Long-Acting Injectable (LAI) Antipsychotics

Generic Name: N/A

Therapeutic Class or Brand Name: Long-Acting Injectable (LAI) Antipsychotics

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), Uzedy (risperidone), Zyprexa Relprevv (olanzapine pamoate)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/20/2024

Date Last Reviewed / Revised: 2/14/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I-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 documented 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 be transitioned from oral or injectable medication to the requested long-acting injectable per manufacturer labeling, and that requested dose and frequency do not exceed FDA-approved maximums (see Table 1).

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

VI. Patient age is appropriate for requested agent (see Table 1).

VII. If requested agent is only indicated for use as monotherapy for the treatment of the diagnosis requested, must provide documentation that the drug will be used as monotherapy (the use of an oral formulation of the requested drug for bridging to LAI is acceptable).

A. Alternatively, the use of antipsychotic polypharmacy is acceptable with documentation satisfying ONE of the following (1, 2, or 3):

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. 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.
- Coadministration with another long-acting injectable (LAI) atypical antipsychotic.
- Contraindication to requested agent, if applicable.

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 (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 (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
    - 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 (aripiprazole lauroxil)
- 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 (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: 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 (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 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 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
- Exclusions:
  - Moderate to severe renal impairment (CrCL< 50 mL/min)

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
- Exclusions:
  - Moderate to severe renal impairment (CrCL< 50 mL/min)

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
- Exclusions:
  - Moderate to severe renal impairment (CrCL< 50 mL/min)

Risperidone

Perseris (risperidone)
- 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 (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 (12.5 mg, 25 mg, 37.5 mg, or 50 mg) per 28 days

Risvan (risperidone)
• 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 (75 mg or 100 mg) per month

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
• Initiation of therapy:
  • Establish oral tolerance in risperidone-naïve patients: Yes
  ▪ Risperidone
  • Oral overlap required: No
  • Loading dose required: No
• Quantity limits:
  • 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: 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:** 1 year.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes documenting medication efficacy and adherence.

Appendix

N/A

References

1. Abilify Asimtufii. Prescribing information. Otsuka Pharmaceutical Co, Ltd; 2023. Accessed October 13, 2024. https://otsuka-us.com/sites/g/files/qhldwo9566/files/media/static/Abilify-Asimtufii-PI.pdf
2. Abilify Maintena. Prescribing information. Otsuka America Pharmaceutical Inc; 2020. Accessed October 13, 2024. https://www.otsuka-us.com/sites/g/files/qhldwo9566/files/media/static/Abilify-M-PI.pdf
3. Aristada Initio. Prescribing information. Alkermes Inc; 2023. Accessed October 13, 2024. https://www.aristada.com/downloadables/ARISTADA-INITIO-PI.pdf
4. Aristada. Prescribing information. Alkermes Inc; 2023. Accessed October 13, 2024. https://www.aristada.com/downloadables/ARISTADA-PI.pdf
5. Zyprexa Relprevv. Prescribing information. CHEPLAPHARM; 2023. Accessed October 13, 2024. https://www.zyprexarelprevvprogram.com/PDF/CHEPLAPHARM%20Prescribing%20Information.pdf
6. Invega Hafyera. Prescribing information. Janssen Pharmaceuticals Inc; 2024. Accessed October 13, 2024. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+HAFYERA-pi.pdf
7. Invega Sustenna. Prescribing information. Janssen Pharmaceuticals Inc; 2024. Accessed October 13, 2024. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+SUSTENNA-pi.pdf
8. Invega Trinza. Prescribing information. Janssen Pharmaceuticals Inc; 2024. Accessed October 13, 2024. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVEGA+TRINZA-pi.pdf
9. Perseris. Prescribing information. Invidior Inc; 2022. Accessed October 13, 2024. https://www.perserishcp.com/prescribing-information.pdf
10. Risperdal Consta. Prescribing information. Janssen Pharmaceuticals Inc; 2021. Accessed October 13, 2024. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RISPERDAL+CONSTA-pi.pdf
11. Risvan. Prescribing information. Laboratorios Farmacéuticos Rovi, S.A.; 2024. Accessed October 14, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214835s000lbl.pdf

12. Rykindo. Prescribing information. Shandong Luye Pharmaceutical Co, Ltd; 2023. Accessed October 13, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212849s000lbl.pdf
13. Uzedy. Prescribing information. Teva Neuroscience, Inc; 2024. Accessed October 13, 2024. https://www.uzedy.com/globalassets/uzedy/prescribing-information.pdf
14. *The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia*. Third edition. American Psychiatric Association; 2021.
15. Goodwin GM; Consensus Group of the British Association for Psychopharmacology. Evidence-based guidelines for treating bipolar disorder: revised second edition--recommendations from the British Association for Psychopharmacology. *J Psychopharmacol*. 2016; 30(6): 495-553. doi:10.1177/0269881116636545.