Effective Date: 01/01/2024
Last Approval/Version: 01/2024
Next Review Due By: 01/2025
Policy Number: C27179-A

Long-Acting Injectable Antipsychotic Agents, IL Medicaid Only

PRODUCTS AFFECTED

Abilify Asimtufii (aripiprazole), Abilify Maintena (aripiprazole), Aristada (aripiprazole), Aristada Initio (aripiprazole), Invega Hafyera (paliperidone), Invega Sustenna (paliperidone), Invega Trinza (paliperidone), Perseris (risperidone), Uzedy (risperidone), Risperdal Consta, Zyprexa Relprevv

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:
Schizophrenia, Bipolar I Disorder

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.

FOR INITIAL REQUESTS:
1. Member must be 18 years of age or older.
2. Member must have a diagnosis of bipolar I disorder.
   OR
3. Member must have a diagnosis of schizophrenia.
   AND
4. For Invega Sustenna: Provider attests to tolerability established with risperidone or oral paliperidone.

OR

5. For Invega Trinza: Provider attests that member has been treated with Invega Sustenna one time per month for at least 4 months.
   OR
6. For Invega Hafyera: Provider attests that member has been adequately treated with Invega Sustenna or Invega Trinza, per label.
   OR
7. Provider attests (or clinical reviewer has found) that member has established tolerability for the oral formulation of the requested drug.
   AND
8. For Non-Preferred/Non-Formulary Long-Acting Injectable Antipsychotics:
   Documentation that member has had a trial and failure of TWO preferred long-acting injectable antipsychotic drugs OR member has an allergy, contraindication or history of intolerability to the preferred drugs.

CONTINUATION OF THERAPY (ALL MEDICATIONS):
Documentation that member meets initial criteria.

DURATION OF APPROVAL:
Initial and Continuation: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older
* Safety and efficacy of Aristada and Aristada Initio have not established in geriatric adults older than 65 years of age.

QUANTITY:

Medication Name	Quantity Limit
Abilify Asimtufii	960 mg IM once every 2 months
Abilify Maintena	400 mg IM once every 4 weeks
Aristada	882 mg IM once every 4 weeks or 1,064 mg IM every 2 months
Aristada Initio	675 mg IM as a single dose up to 10 days after Aristada injection
Invega Hafyera	1,560 mg IM once every 6 months
Invega Sustenna	234 mg IM once every 4 weeks
Invega Trinza	819 mg IM once every 3 months
Perseris	120 mg SC once every 4 weeks
Uzedy	125 mg SC once every 4 weeks or 250 mg SC once every 2 months
Risperdal Consta	50 mg IM once every 2 weeks
Zyprexa Relprevv	300 mg IM once every 2 weeks or 405 mg IM once every 4 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intramuscular: Abilify Asimtufii, Abilify Maintena, Aristada/Aristada Initio, Invega Hafyera, Invega Sustenna, Invega Trinza, Risperdal Consta, Zyprexa Relprevv. Subcutaneous: Perseris, Uzedy.

DRUG CLASS:
Atypical antipsychotic, benzisoxazole

FDA-APPROVED USES:
Indicated for the treatment of schizoaffective disorder as monotherapy or as an adjunct to mood stabilizers and/or antidepressants AND for the maintenance treatment of bipolar I disorder.

COMPENDIAL APPROVED OFF-LABELED USES:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
NONE

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Known hypersensitivity to requested drug or active ingredients.
All other uses of atypical antipsychotics are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

OTHER SPECIAL CONSIDERATIONS:
US Boxed Warning:

- Increased mortality in elderly patients with dementia-related psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- The extended-release intramuscular injection formulation (Zyprexa Relprevv) carries a specific boxed warning related to post-injection delirium/sedation syndrome (PDSS), which is the result of the drug entering the bloodstream too quickly and the development of sedation, delirium, and/or coma from significantly elevated olanzapine plasma concentrations.

BILLING INFORMATION

AVAILABLE DOSAGE FORMS:
Abilify Asimtufii PRSY 720MG/2.4ML
Abilify Asimtufii PRSY 960MG/3.2ML
Abilify Maintena PRSY 300MG
Abilify Maintena PRSY 400MG
Abilify Maintena SRER 300MG
Abilify Maintena SRER 400MG
Aristada PRSY 441MG/1.6ML
Aristada PRSY 662MG/2.4ML
Aristada PRSY 882MG/3.2ML
Aristada PRSY 1064MG/3.9ML
Aristada Initio PRSY 675MG/2.4ML
Invega Hafyera SUSY 1092MG/3.5ML
Invega Hafyera SUSY 1560MG/5ML
Invega Sustenna SUSY 39MG/0.25ML
Invega Sustenna SUSY 78MG/0.5ML
Invega Sustenna SUSY 117MG/0.75ML
Invega Sustenna SUSY 156MG/ML
Invega Sustenna SUSY 234MG/1.5ML
Invega Trinza SUSY 273MG/0.88ML
Invega Trinza SUSY 410MG/1.32ML

Invega Trinza SUSY 546MG/1.75ML
Invega Trinza SUSY 819MG/2.63ML
Perseris PRSY 90MG
Perseris PRSY 120MG
Uzedy SUSY 50MG/0.14ML
Uzedy SUSY 75MG/0.21ML
Uzedy SUSY 100MG/0.28ML
Uzedy SUSY 125MG/0.35ML
Uzedy SUSY 150MG/0.42ML
Uzedy SUSY 200MG/0.56ML
Uzedy SUSY 250MG/0.7ML
RisperDAL Consta SRER 12.5MG
RisperDAL Consta SRER 25MG
RisperDAL Consta SRER 37.5MG
RisperDAL Consta SRER 50MG
ZyPREXA Relprevv SUSR 210MG
ZyPREXA Relprevv SUSR 300MG
ZyPREXA Relprevv SUSR 405MG

REFERENCES

1. Illinois Medicaid Preferred Drug List, Effective January 2024
2. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 01.01.2024
3. **Abilify Asimtufii** (aripiprazole) [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd.; August 2023.
4. **Abilify Maintena** (aripiprazole) [package insert] Tokyo, Japan: Otsuka Pharmaceutical Co., Ltd.; June 2020.
5. **Aristada** (aripiprazole lauroxil) [package insert]. Waltham, MA: Alkermes, Inc.; December 2023.
6. **Aristada Initio** (aripiprazole lauroxil) [package insert]. Waltham, MA: Alkermes, Inc.; December 2023.
7. **Invega Hafyera** (paliperidone palmitate) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.
8. **Invega Sustenna** (paliperidone palmitate) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2022.
9. **Invega Trinza** (paliperidone palmitate) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.
10. **Perseris** (risperidone) [package insert]. Greenville, NC: Patheon Manufacturing Services; December 2022.
11. **Uzedy** (risperidone) [package insert]. Parsippany, NJ: Teva Neuroscience, Inc.; May 2023.
12. **Risperdal Consta** (risperidone) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021.
13. **Zyprexa Relprevv** (olanzapine) [package insert]. Montgomery, AL: H2-Pharma, LLC; October 2023.
14. Clinical Pharmacology [Internet]. Elsevier. c2023- [cited December 2023]. Available at: http://www.clinicalpharmacology.com

SUMMARY OF REVIEW/REVISIONS	DATE
New criteria creation	01/2024