Initial Approval: July 11, 2018
Revised Dates: January 18, 2022;
April 19, 2022; January 19, 2022
July 21, 2021; September 10, 2020
July 8, 2020; October 9, 2019;
April 10, 2019; October 10, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Antipsychotic Medications – Safe Use for All Ages

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific age and dose for each agent is defined in Table 1 below:

Aripiprazole (Abilify®, Abilify Discmelt®, Abilify Maintena®, Aristada®, Aristada Initio™, Abilify MyCite®)
Asenapine (Saphris®, Secuado®)
Brexpiprazole (Rexulti®)
Cariprazine (Vraylar®)
Chlorpromazine
Clozapine (Clozaril®, Fazaclo®, Versacloz®)
Fluphenazine
Haloperidol (Haldol®)
Iloperidone (Fanapt®)
Lumateperone (Caplyta®)
Loxapine (Adasuve®, Loxitane®)
Lurasidone (Latuda®)
Molindone (Moban®)
Olanzapine (Zyprexa®, Zyprexa Zydis®)
Olanzapine pamoate (Zyprexa Relprevv®)
Olanzapine/Fluoxetine (Symbyax®)
Olanzapine/samidorphan (Lybalvi™)
Paliperidone (Invega®)
Paliperidone palmitate (Invega Sustenna®, Invega Trinza®, Invega Hafyera®)
Perphenazine
Pimozide (Orap®)
Quetiapine (Seroquel®, Seroquel XR®)
Risperidone (Perseris™, Risperdal®, Risperdal Consta®, Risperdal M-Tab®)
Thioridazine
Thiothixene
Trifluoperazine
Ziprasidone (Geodon®)

CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIPSYCHOTICS:

- PROVIDER TYPE/DIAGNOSIS:
  - For children **< 6 years of age**:
    - Must be prescribed only by (ages < 4 years) or in consultation/collaboration with (ages 4 – < 6 years) a psychiatrist, neurologist, or developmental/behavioral pediatrician.
  - For patients **≥ 65 years of age** (long-term care, non-dual eligibility group) (must meet one of the following):
    - Diagnosis of schizophrenia, schizoaffective, delusional disorder, unspecified psychotic disorders, Huntington's disease (G10), Tourette's syndrome (F95.2), bipolar disorder, adjunctive treatment of major depressive disorder or irritability associated with autistic disorder.
    - Dementia/major neurocognitive disorder for the treatment of agitation or psychosis when symptoms present a danger to self or others.
- MULTIPLE CONCURRENT USE:
  - For patients receiving multiple antipsychotics concurrently, prior authorization will be required for:
    - Patients **< 18 years of age**, when two or more antipsychotics used concurrently for greater than 60 days (includes oral and long-acting injectables)
      - Must be prescribed by or in consultation/collaboration with a psychiatrist, neurologist, developmental/behavioral pediatrician

- Patients ages ≥ 18 years of age, when three or more antipsychotics used concurrently for greater than 60 days (includes oral and long-acting injectables)
  - Must be prescribed by or in consultation/collaboration with a psychiatrist
- Patients ages ≥ 18 years of age, when two or more concurrent long-acting injectable antipsychotics for greater than 60 days
- Prior authorization will require a written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer, if unable to approve written request.

- DOSING LIMITS:
  - The antipsychotic dose must not exceed the dosing limit listed in Table 1. If the dosing limit is exceeded, prior authorization will be required.
    - Prior authorization will require a written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer, if unable to approve written request.
  - Drugs listed in Table 1 as not approved for the specified age range will require an appeal.
- STEP THERAPY (APPLICABLE TO ALL AGES);
  - ABILIFY MYCITE® (MUST MEET ALL OF THE FOLLOWING):
    - Must meet FDA label requirements for approved use.
    - Documented benefit and no contraindication to aripiprazole tablets
    - Approval period of 12 weeks
    - Not able to receive injections
    - Requires peer-to-peer review
  - SECUADO® (MUST MEET ALL OF THE FOLLOWING)
    - Must be for the treatment of schizophrenia in adults.
    - Must have responded positively to an adequate trial (at least 2 weeks at maximum tolerated doses) of generic asenapine sublingual tablets.
    - Must provide a valid medical reason to require this alternate dosage form.
  - LYBALVI™ (MUST MEET ALL OF THE FOLLOWING)
    - Must have had an adequate trial (at least 2 weeks at maximum tolerated doses) of at least 1 generic product that has a low likelihood of weight-gain (aripiprazole, ziprasidone, loxapine, molindone, pimozide, thiothixene).
    - Patient has been opioid free from a short-acting opioid for the past 7 days and from a long-acting opioid for the past 14 days.
    - Patient has been educated to stop Lybalvi for at least 5 days before starting or re-starting any opioids.

LENGTH OF APPROVAL: No renewal required

Note – General prescribing recommendations:

- Prescriber should attempt to gather fasting plasma glucose, lipid screening, weight, height and Abnormal Involuntary Movement Scale (AIMS) evaluation within the previous 12 months.[1,2]
- Documentation of developmentally-appropriate, comprehensive psychiatric assessment should be completed by the prescriber and documented in the child's medical record.
- Patient assessment should include DSM-5 or most updated edition of DSM diagnosis, screening for parental psychopathology, evaluation of family functioning and gathering collateral information from community resources (e.g.. School).
- Non-psychopharmacological interventions (i.e. training parents or caregivers in evidence-based behavior management) should be initiated before (and maintained, if indicated, during) psychopharmacological treatment is initiated.
- Prochlorperazine is not being managed due to mostly being used for nausea and vomiting.
  - Prochlorperazine was previously removed at the May 18, 2018 MHMAC meeting.

References:

1. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia Third Edition. American Psychiatric Association, 2021. Available at https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841. Accessed on 7/22/2021.
2. Practice Guideline for the Treatment of Patients with Schizophrenia Second Edition. APA 2004. Available at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf. Accessed on 1/23/2020.
3. Psychotropic Medication Utilization Parameters for Children and Youth In Texas Public Behavioral Health (6th Version). The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission, June 2019. Available at https://www.dfps.state.tx.us/Child_Protection/Medical_Services/Psychotropic_Medications.asp. Accessed 10/23/19.
4. Secuado (asenapine) [package insert]. Miami, Fl: Noven Therapeutics, LLC.; Oct 2019.
5. Lybalvi (olanzapine/samidorphan) [package insert]. Waltham, MA: Alkermes, Inc.; May 2021.

TABLE 1. ANTIPSYCHOTIC MEDICATION DOSING LIMITS

Drug	Maximum Daily Dose* < 6yrs	Max Daily Dose* 6 To < 10yrs	Max Daily Dose* 10 To < 16yrs	Max Daily Dose* ≥ 16 To Adults
Aripiprazole (Abilify®, Abilify Discmelt® Abilify MyCite®,)	15mg	20mg	30mg	45mg
Aripiprazole (Abilify Maintena®)	Not approved	Not approved	Not approved	400mg per 28 days
Aripiprazole lauroxil (Aristada®)	Not approved	Not approved	Not approved	882mg/28 days or 1064mg/2 months
Aripiprazole lauroxil (Aristada Initio™)	Not approved	Not approved	Not approved	675 mg single dose
Asenapine (Saphris®)	Not approved	10mg	20mg	20mg
Asenapine (transdermal)(Secuado®)[5]	Not approved	Not approved	Not approved	7.6mg/24h
Brexpiprazole (Rexulti®)	Not approved	Not approved	Age ≥13yrs: 4 mg	4mg
Cariprazine (Vraylar®)	Not approved	Not approved	Not approved	6mg
Chlorpromazine (oral)	40mg	200mg	800mg	1500mg
Clozapine (Clozaril®, Fazaclo®, Versacloz®)	Not approved	300mg	600mg	900mg
Fluphenazine (oral)	Not approved	5mg	10mg	60mg
Fluphenazine HCL and Decanoate (injection)	Not approved	Not approved	Not approved	100mg
Haloperidol (Haldol®)	6mg or 0.15mg/kg/day	6mg	15mg	60mg
Haloperidol Decanoate (Haldol® Decanoate)	Not approved	Not approved	Not approved	500mg per 21 days
Iloperidone (Fanapt®)	Not approved	12mg	24mg	24mg
Loxapine (Loxitane®)	Not approved	30mg	60mg	250mg
Loxapine (Adasuve®)	Not approved	Not approved	Not approved	10mg
Lumateperone (Caplyta®)[6]	Not approved	Not approved	Not approved	42mg
Lurasidone (Latuda®)	Not approved	80mg	120mg	160mg
Molindone (Moban®)	Not approved	Not approved	Not approved	225mg
Olanzapine (Zyprexa®, Zyprexa Zydis®)	Not approved	12.5mg	20mg	40mg
Olanzapine pamoate (Zyprexa Relprevv®)	Not approved	Not approved	Not approved	300mg/14 days or 405mg/28 days
Olanzapine/Fluoxetine (Symbyax®)	Not approved	Not approved	12mg/50mg	18mg/75mg
Olanzapine/samidorphan (Lybalvi™)	Not approved	Not approved	Not approved	20mg/10mg (age ≥18y only)
Paliperidone (Invega®)	Not approved	6mg	12mg	12mg
Paliperidone palmitate (Invega Sustenna®)	Not approved	Not approved	Not approved	234mg per 21 days
Paliperidone palmitate (Invega Trinza®)	Not approved	Not approved	Not approved	819mg per 84 days
Paliperidone palmitate (Invega Hafyera®)	Not approved	Not approved	Not approved	1560mg per 6 months
Perphenazine	Not approved	12mg	22mg	64mg
Pimozide (Orap®)	Not approved	6mg or 0.2mg/kg/day	10mg or 0.2mg/kg/day	20mg
Quetiapine (Seroquel®, Seroquel XR®)	Not approved	400mg	800mg	1200mg
Risperidone (Perseris™)	Not approved	Not approved	Not approved	120 mg per 28 days
Risperidone (Risperdal®, Risperdal M-Tab®)	1.5mg	4mg	6mg	16mg
Risperidone (Risperdal Consta®)	Not approved	Not approved	Not approved	50mg per 14 days
Thioridazine	Not approved	Not approved	Not approved	800mg
Thiothixene	Not approved	Not approved	15mg	60mg
Trifluoperazine	Not approved	15mg	40mg	40mg
Ziprasidone (Geodon®)	Not approved	80mg	160mg	240mg

"Not Approved" means insufficient evidence available or pediatric dosing was reviewed, but not recommended.

* Daily dose unless specified