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

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Rexulti (brexpiprazole)

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

Indiana Medicaid – see State Specific Mandates below
Maryland Medicaid – see State Specific Mandates below
Virginia Medicaid – see State Specific Mandates below
Washington Medicaid – see State Specific Mandates below

Medications	Quantity Limit
Rexulti (brexpiprazole)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rexulti (brexpiprazole) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using for one of the following conditions:
    A. Schizophrenia; **AND**
        1. The individual meets one of the following:
            a. Individual is maintained on a stable dose of Rexulti; **OR**
            b. Individual has had a trial of and inadequate response or intolerance to **one** preferred generic oral atypical antipsychotic;

                Preferred generic oral atypical antipsychotics: risperidone tablet/solution, olanzapine, quetiapine, ziprasidone, aripiprazole tablet, paliperidone

            OR
            c. The preferred generics are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Rexulti does;

    OR
    B. Major Depressive Disorder; **AND**
        1. Individual is maintained on a stable dose of Rexulti;

        OR

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

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2. Individual must use concomitant antidepressant therapy;
   AND
3. Individual has had a trial of and inadequate response or intolerance to either aripiprazole or quetiapine ER*.

   * may be subject to prior authorization

NOTE: Rexulti (brexpiprazole) has a black box warning for an increased mortality risk in elderly individuals with dementia-related psychosis as well as increased risk of suicidal thoughts and behaviors in individuals 24 years in younger using antidepressant therapy. Elderly individuals with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. In trials, the cause of death varied, most appeared to be either cardiovascular or infectious in nature. Rexulti is not approved for use in individuals with dementia-related psychosis. Antidepressant therapy can increase suicidal thoughts and behaviors in individuals 24 years and younger. Monitoring is recommended for clinical worsening and emergence of suicidal thoughts and behaviors. Safety and effectiveness of Rexulti have not been established in pediatrics.

State Specific Mandates		
Virginia Medicaid	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

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

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		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, 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:

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

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		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.
Indiana Medicaid	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. c. 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. b. 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.

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

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	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. a. 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.
Maryland Medicaid		Maryland behavioral health is state carve out
Washington Medicaid		• 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:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed January 30, 2017.

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