Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Aristada Initio (aripiprazole lauroxil)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Indiana Medicaid – See State Specific Mandates
Maryland Medicaid – See State Specific Mandates
Virginia Medicaid – See State Specific Mandates
Washington Medicaid – See State Specific Mandates

Medications	Quantity Limit
Aristada Initio (aripiprazole lauroxil)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Aristada Initio (aripiprazole lauroxil) extended-release injectable suspension may be approved if the following criteria are met:

I. Individual has a diagnosis or schizophrenia; **AND**
II. Individual has established tolerability with oral aripiprazole; **AND**
III. Individual is initiating or re-initiating therapy with Aristada; **AND**
IV. Individual will use in conjunction with first Aristada (aripiprazole lauroxil) injection (Note: first Aristada injection may be administered on the same day as Aristada Initio or up to 10 days thereafter); **AND**
V. Individual will use in conjunction with one 30 mg dose of oral aripiprazole for the following regimens:
    A. Individual is initiating therapy with Aristada; **OR**
    B. Individual is re-initiating therapy with Aristada after greater than 7 weeks since last Aristada 441 mg injection or greater than 12 weeks after all other strengths of Aristada.

Requests for Aristada Initio (aripiprazole lauroxil) extended-release injectable suspension may not be approved for the following criteria:

I. Individual is using for repeat Aristada dosing; **OR**
II. Individual has not established tolerability to oral aripiprazole.

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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State Specific Mandates		
Indiana	8/15/15	1. Invega Trinza – change effective 8/15/2015 a. Invega Trinza will be allowed after the individual has been stabilized on at least 4 months of therapy on Invega Sustenna. b. If there is not a 4 month prescription history of Invega Sustenna, the medication request will need to be evaluated. **90 days' supply will be authorized; limit of 4 injections per year.**
	10/1/15	1. Beginning 10/1/2015, only individuals 18 and over may receive long-acting injectable antipsychotic agents. a. For children under 18, PA requests will be denied; oral medications should be utilized. **Exception: Children of adult size (16 and 17 years old only) may obtain a prescription for long-acting injectable antipsychotic agents for a diagnosis of schizophrenia ONLY.**
	4/1/16	1. Beginning 04/15/2016, only individuals 18 and over may receive the following oral antipsychotic agents: clozapine, Fanapt, Latuda, Loxapine, Vraylar, Perphenazine, fluphenazine, Rexulti, ziprasidone. **Exception: Children of adult size (16 and 17 years old only) may obtain a prescription for the above listed antipsychotic agents for a diagnosis of schizophrenia ONLY.**
MD		• Maryland behavioral health is state carve out
Virginia	10/1/15	**Virginia Medicaid:** Individuals 17 years of age and younger will require prior authorization for all antipsychotic agents, aligning with Virginia Medicaid FFS program requirements. I. Starting 10/1/15, members utilizing all antipsychotics ***except the following*** will follow the criteria outlined here: chlorpromazine, haloperidol (tablets or liquid), Risperdal (riserpidone) tablets or solution, trifluoperazine. II. Starting 11/1/15, **all** members will follow the criteria outlined here. Per DMAS: Effective March 1, 2015, the Department of Medical Assistance Services (DMAS) will expand its typical and atypical antipsychotic service authorization (SA) requirement (also known as a PA or prior authorization) to any member under the age of eighteen (18) enrolled in Virginia Medicaid's fee-for-service program. The SA requirement for members under the age of eighteen (18) are as follows: I. The drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND, II. the member must have an appropriate diagnosis, as indicated on the attached SA form AND, III. the member must be participating in a behavioral management program AND,

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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		IV. Written, informed consent for the medication must be obtained from the parent or guardian. SAs will be given for six (6) months, after which a new SA will need to be obtained. If the SA criteria listed above are not met, a thirty (30) day emergency fill will be allowed and the SA request will be reviewed by a board certified Child and Adolescent Psychiatrist. Failure to complete the SA process and meet the clinical criteria during this thirty (30) day period will result in the denial of subsequent pharmacy claims for the drug. Service authorization does not guarantee payment for the drug; payment is contingent upon passing all edits contained within the claims payment process, the individual's continued Medicaid eligibility, the provider's continued Medicaid eligibility, and the ongoing medical necessity for the drug. SA criteria document:  Microsoft Word 97 - 2003 Document In addition, use of preferred atypical antipsychotic agents prior to a non-preferred atypical antipsychotic will still be required. The preferred oral atypical antipsychotic agents are as follows: risperidone, olanzapine, quetiapine fumarate, ziprasidone, aripiprazole tablets, paliperidone. Trial and failure of one of these products is required prior to use of a non-preferred atypical antipsychotic unless the following applies: I. Latuda is requested and individual is diagnosed with bipolar disorder along with significant cardiovascular risk factors (such as a high risk of QTc prolongation) or is at high risk for complications related to weight gain. **Requests for individuals 18 and over will follow criteria outlined below:** **<u>All antipsychotic agents are approved for use in individuals 18 and older.</u>** However, use of preferred atypical antipsychotic agents prior to a non-preferred atypical antipsychotic will still be required. The preferred oral atypical antipsychotic agents are as follows: risperidone, olanzapine, quetiapine fumarate, ziprasidone, aripiprazole tablets, paliperidone. Trial and failure of one of these products is required prior to use of a non-preferred oral atypical antipsychotic unless the following applies: I. Latuda is requested and individual is diagnosed with bipolar disorder along with significant cardiovascular risk factors (such as a high risk of QTc prolongation) or is at high risk for complications related to weight gain.

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Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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WA		• Amerigroup will follow the Washington Health Care PDL for Coverage Provide indefinite coverage for all members regardless of formulary status ONLY IF PREVIOUSLY PRESCRIBED

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Aristada Initio (aripiprazole lauroxil extended-release injection) [package insert]. Altham, MA. Alkermes, Inc.; June 2018.