Applicable Drugs: Abilify Asimtufii (aripiprazole), Abilify Maintena (aripiprazole monohydrate), Aristada (aripiprazole lauroxil), Aristada Initio (aripiprazole lauroxil), Erzofri (paliperidone palmitate), Invega Hafyera (paliperidone palmitate), Invega Sustenna, (paliperidone palmitate), Invega Trinza (paliperidone palmitate), Risperdal Consta (risperidone), Rykindo (risperidone), Uzedy (risperidone), Weltruza (olanzapine), Zyprexa Relprevv (olanzapine pamoate)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/20/2024

Date Last Reviewed / Revised: 10/6/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through X are met)

I. Documented diagnosis of at least one of the following (A through C):
   A. Bipolar Disorder Type I (BD1)
   B. Schizoaffective disorder (SZA)
   C. Schizophrenia (SCZ)

II. Documentation that member meets at least one of the following criteria (A, B, **or** C):
   A. Member has history of non-adherence to oral antipsychotic therapy.
   B. LAI therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission.
   C. The requested medication is a continuation of therapy (claims history and/or provider administration records required).

III. Documentation that tolerability with an oral formulation of the requested LAI has been established (see Table 1 for additional information).

IV. Documentation that the individual will transition from oral or injectable medication to the requested LAI per manufacturer labeling, and that the requested dose and frequency do not exceed FDA-approved maximums (see Table 1).

V. Documentation confirming the product will be administered at the specific dispensing pharmacy by a health care provider (pharmacy name and location required).

VI. Minimum age requirement: 18 years old.

VII. Documentation that the member meets criteria A **or** B:

A. The requested LAI antipsychotic will be used as monotherapy for those medications and diagnoses that require it per FDA labeling. (Exception: short-term oral antipsychotic overlap bridging to LAI).

B. The requested long-acting injectable (LAI) antipsychotic will be used at the maximum FDA-approved labeled dose with an oral antipsychotic to augment treatment for persistent or refractory symptoms. Criteria 1, 2, **or** 3 must be met:

1. Documented failure of three or more monotherapy antipsychotic trials.
2. Inadequate control despite current treatment with clozapine.
3. Cross-titration of two agents, with a documented planned date for stopping one agent.

VIII. Treatment is prescribed by or in consultation with a psychiatrist or psychiatric provider.

IX. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

X. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Diagnosis of dementia-related psychosis.
- Coadministration with another long-acting injectable (LAI) atypical antipsychotic.

OTHER CRITERIA

Table 1. FDA Indications, initiation requirements, quantity limits

LONG-ACTING INJECTABLE ATYPICAL ANTIPSYCHOTICS
Aripiprazole

Abilify Asimtufii (aripiprazole)
• Indication(s):
  • BD-I (maintenance monotherapy), Age ≥ 18 years
  • SCZ, Age ≥ 18 years
• Initiation of therapy:
  • Establish oral tolerance in aripiprazole-naïve patients: Yes
  ▪ Aripiprazole x 14 days
  • Oral overlap required: Yes [exception-patient is established on Abilify Maintena (aripiprazole monohydrate)]
  ▪ 1-day initiation: One Abilify Asimtufii (aripiprazole) 960mg IM injection, one Abilify Maintena (aripiprazole monohydrate) 400 mg IM injection, and one dose of oral aripiprazole 20mg on Day 1

- 14-day initiation: One Abilify Asimtufii (aripiprazole) 960mg IM injection and continue oral aripiprazole (10-20 mg/day) or current oral antipsychotic (if known to tolerate aripiprazole) x 14 consecutive days
- Loading dose required: No
- Quantity limits:
  - 1 syringe (720 mg or 960 mg) per 2 months

Abilify Maintena (aripiprazole monohydrate)
- Indication(s):
  - BD-I (maintenance monotherapy), Age ≥ 18 years
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in aripiprazole-naïve patients: Yes
    - Aripiprazole x 14 days
  - Oral overlap required: Yes
    - 1-day initiation: Two Abilify Maintena (aripiprazole monohydrate) 400 mg IM injections in different sites, and one dose of oral aripiprazole 20mg on day 1
    - 14-day initiation: One Abilify Maintena (aripiprazole monohydrate) 400 mg IM injection and continue oral aripiprazole (10-20 mg/day) or current oral antipsychotic (if known to tolerate aripiprazole) x 14 consecutive days
  - Loading dose required: No
- Quantity limits:
  - 1 syringe or vial (300 mg or 400 mg) per month

Aristada Initio (aripiprazole lauroxil)
- Indication(s):
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in aripiprazole-naïve patients: Yes
    - Aripiprazole x 14 days
  - One Aristada Initio (aripiprazole lauroxil) 675mg IM loading dose with one 30 mg dose of oral aripiprazole on Day 1. The first dose of Aristada (aripiprazole lauroxil) IM injection (441 mg, 662 mg, 882 mg, or 1064 mg) may be administered up to 10 days after the loading dose of Aristada Initio (aripiprazole lauroxil).
- Quantity limits:
  - 1 syringe (675 mg) as a one-time dose

Aristada (aripiprazole lauroxil)
- Indication(s):
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in aripiprazole-naïve patients: Yes
    - Aripiprazole x 14 days
  - Initial treatment requires oral overlap **or** a loading dose:

- Oral overlap: One Aristada (aripiprazole lauroxil) IM injection (441 mg, 662 mg, 882 mg, or 1064 mg) along with oral aripiprazole (10-20 mg/day) x 21 consecutive days.
- Loading dose: One Aristada Initio (aripiprazole lauroxil) 675mg IM loading dose with one 30 mg dose of oral aripiprazole on Day 1. The first dose of Aristada (aripiprazole lauroxil) IM injection (441 mg, 662 mg, 882 mg, or 1064 mg) may be administered up to 10 days after the loading dose of Aristada Initio(aripiprazole lauroxil).

- Quantity limits:
  - 441 mg, 662 mg: 1 syringe per month
  - 882 mg: 1 syringe per month
  - 1,064 mg: 1 syringe per 2 months

Olanzapine

Weltruza (olanzapine)

- Indications:
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in olanzapine-naïve patients: Yes
    - Olanzapine
  - Oral overlap required: No
  - Loading dose required: No
- Quantity limits:
  - 1 syringe kit (318 mg, 425 mg, 531 mg) per month

Zyprexa Relprevv (olanzapine pamoate)

- Indications:
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in olanzapine-naïve patients: Yes
    - Olanzapine
  - Oral overlap required: No
  - Loading dose required: Yes

Target oral olanzapine dose	Zyprexa Relprevv (olanzapine pamoate) dosing for weeks 1-8
10 mg/day	210 mg IM q 2 weeks **or** 405 mg q 4 weeks
15-20 mg/day	300 mg IM q 2 weeks

- Considerations:
  - Risk Evaluation and Mitigation Strategies (REMS): Zyprexa Relprevv (olanzapine pamoate) Patient Care Program
    - Requires prescriber, healthcare facility, patient, and pharmacy enrollment.
    - Zyprexa Relprevv (olanzapine pamoate) may only be administered in certified health care facilities where the individual must be observed for at least 3 hours post-injection.

- Quantity limits:
  - 210 mg, 300 mg: 2 vials (convenience kits) per 4 weeks
  - 405 mg: 1 vial (convenience kit) per 4 weeks

Paliperidone

Erzofri (paliperidone palmitate)
- Indication(s):
  - SCZ, Age ≥ 18 years
  - SZA (monotherapy or as an adjunct to mood stabilizers or antidepressants), Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in paliperidone-naïve patients: Yes
    - Paliperidone or risperidone
  - Oral overlap required: No
  - Loading dose required: Yes
    - Day 1: 351 mg IM (234 mg for CrCL ≥ 50 mL/min to < 80 mL/min)
- Quantity limits:
  - New start:
    - Day 1: One syringe (351 mg or 234 mg) x 1 dose
  - Continuation of therapy: 1 syringe (39 mg, 78 mg, 117 mg, 156 mg, or 234 mg) per month

Invega Hafyera (paliperidone palmitate)
- Indication(s):
- SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Must be established on LAI paliperidone:
    - Invega Sustenna (paliperidone palmitate) ≥ 4 months (with the last 2 doses being 156 mg or 234 mg) **OR**
    - Invega Trinza (paliperidone palmitate) ≥ 3 months (at doses of 546 mg or 819 mg)
  - Oral overlap required: No
  - Loading dose required: No
- Quantity limits:
  - 1 syringe (1,092 mg or 1,560 mg) per 6 months

Invega Sustenna (paliperidone palmitate)
- Indication(s):
  - SCZ, Age ≥ 18 years
  - SZA (monotherapy or as an adjunct to mood stabilizers or antidepressants), Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in paliperidone-naïve patients: Yes
    - Paliperidone or risperidone
  - Oral overlap required: No

- Loading dose required: Yes
  - Day 1: 234 mg IM (156 mg for CrCL ≥ 50 mL/min to < 80 mL/min)
  - Day 8: 156 mg IM (117 mg for CrCL ≥ 50 mL/min to < 80 mL/min)
- Quantity limits:
  - New start:
    - Day 1: One syringe (234 mg or 156 mg) x 1 dose
    - Day 8: One syringe (156 mg or 117 mg) x 1 dose
  - Continuation of therapy: 1 syringe (39 mg, 78 mg, 117 mg, 156 mg, or 234 mg) per month

Invega Trinza (paliperidone palmitate)
- Indication(s):
  - SCZ, Age ≥ 18 years
- Initiation of therapy:
  - Must be established on LAI paliperidone:
    - Invega Sustenna (paliperidone palmitate) ≥ 4 months (last two doses of Invega Sustenna must be the same dosage strength)
  - Oral overlap required: No
  - Loading dose required: No
- Quantity limits:
  - 1 syringe (273 mg, 410 mg, 546 mg, 819 mg) per 3 months

Risperidone

Risperdal Consta (risperidone)
- Indication(s):
  - SCZ, Age ≥ 18 years
  - BD-I (monotherapy or adjunctive therapy to lithium or valproate), Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in risperidone-naïve patients: Yes
    - Risperidone
  - Oral overlap required: Yes
    - Risperidone or another antipsychotic x 21 days
  - Loading dose required: No
- Quantity limits:
  - 2 vial kits (25 mg) per 28 days

Rykindo(risperidone)
- Indication(s):
  - SCZ, Age ≥ 18 years
  - BD-I (monotherapy or adjunctive therapy to lithium or valproate), Age ≥ 18 years
- Initiation of therapy:
  - Establish oral tolerance in risperidone-naïve patients: Yes
    - Risperidone
  - Oral overlap required: Yes
    - Risperidone x 7 days [exception: patient is established on Risperdal Consta (risperidone)]

• Loading dose required: No • Quantity limits: • 2 single-dose kits (12.5 mg, 25 mg, 37.5 mg, or 50 mg) per 28 days
Uzedy (risperidone) • Indication(s): • SCZ, Age 18 years • BD-I (monotherapy or adjunctive therapy to lithium or valproate), Age ≥ 18 years • Initiation of therapy: • Establish oral tolerance in risperidone-naïve patients: Yes ▪ Risperidone • Oral overlap required: No • Loading dose required: No • Quantity limits: • SCZ ▪ 50 mg, 75 mg, 125 mg: 1 syringe per month ▪ 100 mg: 1 syringe per month or 2 months ▪ 150 mg, 200 mg, 250 mg: 1 syringe per 2 months • BD-I ▪ 50 mg, 75 mg, 100 mg: 1 syringe per month
BD-I: bipolar I disorder, LAI: long-acting injectable, SCA: schizoaffective disorder, SCZ: schizophrenia

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Requested quantities not exceeding limits listed in Table 1.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes documenting medication efficacy and adherence.

APPENDIX

N/A

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.