Clinical Policy: Aripiprazole Long-Acting Injections (Abilify Maintena, Abilify Asimtufii, Aristada, Aristada Initio)

Reference Number: CP.PHAR.290
Effective Date: 12.01.16
Last Review Date: 08.26
Line of Business: Commericial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Aripiprazole monohydrate (Abilify Maintena®, Abilify Asimtufii®) and aripiprazole lauroxil (Aristada®, Aristada Initio®) are atypical antipsychotics.

FDA Approved Indication(s)

Abilify Maintena and Abilify Asimtufii are indicated:

- For the treatment of schizophrenia in adults
- For maintenance monotherapy treatment of bipolar I disorder in adults

Aristada is indicated:

- For the treatment of schizophrenia in adults

Aristada Initio, in combination with oral aripiprazole, is indicated:

- For the initiation of Aristada when used for the treatment of schizophrenia in adults

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Abilify Maintena, Abilify Asimtufii, Aristada, and Aristada Initio are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Prescribed by or in consultation with a psychiatrist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*) and has established tolerability to oral aripiprazole;
   b. Therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission;
5. One of the following (a, b, c, or d):
   a. Abilify Maintena: Dose does not exceed one of the following (i or ii):

i. 800 mg one-time dose (*used in conjunction with an oral one-time 20 mg dose of aripiprazole*), followed by 400 mg per month;
ii. 400 mg per month;

b. Abilify Asimtufii: Dose does not exceed 960 mg per 2 months;
c. Aristada: Dose does not exceed one of the following (i, ii, or iii):
i. 882 mg per month;
ii. 882 mg per 6 weeks;
iii. Dose does not exceed 1,064 mg per 2 months;
d. Aristada Initio: Dose does not exceed 675 mg one-time dose *(used in conjunction with Aristada and an oral one-time 30 mg dose of aripiprazole)*.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Bipolar Disorder (must meet all)**:**
1. Diagnosis of bipolar disorder;
2. Request is for Abilify Maintena or Abilify Asimtufii;
3. Prescribed by or in consultation with a psychiatrist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
a. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*) and has established tolerability to oral aripiprazole;
b. Therapy was initiated in an inpatient setting during a recent (within 60 days) hospital admission;
6. One of the following (a or b):
a. Abilify Maintena: Dose does not exceed one of the following (i or ii):
i. 800 mg one-time dose (*used in conjunction with an oral one-time 20 mg dose of aripiprazole*), followed by 400 mg per month;
ii. 400 mg per month;
b. Abilify Asimtufii: Dose does not exceed 960 mg per 2 months.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
a. For drugs on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports one of the following (a or b):
   a. Member is currently receiving Abilify Maintena, Abilify Asimtufii, or Aristada for bipolar disorder or schizophrenia and has received this medication for at least 30 days;
   b. Therapy was initiated in an inpatient setting for a covered indication during a recent (within 60 days) hospital admission;
2. Member is responding positively to therapy;
3. If request is for a dose increase, one of the following (a, b, or c):
   a. Abilify Maintena: New dose does not exceed 400 mg per month;
   b. Abilify Asimtufii: New dose does not exceed 960 mg per 2 months;
   c. Aristada, New dose does not exceed one of the following (i, ii, or iii):
      i. 882 mg per month;
      ii. 882 mg per 6 weeks;
      iii. 1,064 mg per 2 months.

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace/ICHRA and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace/ICHRA and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace/ICHRA and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid and HIM.PA.154 for health insurance marketplace/ICHRA, or evidence of coverage documents;

B. Dementia-related psychosis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	Bipolar Disorder and Schizophrenia Adults: 10-15 mg PO QD	30 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed warnings

- Contraindication(s): known hypersensitivity to aripiprazole
- Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis

Appendix D: Examples of Oral Antipsychotics – Generic (Brand)

Typical/First Generation Antipsychotics†	Atypical/Second Generation Antipsychotics
• Chlorpromazine (Thorazine®) • Fluphenazine (Prolixin®) • Haloperidol (Haldol®) • Loxapine (Loxitane®) • Perphenazine (Trilafon®) • Pimozide (Orap®) • Thioridazine (Mellaril®) • Thiothixene (Navane®) • Trifluoperazine (Stelazine®)	• Aripiprazole (Abilify®)* • Asenapine maleate (Saphris®) • Brexpiprazole (Rexulti®) • Cariprazine (Vraylar®) • Clozapine (Clozaril®) • Iloperidone (Fanapt®) • Lumateperone (Caplyta®) • Lurasidone (Latuda®) • Olanzapine (Zyprexa®)* • Olanzapine/fluoxetine (Symbyax®) • Paliperidone (Invega®)* • Quetiapine (Seroquel®) • Risperidone (Risperdal®)* • Ziprasidone (Geodon®)

†Most typical/first generation antipsychotics are available only as generics in the U.S.
**Long-acting injectable formulation available*

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Aripiprazole monohydrate (Abilify Maintena)	Schizophrenia, bipolar I disorder	The recommended starting and maintenance dose is 400 mg IM monthly (no sooner than 26 days after the previous injection). Dose can be reduced to 300 mg in patients with adverse reactions. There are two ways to initiate treatment with Abilify Maintena: 1. 1-day initiation: Administer two separate 400 mg IM injections (total dose of 800 mg IM) and a single oral dose of aripiprazole 20 mg 2. 14-day initiation: In conjunction with first Abilify Maintena 400 mg dose, take 14 consecutive days of concurrent oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic • Used in combination with oral aripiprazole for the first 14 consecutive days. • Known CYP2D6 poor metabolizers: Recommended starting and maintenance dose is 300 mg IM monthly as a single injection.	400 mg/month
Aripiprazole monohydrate (Abilify Asimtufii)	Schizophrenia, bipolar I disorder	The recommended dose is 960 mg IM once every 2 months (56 days after the previous injection). Dose can be reduced to 720 mg in patients with adverse reactions. There are two ways to initiate treatment with Abilify Asimtufii in patients receiving oral antipsychotics: 1. 1-day initiation: Administer one IM injection of Abilify Asimtufii 960 mg, one IM injection of Abilify Maintena 400 mg and a single oral dose of aripiprazole 20 mg 2. 14-day initiation: In conjunction with first Abilify Asimtufii 960 mg dose, take 14 consecutive days of	960 mg/2 month

Drug Name	Indication	Dosing Regimen	Maximum Dose
		concurrent oral aripiprazole (10 mg or 20 mg) or current oral antipsychotic • Patients receiving Abilify Maintena: Administer Abilify Asimtufii 960 mg IM (once every 2 months as a single injection) in place of the next scheduled injection of the Abilify Maintena. • Known CYP2D6 poor metabolizers: Recommended dose is 720 mg IM once every 2 months as a single injection.	
Aripiprazole lauroxil (Aristada)	Schizophrenia	*Initiation Method 1:* Administer one IM injection of Aristada Initio 675 mg (deltoid or gluteal muscle) and one dose of oral aripiprazole 30mg in conjunction with the first Aristada injection. • First Aristada injection may be started on same day or up to 10 days after administration of Aristada Initio • Avoid injection of both Aristada and Aristada Initio into the same deltoid or gluteal muscle. *Initiation Method 2:* Used in combination with oral aripiprazole for the first 21 consecutive days. Depending on individual patient's needs, treatment can be initiated at a dose of 441 mg, 662 mg, or 882 mg IM administered monthly; 882 mg administered every 6 weeks; or 1064 mg administered every 2 months. Dose adjustments are required for 1) known CYP2D6 poor metabolizers and 2) for patients taking CYP3A4 inhibitors, CYP2D6 inhibitors, or CYP3A4 inducers for more than 2 weeks.	882 mg/month

Drug Name	Indication	Dosing Regimen	Maximum Dose
Aripiprazole lauroxil (Aristada Initio)	Schizophrenia *(therapy initiation only)*	Single dose of 675 mg IM injection, in combination with a single dose of 30 mg oral aripiprazole, to initiate Aristada treatment or to re-initiate Aristada treatment. Aristada may be started at the same time or within 10 days of Aristada Initio/oral aripiprazole.	675 mg once

VI. Product Availability

Drug Name	Availability
Aripiprazole monohydrate (Abilify Maintena)	Extended-release powder for suspension for injection (single-dose pre-filled dual chamber syringes and single-dose vials): 300 mg and 400 mg
Aripiprazole monohydrate (Abilify Asimtufii)	Extended-release injectable suspension (single-dose pre-filled syringes): 720 mg/2.4 mL, 960 mg/3.2 mL
Aripiprazole lauroxil (Aristada)	Extended-release injectable suspension (single-use pre-filled syringes): 441 mg/1.6 mL, 662 mg/2.4 mL, 882 mg/3.2 mL or 1,064 mg/3.9 mL
Aripiprazole lauroxil (Aristada Initio)	Extended-release injectable suspension (single-use pre-filled syringe): 675 mg/2.4 mL

VII. References

1. Abilify Maintena Prescribing Information. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2026. Available at: https://www.abilifymaintenahcp.com/. Accessed April 7, 2026.
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3. Aristada Initio Prescribing Information. Waltham, MA: Alkermes, Inc.; January 2025. Available at: https://www.aristada.com/. Accessed April 7, 2026.
4. Abilify Asimtufii Prescribing Information. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2025. Available at: https://www.abilifyasimtufiihcp.com/. Accessed April 7, 2026.
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6. Keepers G, Fochtmann L, Anzia J, et al. American Psychiatric Association practice guideline for the treatment of patients with schizophrenia, third edition (2020). Available at: https://psychiatryonline.org/doi/10.1176/appi.books.9780890424841. Accessed May 28, 2026
7. McDonagh MS, Dana T, Selph S, Devine EB, et al. Treatments for schizophrenia in adults: A systematic review. Comparative Effectiveness Review No. 198. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 17(18)-EHC031-EF. Rockville, MD: Agency for Healthcare Research and Quality; October 2017.

8. Hirschfield RMA, Bowden CL, Gitlin MJ, et al. American Psychiatric Association practice guideline for the treatment of patients with bipolar disorder, second edition (2010). Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf . Accessed May 28, 2026.
9. Butler M, Urosevic S, Desai P, et al. Treatment for bipolar disorder in adults: A systematic review. Comparative Effectiveness Review No. 208. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I.) AHRQ Publication No. 18-EHC012-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2018.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0401	Injection, aripiprazole (abilify maintena), 1 mg
J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg
J1944	Injection, aripiprazole lauroxil, (aristada), 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.20.22	
3Q 2023 annual review: no significant changes; template changes applied to continued therapy section; references reviewed and updated. RT4: Added newly approved formulation Abilify Asimtufii to the policy.	04.11.23	08.23
Added HCPCS code [J0402]	10.26.23	
Revised HCPCS code [J0401] description.	06.03.24	
3Q 2024 annual review: no significant changes; added Commercial line of business; references reviewed and updated.	05.09.24	08.24
3Q 2025 annual review: for Abilify Maintena added criterion option for 800 mg once-time dose followed by 400 mg per month for new dosing regimen for 1-day initiation regimen per updated PI; updated Section V for Abilify Maintena and Abilify Asimtufii per PI; references reviewed and updated.	04.24.25	08.25
Clarified intent of the criterion regarding maximum dose with revision from “any” of the following to “one” of the following.	10.02.25	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2026 annual review: no significant changes; added ICHRA line of business; revised initial approval duration from 6 months to 12 months for chronic disease maintenance; references reviewed and updated.	04.07.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.