Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 106.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Injectable Antipsychotic Medications

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Injectable Antipsychotic Medications

II. Purpose/Objective:
To provide a policy of coverage regarding Injectable Antipsychotic Medications

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Injectable Antipsychotic Medications

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

The following Injectable Antipsychotic Medications (Invega Trinza, Invega Sustenna, Invega Hafyera, Aristada, Aristada Initio, Abilify Asimtufii, Abilify Maintena, Zyprexa Relprevv, Risperdal Consta, Rykindo, Perseris, or Uzedy) will be considered medically necessary for the Commercial, Exchange and CHIP lines of business when the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a history of poor adherence to oral medications and documentation that education to improve adherence has been attempted **AND**
- Medical record documentation of use for an FDA approved indication.
    - Abilify Asimtufii – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Aristada – Schizophrenia
    - Aristada Initio – Initiation of Aristada (in combination with oral aripiprazole) to treat schizophrenia
    - Invega Hafyera - Schizophrenia
    - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
    - Invega Trinza – Schizophrenia
    - Perseris - Schizophrenia
    - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Rykindo – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Uzedy - Schizophrenia
    - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.
- In addition: The following criteria should apply to Invega Hafyera:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months OR Invega Trinza for at least 3 months.

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

LIMITATIONS:
The following quantity limits should apply (please enter claims payment note, when entering authorization)

- Abilify Asimtufii - One syringe per 56 days (960 mg/3.2 mL, 720 mg/2.4 mL)
- Abilify Maintena – One syringe or vial per 28 days
- Aristada – One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Aristada Initio – Enter claims payment note as follows:
    - Aristada Initio – Rx Count of 1, quantity limit of 2.4mL (one syringe) per 28 days
    - Aristada – Open-ended authorization with quantity limit: One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Invega Hafyera – One syringe per 168 days (6 months)
- Invega Sustenna – two syringes per 1 week, then one syringe per 28 days thereafter

  Enter claims payment note as follows to account for loading dose in the first week:
  - Rx Count of 1 approved by GPI-14 for 234 mg, quantity limit 1
  - Rx Count of 1 approved by GPI-14 for 156 mg, quantity limit 1

- Open-ended authorization for quantity limit 1 syringe per month, request to be approved by GPI-14 for the prescribed strength.

- Invega Trinza – One syringe per 84 days (3 months)
- Perseris - One syringe kit per 28 days
- Risperdal Consta – Two vials per 28 days
- Rykindo – One syringe per 14 days
- Uzedy - One syringe per 28 days (50 mg/0.14 mL, 75 mg/0.21mL, 100 mg/0.28mL, 125 mg/0.35mL), one syringe per 56 days (150 mg/0.42 mL, 200 mg/0.56 mL, 250 mg/0.7 mL)
- Zyprexa Relprevv – Two vials per 28 days

Note: PA is not required for inpatient or ER use for any of these medications.

Note: Only members with documented adherence issues will be eligible for medications delivered via injection

Note: The FDA approved dosing of induction into treatment with Aristada includes oral aripiprazole, Aristada Initio and Aristada (outlined below) and it is appropriate for the member to receive all the mentioned products over the course of one month for treatment initiation.

- One 30mg dose of oral aripiprazole (given on Day 1)
- One 675mg dose of Aristada Initio (given on Day 1)
- One (first) dose of Aristada (441mg, 662mg, 882mg, or 1064mg) (given on Day 1 or up to 10 days after the dose of Aristada Initio)

The following Injectable Antipsychotic Medications (Invega Trinza, Invega Sustenna, Invega Hafyera, Aristada, Aristada Initio, Abilify Asimtufii, Abilify Maintena, Zyprexa Relprevv, Risperdal Consta, Perseris, or Uzedy) will be considered medically necessary for the Medicare line of business when the following criteria are met:

- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of use for an FDA approved indication.
    - Abilify Asimtufii – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Abilify Maintena – Schizophrenia or maintenance monotherapy treatment of Bipolar I Disorder
    - Aristada – Schizophrenia
    - Aristada Initio – Initiation of Aristada (in combination with oral aripiprazole) to treat schizophrenia
    - Invega Hafyera - Schizophrenia
    - Invega Sustenna – Schizophrenia or Schizoaffective disorders as monotherapy and as an adjunct to mood stabilizers or antidepressants
    - Invega Trinza – Schizophrenia
    - Perseris- Schizophrenia
    - Risperdal Consta – Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Rykindo– Schizophrenia or Bipolar I Disorder as monotherapy or as adjunctive therapy to lithium or valproate
    - Uzedy - Schizophrenia
    - Zyprexa Relprevv – Schizophrenia
- In addition: The following criteria should apply to Invega Trinza:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months.
- In addition: The following criteria should apply to Invega Hafyera:
    - Medical record documentation that the patient has been adequately treated with Invega Sustenna for at least 4 months OR Invega Trinza for at least 3 months.

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

LIMITATIONS:

The following quantity limits should apply (please enter claims payment note, when entering authorization)

- Abilify Asimtufii – One syringe per 56 days (960 mg/3.2 mL, 720 mg/2.4 mL)
- Abilify Maintena – One syringe or vial per 28 days
- Aristada – One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Aristada Initio – Enter claims payment note as follows:
    - Aristada Initio – Rx Count of 1, quantity limit of 2.4mL (one syringe) per 28 days
    - Aristada – Open-ended authorization with quantity limit: One syringe per 28 days (441mg/1.6ml, 662mg/2.4ml, 882mg/3.2ml strength), one syringe per 56 days (1064mg/3.9ml strength)
- Invega Hafyera – One syringe per 168 days (6 months)
- Invega Sustenna – two syringes per 1 week, then one syringe per 28 days thereafter

  Enter claims payment note as follows to account for loading dose in the first week:

  - Rx Count of 1 approved by GPI-14 for 234 mg, quantity limit 1
  - Rx Count of 1 approved by GPI-14 for 156 mg, quantity limit 1
  - Open-ended authorization for quantity limit 1 syringe per month, request to be approved by GPI-14 for the prescribed strength.
- Invega Trinza – One syringe per 84 days (3 months)
- Perseris - One syringe kit per 28 days
- Risperdal Consta – Two vials per 28 days
- Rykindo – One syringe per 14 days
- Uzedy - One syringe per 28 days (50 mg/0.14 mL, 75 mg/0.21mL, 100 mg/0.28mL, 125 mg/0.35mL), one syringe per 56 days (150 mg/0.42 mL, 200 mg/0.56 mL, 250 mg/0.7 mL)

- Zyprexa Relprevv – Two vials per 28 days

Note: PA is not required for inpatient or ER use for any of these medications.

Note: Only members with documented adherence issues will be eligible for medications delivered via injection

Note: The FDA approved dosing of induction into treatment with Aristada includes oral aripiprazole, Aristada Initio and Aristada (outlined below) and it is appropriate for the member to receive all the mentioned products over the course of one month for treatment initiation.

- One 30mg dose of oral aripiprazole (given on Day 1)
- One 675mg dose of Aristada Initio (given on Day 1)
- One (first) dose of Aristada (441mg, 662mg, 882mg, or 1064mg) (given on Day 1 or up to 10 days after the dose of Aristada Initio)

AUTHORIZATION DURATION:
For Aristada Initio: Approval will be for a one-time fill/visit (authorization duration of 1 month) of Aristada Initio AND a lifetime authorization of Aristada will also be entered.

All other approvals will be made for a lifetime authorization of the specific approved injectable.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Invega Trinza extended-release injectable suspension [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; August 2021.
2. Invega Sustenna extended-release injectable suspension [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; July 2022.
3. Invega Hafyera [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; August 2021.
4. Aristada [prescribing information]. Waltham, MA: Alkermes Inc; March 2021.
5. Aristada Initio [prescribing information]. Waltham, MA: Alkermes Inc; March 2021.
6. Abilify Asimtufii [prescribing information]. Deerfield, IL: Otsuka America Pharmaceutical Inc; April 2023.
7. Abilify Maintena [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; June 2020.
8. Zyprexa Relprevv [prescribing information]. Indianapolis, IN: Lilly USA LLC; November 2021.
9. Risperdal Consta [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; February 2021.
10. Perseris [prescribing information]. North Chesterfield, VA: Indivior Inc; December 2022.
11. Uzedy [prescribing information]. Parsippany, NJ: Teva Neuroscience Inc; May 2023.
12. Rykindo [prescribing information]. Yantai, Shandong, 264670: Shandong Luye Pharmaceutical Co. Ltd.; Jan 2023

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 04/13

Revised: 7/13, 08/14, 03/24/15 (auth duration), 09/15/15 (Invega Trinza added), 1/19/16 (updated criteria), 7/19/16 (Invega QL updated), 7/18/17 (aristada QL updated), 9/19/17 (Abilify-bipolar), 9/27/18 (revised grandfather language), 11/20/18 (aristada initio), 3/19/19 (perseris), 12/28/21 (Invega Hafyera), 12/20/22 (LOB carve out), 7/18/23 (Medicaid business segment, Abilify Asimtufii, Uzedy), 12/31/23 (references added), 3/19/24 (Rykindo), 3/17/25 (LOB table, taglines)

Reviewed: 08/14, 8/30/18, 2/1/20, 1/19/21

MA UM Committee approval: 12/31/23, 5/22/24, 4/29/25