed at least a one-month trial to TWO (2) of the following:
    a. Aripiprazole (Abilify); *and/or*
    b. Lurasidone (Latuda); *and/or*
    c. Olanzapine (Zyprexa); *and/or*
    d. Risperidone (Risperdal); *and/or*
    e. Paliperidone (Invega); *and/or*
    f. Quetiapine (Seroquel); *and/or*
    g. Ziprasidone (Geodon); *AND*

Schizoaffective Disorder:

1. The requested medication is prescribed by or in consultation with a psychiatrist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of schizoaffective disorder; *AND*
4. The member is unable to use or has tried and failed at least a one-month trial to BOTH of the following:
    a. Paliperidone; *and*
    b. ONE (1) of the following:
        i. Aripiprazole (Abilify); *or*
        ii. Lurasidone (Latuda); *or*
        iii. Olanzapine (Zyprexa); *or*
        iv. Risperidone (Risperdal); *or*
        v. Quetiapine (Seroquel); *or*
        vi. Ziprasidone (Geodone); *AND*

If the above prior authorization criteria are met for the applicable indication, asenapine (Saphris) will be approved for up to a lifetime.

Agitation/Aggression associated with psychiatric disorders, substance intoxication, or other organic causes

1. The requested medication is prescribed by or in consultation with a psychiatrist; *AND*
2. The member is 18 years of age or older; *AND*
3. The member has severe agitation/aggression requiring pharmacotherapy associated with ONE (1) of the following:
    a. Psychiatric disorder (e.g. bipolar disorder, schizophrenia); *or*
    b. Substance intoxication; *or*
    c. Other organic causes (e.g., central nervous system diseases including Parkinson's, Alzheimer's, other dementias, encephalitis, meningitis, or brain trauma); *AND*
4. The member has not responded to less invasive management strategies, such as verbal de-escalation; *AND*
5. The member is characterized by ONE (1) of the following:
    a. The member is unable to use or has tried and failed first-line immediate-acting intramuscular (e.g., aripiprazole IM, lorazepam IM, olanzapine IM, ziprasidone IM) or inhaled medications (e.g., loxapine inhaled); *or*
    b. The member exhibits milder symptoms and is willing to take oral medication; *AND*
6. The requested dose is within FDA approved labeling or generally accepted guidelines (i.e., 10 mg as a single dose); *AND*
7. Chart documentation is provided detailing the symptoms and management that support the criteria above.

If the above prior authorization criteria are met for the applicable indication, asenapine (Saphris) will be approved for up to 7-days.

Medical Necessity Criteria for Reauthorization

Agitation/Aggression associated with psychiatric disorders, substance intoxication, or other organic causes

Reauthorization for up to 14-days will be granted if there is documentation indicating that the member's symptoms have responded (i.e., improvement in agitation/aggression symptoms) but aggressive behavior is not yet fully resolved or controlled.

Experimental or Investigational / Not Medically Necessary

Asenapine (Saphris) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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