

Clinical Policy Title:	aripiprazole orally disintegrating tablet
Policy Number:	RxA.338
Drug(s) Applied:	Abilify Discmelt®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All Line of Business

Background

Aripiprazole orally disintegrating tablet (ODT) is an atypical antipsychotic. Aripiprazole ODT is indicated:

- For the treatment of schizophrenia
- For the acute treatment of manic and mixed episodes associated with bipolar I disorder
- For the adjunctive treatment of major depressive disorder
- For the treatment of irritability associated with autistic disorder
- For the treatment of Tourette’s disorder

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
aripiprazole ODT	Schizophrenia	Adults: 10 to 15 mg orally once daily Adolescents: initial: 2 mg once daily; target: 10 mg once daily	30 mg/day
	Bipolar mania	Adults, as monotherapy: 15 mg once daily Adults, as adjunct to lithium or valproate: 10 to 15 mg once daily	30 mg/day
		Pediatric, as monotherapy or as an adjunct to lithium or valproate: initial: 2 mg once daily; target: 10 mg once daily	
	Major depressive Disorder	Adults, as adjunct to antidepressants: initial: 2 to 5 mg once daily; target: 5 to 10 mg once daily	15 mg/day
	Irritability associated with autistic disorder	Pediatric: initial: 2 mg once daily; target: 5 to 10 mg once daily	15 mg/day
	Tourette’s disorder	Weight less than 50 kg: initial: 2 mg once daily; target: 5 mg once daily	Weight less than 50 kg: 10 mg/day
Weight 50 kg or greater: initial: 2 mg once daily; target: 10 mg once daily		Weight 50 kg or greater: 20 mg/day	

****Known CYP2D6 poor metabolizers: half of the usual dose**

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Dosage Forms

- Orally disintegrating tablets: 10 mg, 15 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Schizophrenia (must meet all):

- Diagnosis of one of the following (a, b, c, d, or e):
 - Schizophrenia;
 - Bipolar disorder;
 - Major depressive disorder;
 - Autistic disorder;
 - Tourette's disorder.
- Member meets one of the following (a, b, c, d, or e):
 - Schizophrenia: Age 13 years of age or older;
 - Bipolar disorder: Age 10 years of age or older;
 - Major depressive disorder: Age 18 years of age or older;
 - Autistic disorder: Age between 6 and 18 years;
 - Tourette's disorder: Age between 6 and 17 years.
- Medical justification supports inability to use generic aripiprazole tablet and/or oral solution.
- For major depressive disorder, aripiprazole ODT will be used concurrently with an antidepressant.
- Dose does not exceed:
 - Schizophrenia, bipolar disorder: 30 mg (2 tablets) per day;
 - Major depressive disorder, autistic disorder: 15 mg (1 tablet) per day;
 - Tourette's syndrome (i or ii):
 - Weight less than 50 kg: 10 mg (1 tablet) per day;
 - Weight 50 kg or greater: 20 mg (2 tablets) per day.

Approval duration:

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

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

- Member meets one of the following (a or b):
 - Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
 - Documentation supports that member is currently receiving aripiprazole ODT for bipolar disorder or schizophrenia and has received this medication for at least 30 days.
- Member is responding positively to therapy.
- If request is for a dose increase, new dose does not exceed:
 - Schizophrenia, bipolar disorder: 30 mg (2 tablets) per day;
 - Major depressive disorder, autistic disorder: 15 mg (1 tablet) per day;
 - Tourette's syndrome (i or ii):
 - Weight less than 50 kg: 10 mg (1 tablet) per day;
 - Weight 50 kg or greater: 20 mg (2 tablets) per day.

Approval duration:

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

ODT: orally disintegrating tablet

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®) tablet or oral solution	Bipolar Disorder and Schizophrenia Adults: 10 to 15 mg orally once daily	Bipolar Disorder and Schizophrenia: 30 mg/day
	Major Depressive Disorder, Autistic Disorder, and Tourette's Disorder 5 to 10 mg orally once daily	Major Depressive Disorder, Autistic Disorder: 15 mg/day
		Tourette's Disorder: 20 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.

**Off-label*

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Known hypersensitivity to aripiprazole
- Boxed warning(s):
 - Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.

References

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 8. Murphy TK, Lewin AB, Storch EA, Stock S, and the American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and treatment of children and adolescents with tic disorders. *J Am Acad Child Adolesc Psychiatry*. 2013; 52(12): 1341-1359.
 9. Volkmar F, Siegel M, Woodbury-Smith M, et al. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry* 2014; 53: 237.
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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy updated. <ol style="list-style-type: none"> 1. Formatting updated. 2. References updated. 3. Lines of business updated. 4. Continued therapy criteria was rephrased to “Currently receiving medication that has been authorized by RxAdvance...”. 	06/15/2020	09/14/2020