

Generic Name: N/A

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

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/20/2024

Date Last Reviewed / Revised: 5/20/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I-VI are met)

- I. Documented diagnosis of **one** of the following A through C:
 - A. Bipolar I (BD-I)
 - B. Schizoaffective disorder (SZA)
 - C. Schizophrenia (SCZ)
- II. Age \geq 18 years
- III. Documentation of A, B, C, or D:
 - A. History of non-adherence to oral antipsychotic therapy.
 - i. Oral antipsychotic adherence has been less than 80% in the past six months.
 - ii. Strategies to improve patient adherence have been unsuccessful (eg, pill boxes, smartphone reminders, simplified dosing regimens).
 - B. Therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission.
 - C. The patient is unable/refuses to take oral antipsychotic alternatives.
 - D. The requested medication is a continuation of therapy (pharmacy claims history and/or provider administration records required).
- IV. Medication is prescribed in accordance with FDA labeling and is supported by current clinical practice guidelines. Refer to Table 1 for medication-specific criteria.
- V. Documentation that the individual has established tolerance to an oral atypical antipsychotic medication if required per manufacturer labeling. Refer to Table 1 for tolerance requirements.

- VI. Documentation that the individual will be transitioned from oral or injectable medication to the requested long-acting injectable per manufacturer labeling. Refer to Table 1 for overlap requirements.
- VII. Treatment must be prescribed by or in consultation with a psychiatrist.
- VIII. Refer to the plan document for the list of preferred products. The requested agent must have documented treatment failure or contraindication to the preferred product(s) if the requested agent is not listed as a preferred product.

EXCLUSION CRITERIA

- Diagnosis of dementia-related psychosis.
- Renal impairment:
 - Invega Hafyera: Mild, moderate, or severe renal impairment (creatinine clearance (CrCL) < 90 mL/min)
 - Invega Sustenna and Invega Trinza: Moderate to severe renal impairment (CrCL < 50 mL/min)
- 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

- 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 (10-20 mg/day) or another antipsychotic x 14 days
 - Loading dose required: No
- Quantity limits:
 - 1 syringe (720 mg or 960 mg) per 2 months

Abilify Maintena

- 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
 - Aripiprazole (10-20 mg/day) or another antipsychotic x 14 days
- Loading dose required: No
- Quantity limits:
 - 1 syringe or vial (300 mg or 400 mg) per month

Aristada Initio

- Indication(s):
 - SCZ, Age ≥ 18 years
- Initiation of therapy:
 - Establish oral tolerance in aripiprazole-naïve patients: Yes
 - Aripiprazole x 14 days
 - Aristada Initio is given as a single loading dose with one 30mg dose of oral aripiprazole in conjunction with the first dose of Aristada injection
- Quantity limits:
 - 1 syringe (675 mg) as a one-time dose

Aristada

- 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: Aripiprazole (10-20 mg/day) x 21 days
 - Loading dose: Aristada Initio is given as a single loading dose with one dose of 30mg oral aripiprazole.
- Quantity limits:
 - 441 mg, 662 mg: 1 syringe per month
 - 882 mg: 1 syringe per month or 6 weeks
 - 1,064 mg: 1 syringe per 2 months

Olanzapine

Zyprexa Relprevv

- 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 dosing for weeks 1-8
10 mg/day	210 mg q 2 weeks or 405 mg q 4 weeks
15-20 mg/day	300 mg every 2 weeks

- Considerations:
 - Risk Evaluation and Mitigation Strategies (REMS): Zyprexa Relprevv Patient Care Program
 - Requires prescriber, healthcare facility, patient, and pharmacy enrollment.
 - Zyprexa Relprevv 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

Invega Hafyera

- Indication(s):
- SCZ, Age ≥ 18 years
- Initiation of therapy:
 - Must be established on LAI paliperidone:
 - Invega Sustenna ≥ 4 months (with the last 2 doses being 156 mg or 234 mg) **OR**
 - Invega Trinza ≥ 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

- 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

- Indication(s):
 - SCZ, Age ≥ 18 years
- Initiation of therapy:

- Must be established on LAI paliperidone:
 - Invega Sustenna \geq 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

Perseris

- Indication(s):
 - SCZ, 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:
 - 1 single-dose kit (90 mg or 120 mg) per month

Risperdal Consta

- Indication(s):
 - SCZ, Age \geq 18 years
 - BD-I (monotherapy or adjunctive therapy to lithium or valproate), Age \geq 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 (12.5 mg, 25 mg, 37.5 mg, or 50 mg) per 28 days

Risvan

- Indication(s):
 - SCZ, Age \geq 18 years
- Initiation of therapy:
 - Establish oral tolerance in risperidone-naïve patients: Yes
 - Risperidone
 - Oral overlap required: No
 - Loading dose required: No
- Quantity limits:
 - 1 single-dose kit (75 mg or 100 mg) per month

Rykindo

- Indication(s):
 - SCZ, Age \geq 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)
 - 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

- Indication(s):
 - SCZ, 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:
 - Uzedy 50 mg, 75 mg, 125 mg: 1 syringe per month
 - Uzedy 100 mg: 1 syringe per month or 2 months
 - Uzedy 150 mg, 200 mg, 250 mg: 1 syringe per 2 months

BD-I: bipolar I disorder, CrCL: creatinine clearance, 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:** 6 months.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes documenting that current medical necessity criteria are met, as well as 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.