Original Effective Date: 04/01/2014
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Next Review Due By: 01/2026
Policy Number: C5016-A

Antipsychotics

PRODUCTS AFFECTED

Abilify, aripiprazole oral solution, aripiprazole orally disintegrating tab, asenapine, Caplyta (lumateperone), Cobenfy (xanomeline/trospium), Equetro (carbamazepine), Fanapt (iloperidone), Invega (paliperidone) Extended-Release Tablets, Latuda (lurasidone), lurasidone, Lybalvi (olanzapine-samidorphan), Opipza (aripiprazole oral film), paliperidone ER tab, Rexulti (brexpiprazole), Saphris (asenapine) sublingual tab, Secuado (asenapine) patch, Vraylar (cariprazine)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
FDA approved uses and compendia supported uses

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Requested use is for an FDA-approved indication OR an indication supported in the compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines)
   AND
2. Documentation of ONE of the following:
   (a) The member's medication history (from claims or documentation) includes use of a minimum of three preferred generic formulary atypical antipsychotic agents with matching indication OR member has a documented FDA labeled contraindication or serious side effects to all preferred generic formulary atypical antipsychotic agents with matching indication OR Request is for Cobenfy (trospium/xanomeline) and member is experiencing tardive dyskinesia on current antipsychotic therapy
   OR
   (b) Documentation that the member is using the requested agent AND is at risk if therapy is changed OR has recently (within 48 hours) been discharged from an inpatient facility
   OR
   (c) Prescriber provides a treatment plan of utilization of non-preferred oral agent in order to bridge to long-acting injectable therapy
   OR
   (d) Request is for a non-preferred dosage form of aripiprazole for Tourette's Disorder AND the member has a documented treatment failure, serious side effects or clinical contraindication to generic haloperidol and pimozide within the last 90 days AND trial/failure of a preferred aripiprazole dosage form
   MOLINA REVIEWER NOTE: For Nevada Marketplace, please see Appendix

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time with documented medical rationale from prescriber
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

None

AGE RESTRICTIONS:

LATUDA (lurasidone), SAPHRIS (asenapine): 10 years of age and older
INVEGA (paliperidone), EQUETRO (carbamazepine): 12 years of age and older
ABILIFY (aripiprazole), OPIPZA (aripiprazole): 6 years and older
REXULTI (brexpiprazole): 13 years of age and older
CAPLYTA (lumateperone), COBENFY (xanomeline/trospium), FANAPT (iloperidone), LYBALVI (olanzapine and samidorphan), VRAYLAR (cariprazine), SECUADO (asenapine): 18 years of age and older

QUANTITY:

N/A

PLACE OF ADMINISTRATION:

The recommendation is that oral and transdermal medications in this policy will be for pharmacy benefit

coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Transdermal

DRUG CLASS:
Atypical Antipsychotic

FDA-APPROVED USES:
Abilify Oral Tablets and Oral Solution are indicated for the treatment of: Schizophrenia, Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder, Adjunctive Treatment of Major Depressive Disorder, Irritability Associated with Autistic Disorder, Treatment of Tourette's Disorder

Caplyta (lumateperone) capsules are indicated for the treatment of schizophrenia in adults, and depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate.

Cobenfy (xanomeline/trospium) is indicated for the treatment of schizophrenia in adults.

Equetro (carbamazepine) is indicated for the treatment of acute manic or mixed episodes associated with bipolar I disorder, for the treatment of the pain associated with trigeminal neuralgia, and as an anti-epileptic drug (AED) indicated for the treatment of partial seizures with complex symptomatology, generalized tonic-clonic seizures, and mixed seizures

Fanapt (iloperidone) is indicated for the treatment of schizophrenia in adults.

Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizophrenia in adults and adolescents ages 12-17, and treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressant therapy in adults.

Latuda (lurasidone) is indicated for the treatment of schizophrenia in adults and adolescents 13 to 17 years, depressive episodes associated with bipolar I disorder (bipolar depression) in adults and pediatric patients 10 to 17 years as monotherapy or adjunctive therapy with lithium or valproate in adults

Lybalvi (olanzapine-samidorphan) is indicated for the treatment of schizophrenia in adults, and bipolar I disorder in adults as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate, or maintenance monotherapy treatment

Opipza (aripiprazole oral film) is indicated for treatment of schizophrenia in patients ages 13 years and older, adjunctive treatment of major depressive disorder (MDD) in adults, irritability associated with autistic disorder in pediatric patients 6 years and older, and treatment of Tourette's disorder in pediatric patients 6 years and older

Rexulti (brexpiprazole) is indicated as adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults, treatment of schizophrenia in adults and pediatric patients ages 13 years and older, and treatment of agitation associated with dementia due to Alzheimer's disease. *Limitations of use: Rexulti is not indicated as an as needed ("prn") treatment for agitation associated with dementia due to Alzheimer's disease.*

Saphris (asenapine) sublingual tab is indicated for: Schizophrenia, Acute treatment of manic or mixed episodes associated with Bipolar I disorder as monotherapy or adjunctive treatment to lithium or

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

Secuado (asenapine) patch is indicated for the treatment of adults with schizophrenia .

Vraylar (cariprazine) is indicated for the treatment of schizophrenia in adults, acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults, and adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults.

COMPENDIAL APPROVED OFF-LABELED USES:

Aripiprazole: Delusional disorder, Huntington disease-associated chorea (alternative agent), Obsessive-compulsive disorder, treatment resistant (adjunctive therapy to antidepressants), borderline personality disorder
Invega: Delusional infestation (also called delusional parasitosis), psychosis/agitation associated with dementia
Latuda: Major depressive disorder with mixed features; psychosis/agitation associated with dementia
Rexulti: Psychosis/agitation associated with dementia
Saphris: psychosis/agitation associated with dementia
Vraylar: Major depressive disorder, unipolar, augmentation of antidepressant; Psychosis/agitation associated with dementia

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Nevada (Source: Nevada Legislature)

"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
    b. The drug is prescribed by:
        i. A psychiatrist
        ii. A physician assistant under the supervision of a psychiatrist;
        iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
        iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
    c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…

3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage*

for the recommended drug."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Schizophrenia

The initial choice of antipsychotic medication or the decision to switch to a new antipsychotic should be made on an individual basis, considering prior treatment response, side effect experience; adherence history; relevant medical history, risk factors; individual medication side effect profile; and long-term treatment planning. Clozapine can be effective for psychotic symptoms in patients not responding to other drugs and appears to be more effective vs other antipsychotics in decreasing the risk of suicide. Although clozapine is the most effective antipsychotic drug, it is reserved for refractory disease due to its potential hematologic toxicity and strict monitoring requirements. Olanzapine may have some slight advantages over other drugs in efficacy, but its adverse effects on weight and metabolism may be unacceptable for long term use. Some patients who do not respond to one antipsychotic may respond to another. Long-acting injectable antipsychotics may be useful when adherence is a problem.

Bipolar Disorder

For acute manic episodes, patients not already taking long-term treatment for bipolar disorder should consider oral administration of a dopamine antagonist when seeking rapid anti-manic effect. Systematic comparison of data from clinical trials suggests haloperidol, olanzapine, risperidone and quetiapine are particularly effective in short-term reduction of symptoms. Aripiprazole, other dopamine antagonists and partial agonists, carbamazepine and lithium are also options. For acute depressive episodes, patients not already taking long-term treatment for bipolar disorder should consider quetiapine, lurasidone or olanzapine. Dopamine antagonists have the inherent advantage of being anti-manic treatments. Only the combination of fluoxetine with olanzapine has support as a specific treatment. For bipolar mania, second-generation antipsychotics, lithium, and valproate are effective for treatment of acute manic episodes.

Both lithium and valproate may take days to weeks to have a full therapeutic effect. Treatment of an acute manic episode with these agents generally requires addition of an antipsychotic drug. For bipolar depression, quetiapine and lurasidone and combination olanzapine/fluoxetine have been shown to be effective in treating bipolar depression. Antidepressant drugs (e.g., SSRIs or bupropion can be effective for treatment of bipolar depression, but they can precipitate mania and generally should be used only as an adjunct to mood-stabilizing drugs such as lithium. Lithium has been shown to have protective effects against suicide and self- harm when used for treatment of bipolar depression. Lamotrigine may be modestly effective for this indication, but its usefulness in treating an acute episode is limited by the amount of time required for safe titration to an effective dose. Antipsychotics can cause somnolence, weight gain, diabetes, extrapyramidal symptoms, QT interval prolongation, and hyperprolactinemia.

Bipolar patients are particularly susceptible to extrapyramidal effects; quetiapine appears to have the lowest risk. Lurasidone appears to have minimal metabolic effects, but more studies are needed. DRESS (drug reaction with eosinophilia and systemic symptom syndrome) has been reported rarely with olanzapine and ziprasidone. Atypical antipsychotics are less likely to produce extrapyramidal side effects than typical antipsychotics used at conventional doses, which is of particular significance in bipolar disorder because of an apparently greater risk of motor side effects, including tardive dyskinesia.

Depression

Selective serotonin reuptake inhibitors (SSRIs) along with serotonin norepinephrine reuptake inhibitors (SNRIs), bupropion, and mirtazapine are considered first line treatment options for adults with major depressive disorder (MDD). Guidelines do not consider antipsychotics as a first line treatment of major depressive disorder without psychosis. However, they suggest that psychotic depression typically responds better to the combination of an antipsychotic and an antidepressant medication rather than

either component alone, although some research has shown comparable responses for anti-depressive treatment or antipsychotic treatment alone. Augmentation with antipsychotic drugs may be helpful when the response to antidepressant agents is inadequate, but adverse effects (e.g., weight gain, extrapyramidal symptoms) can occur. A second agent may be considered if there is partial/insufficient response on current antidepressant, there is good tolerability of current antidepressant, and switching antidepressants has been unsuccessful. Establish the safety of the proposed combination. Choose the combinations with the best evidence base first. Consider adding quetiapine, aripiprazole, or lithium as first-line add on treatments

Autism

Practice Parameters-American Academy of Child and Adolescent Psychiatry (AACAP, 2014) suggest pharmacotherapy may be offered when there is a specific target symptom or comorbid condition, potentially increasing patient ability to profit from educational and other interventions and allow less restrictive environments through management of severe and challenging behaviors.

Frequent targets for pharmacologic intervention include associated comorbid conditions (e.g., anxiety, depression) and other features (e.g., aggression, self-injurious behavior, hyperactivity, inattention, compulsive-like behaviors, repetitive or stereotypic behaviors, and sleep disturbances). Various considerations (e.g., adverse effects) should inform pharmacologic treatment. Risperidone and aripiprazole have been FDA approved for the treatment of irritability (e.g., physical aggression, severe tantrum behavior) associated with autism. There is a growing body of controlled evidence for pharmacologic intervention. The guideline provides a summary chart of medications supported by RCTs for use in children with autism spectrum disorder (ASD), including target symptoms, ages, dosing, potential adverse effects, and outcomes. Antipsychotics supported by RCTs showing positive effects on various target symptoms in ASD include aripiprazole, haloperidol, olanzapine, and risperidone. Combining medication with parent training is moderately more efficacious than medication alone for decreasing serious behavioral disturbance and modestly more efficacious for adaptive functioning. Individuals with ASD may be nonverbal, so treatment response is often judged by caregiver report and observation of specific behaviors. Although this may help document the effectiveness of the selected medication, an overall goal of treatment is to facilitate the child's adjustment and engagement with educational intervention. For medical therapies for children with ASD relative to placebo, five studies addressing risperidone and aripiprazole reported significant improvements in challenging behavior in the short term (<6 months) but also significant harms including weight gain, appetite changes, and EPS. Longer term effectiveness was reported in uncontrolled extensions. Two small studies comparing risperidone and aripiprazole reported no significant differences and effects or weight gain between agents.

Dementia-Related Psychosis (off-label use)

Concerns have emerged in recent years regarding the safety of both atypical and typical classes of antipsychotic medications when used in the elderly dementia population. In June 2008, the FDA warned healthcare professionals that both typical and atypical antipsychotics are associated with an increased risk of death in elderly patients being treated for dementia related psychosis. As a result, a Black Box Warning on increased risk of mortality in these patients appears on the product labeling of all atypical and typical antipsychotic drugs. The APA Practice Guideline for Treatment of Patients with Alzheimer's disease and Other Dementias and the NICE guidelines on dementia currently recommend that nonpharmacologic interventions be attempted before a trial of antipsychotic drug therapy and that the interventions attempted be guided by the patient's level of distress and the risk to the patients and caregiver. In addition, the FDA states that physicians who prescribe antipsychotics to elderly patients with dementia-related psychosis should discuss the risk of increased mortality with their patients, patients' families, and caregivers. The APA Guideline Watch (2014) states new evidence indicates that antipsychotics provide weak benefits for the treatment of psychosis and agitation in patients with dementia. Adverse effects of antipsychotics include sedation, metabolic effects, and cognitive impairment. For many patients with Alzheimer's disease, antipsychotics can be tapered and discontinued without significant signs of withdrawal or return of behavioral symptoms.

Antipsychotic drug therapy generally is reserved for patients who have severe symptoms or when associated agitation, combativeness, or violent behavior puts the patient or others in danger. Current evidence indicates that the atypical antipsychotics can provide modest improvement in behavioral manifestations; some evidence suggests that efficacy may be better for psychosis than for other manifestations. Antipsychotic efficacy appears to be similar among available agents and therefore the

choice of agent should be based on adverse effect profile and other patient considerations: to minimize adverse effects, the lowest possible effective dose should be used.

Tourette's Disorder

A review (2015) on treatment of Tourette's syndrome suggests alpha-2 agonists (clonidine and guanfacine) are less effective than antipsychotics but are usually recommended as initial pharmacotherapy due to low side effects. Atypical neuroleptics (aripiprazole or risperidone) are typically used if the alpha-2 agonists are ineffective or intolerable. Canadian Guidelines for Pharmacotherapy of Tic Disorders (2012) provide strong recommendations for use of clonidine and guanfacine (children only) for the treatment of tics. They provide weak recommendations for use of pimozide, haloperidol, fluphenazine, metoclopramide (children only), risperidone, aripiprazole, olanzapine, quetiapine, ziprasidone, topiramate, baclofen (children only), botulinum toxin injections, tetrabenazine, and cannabinoids (adults only) for the treatment of tics. While evidence supports efficacy of many antipsychotics for treatment of tics, the high rates of side effects associated with these medications resulted in only weak recommendations for these drugs. The American Academy of Child & Adolescent Psychiatry and the European Child and Psychiatry guideline state that atypical antipsychotics are effective in Tourette's Disorder (TD). At the time the guidelines were published, no atypical antipsychotics were FDA approved, and only haloperidol and pimozide had been approved for TD. However, most clinicians use atypical antipsychotics prior to the two approved agents. The guidelines found that risperidone is the most well studied non-FDA labeled atypical antipsychotic for the treatment of TD. Risperidone was found to be at least as effective as clonidine, haloperidol, and pimozide; with less frequent and severe side effects. The most common adverse reaction with risperidone therapy was mild to moderate sedation. No clinically significant extrapyramidal symptoms were observed. Ziprasidone showed efficacy compared to placebo in one randomized controlled trial. However, ECG screenings are recommended if ziprasidone treatment is considered. Olanzapine was studied in several open-label trials and 1 double-blind crossover study with pimozide. Although olanzapine was shown to be effective, weight gain was observed. Due to the metabolic effects, olanzapine, it is not recommended as a first line medication for TD. Quetiapine has also shown efficacy in TD in small scale studies with the most common side effects being sedation and weight gain.

Genetic Testing and Psychiatric Medication Choice

Pharmacogenomics is the study of the relationship between a genetic variation and how the body responds to medication. The America Psychiatric Association (APA) has a statement on pharmacogenomic testing based on results of their own task force looking at novel biomarkers and treatments. This task force determined "there is not sufficient information to support the widespread use of pharmacogenetic testing in clinical practice." The 2020 International Society of Psychiatric Genetics (ISPG) guidelines on genetic testing states "Pharmacogenetic testing should be viewed as a decision-support tool to assist in thoughtful implementation of good clinical care. We recommend HLA-A and HLA-B testing prior to use of carbamazepine and oxcarbazepine, in alignment with regulatory agencies and expert groups. Evidence to support widespread use of other pharmacogenetic tests at this time is still inconclusive, but when pharmacogenetic testing results are already available, providers are encouraged to integrate this information into their medication selection and dosing decisions. Genetic information for CYP2C19 and CYP2D6 would likely be most beneficial for individuals who have experienced an inadequate response or adverse reaction to a previous antidepressant or antipsychotic trial." The Pharmacogenomics Knowledgebase (PharmGKB) has summaries of genotype based *dosing* recommendations only, including the following:

- Aripiprazole: The Royal Dutch Pharmacists Association - Pharmacogenetics Working Group (DPWG) recommends reducing maximum dose of aripiprazole for patients carrying poor metabolizer alleles of CYP2D6.
- Antidepressants: The French National Network of Pharmacogenetics (Réseau national de pharmacogénétique (RNPGx)) recommends CYP2D6 and CYP2C19 genotyping before initiating an antidepressant treatment, especially in patients with a high risk of toxicity.
- Brexpiprazole: The Royal Dutch Pharmacists Association - Pharmacogenetics Working Group (DPWG) recommends to use half of the standard dose of brexpiprazole for patients carrying

poor metabolizer alleles of CYP2D6.
- Duloxetine: There are currently no dosing recommendations for duloxetine based on CYP2D6 genotype.

At this time, there are no guidelines found that support the use of pharmacogenomic testing to make therapeutic treatment decisions based on the results of that testing. These tests may be beneficial to help guide dosing and toxicity concerns of specific agents for those with suboptimal responses or at risk of toxicity.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of atypical antipsychotics are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

Contraindications to aripiprazole, Abilify, Opipza include: known hypersensitivity to aripiprazole

Contraindications to Caplyta (lumateperone) include: known hypersensitivity to lumateperone or any components of Caplyta

Contraindications to Cobenfy (xanomeline and trospium) include: urinary retention, moderate or severe hepatic impairment, gastric retention, history of hypersensitivity to Cobenfy or trospium chloride, untreated narrow-angle glaucoma.

Contraindications to Equetro (carbamazepine) include: Bone marrow depression, Known hypersensitivity to carbamazepine, Known hypersensitivity to tricyclic antidepressants, Concomitant use with monoamine oxidase inhibitors (MAOIs) or use within 14 days of discontinuing an MAOI, Concomitant use with delavirdine or other non-nucleoside reverse transcriptase inhibitors that are substrates for CYP3A4 (Equetro decreases efficacy of these drugs), Concomitant use of nefazodone

Contraindications to Fanapt (iloperidone) include: known hypersensitivity to Fanapt or any components of the formulation

Contraindications to Invega (paliperidone) include: known hypersensitivity to paliperidone, risperidone, or to any excipients in Invega

Contraindications to Latuda (lurasidone) include: Known hypersensitivity to LATUDA or any components in the formulation, Concomitant use with a strong CYP3A4 inhibitor (e.g., ketoconazole), Concomitant use with a strong CYP3A4 inducer (e.g., rifampin)

Contraindications to Lybalvi (olanzapine/samidorphan) include: patients using opioids, patients undergoing acute opioid withdrawal

Contraindications to Rexulti (brexpiprazole) include: known hypersensitivity to Rexulti or any of its components

Contraindications to Saphris (asenapine) include: Severe hepatic impairment (Child-Pugh C), Known hypersensitivity to Saphris (asenapine), or to any components in the formulation

Contraindications to Secuado (asenapine) include: Severe hepatic impairment (Child-Pugh C), Known hypersensitivity to Secuado (asenapine), or to any components in the transdermal system

Contraindications to Vraylar (cariprazine) include: known hypersensitivity to Vraylar

OTHER SPECIAL CONSIDERATIONS:

Aripiprazole has a black box warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors with antidepressant drugs.

Caplyta (lumateperone), Latuda (lurasidone), Rexulti (brexpiprazole), Vraylar (cariprazine) have a black box warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.

Equetro (carbamazepine) has a black box warning for serious dermatologic reactions and aplastic anemia and agranulocytosis.

Fanapt (iloperidone), Invega (paliperidone), Lybalvi (olanzapine and samidorphan), Saphris (asenapine), Secuado (asenapine) have a black box warning for increased mortality in elderly patients with dementia-

related psychosis.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Abilify TABS 2MG, 5MG, 10MG, 15MG, 20MG, 30MG
ARIPiprazole SOLN 1MG/ML
ARIPiprazole TBDP 10MG, 15MG
Asenapine Maleate SUBL 2.5MG, 5MG, 10MG
Caplyta CAPS 10.5MG, 21MG, 42MG
Cobenfy CAPS 50-20MG, 100-20MG, 125-30MG
Cobenfy Starter Pack CPPK 50-20 & 100-200MG
Equetro CP12 100MG, 200MG, 300MG
Fanapt TABS 1MG, 2MG, 4MG, 8MG, 20MG, 12MG
Fanapt Titration Pack TABS 1 & 2 & 4 & 6MG
Invega TB24 1.5MG, 3MG, 6MG, 9MG
Latuda TABS 20MG, 40MG, 60MG, 80MG, 120MG
Lurasidone HCl TABS 20MG, 40MG, 60MG, 80MG, 120MG
Lybalvi TABS 5-10MG, 10-10MG, 15-10MG, 20-10MG
Opipza FILM 2MG, 5MG, 10MG
Paliperidone ER TB24 1.5MG, 3MG, 6MG, 9MG
Rexulti TABS 0.25MG, 0.5MG, 1MG, 2MG, 3MG, 4MG
Saphris SUBL 2.5MG, 5MG, 10MG
Secuado PT24 3.8MG/24HR, 5.7MG/24HR, 7.6MG/24HR
Vraylar CAPS 1.5MG, 3MG, 4.5MG, 6MG
Vraylar CPPK 1.5 & 3MG

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3. Rexulti (brexpiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; May 2024.
4. Fanapt (iloperidone) [prescribing information]. Washington, DC: Vanda Pharmaceuticals, Inc; April 2024.

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Di scontinuation Available Dosage Forms References	Q1 2025
REVISION- Notable revisions: Products Affected Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Age Restrictions Quantity FDA-Approved Uses Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file