

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|-------------------------------------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | NA | NA | X | NA | X | X | NA | X | X | X | NA | NA | NA |

*FHK- Florida Healthy Kids

Invega Trinza (paliperidone palmitate extended release injection)

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

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

| Medications | Quantity Limit |
|---|----------------------|
| Invega Trinza (paliperidone palmitate extended release injection) 273 mg kit, 410 mg kit, 543 mg kit, 819 mg kit* | 1 kit every 3 months |

APPROVAL CRITERIA

Requests for Invega Trinza (paliperidone palmitate extended release injection) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using in the treatment of schizophrenia; **AND**
- III. Individual has been adequately treated with Invega Sustenna for at least four (4) months.


Note: Invega Trinza (paliperidone palmitate) has a black box warning regarding use in elderly individuals with dementia-related psychosis. Such individuals are at an increased risk of death; therefore, it is not approved for the treatment of dementia-related psychosis.

| State Specific Mandates | | |
|-------------------------|---------|--|
| Virginia | 10/1/15 | <p style="text-align: center;"><u>Virginia Medicaid:</u></p> <p>Individuals 17 years of age and younger will require prior authorization for all antipsychotic agents, aligning with Virginia Medicaid FFS program requirements.</p> <ol style="list-style-type: none"> I. Starting 10/1/15, members utilizing all antipsychotics <u>except the following</u> will follow the criteria outlined here: chlorpromazine, haloperidol (tablets or liquid), Risperdal (risperidone) tablets or solution, trifluoperazine. |

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
WEB-PEC-0450-16

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|-------------------------------------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | NA | NA | X | NA | X | X | NA | X | X | X | NA | NA | NA |

*FHK- Florida Healthy Kids

| | | |
|--|--|--|
| | | <p>II. Starting 11/1/15, all members will follow the criteria outlined here.</p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>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.</p> <div style="text-align: center;">  <p>Microsoft Word 97 - 2003 Document</p> </div> <p>SA criteria document:</p> <p>In addition, use of preferred atypical antipsychotic agents prior to a non-preferred atypical antipsychotic will still be required.</p> <p>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:</p> <ol style="list-style-type: none"> 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. <p>Requests for individuals 18 and over will follow criteria outlined below:</p> |
|--|--|--|

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|-------------------------------------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
| Applicable | X | NA | NA | X | NA | X | X | NA | X | X | X | NA | NA | NA |

*FHK- Florida Healthy Kids

| | | |
|---------|---------|---|
| | | <p>All antipsychotic agents are approved for use in individuals 18 and older. 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:</p> <p>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.</p> |
| Indiana | 8/15/15 | <p>1. Invega Trinza – change effective 8/15/2015</p> <p>a. Invega Trinza will be allowed after the individual has been stabilized on at least 4 months of therapy on Invega Sustenna.</p> <p>b. If there is not a 4 month prescription history of Invega Sustenna, the medication request will need to be evaluated.</p> <p>90 days' supply will be authorized; limit of 4 injections per year.</p> |
| | 10/1/15 | <p>1. Beginning 10/1/2015, only individuals 18 and over may receive long-acting injectable antipsychotic agents.</p> <p>a. For children under 18, PA requests will be denied; oral medications should be utilized.</p> <p>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.</p> |
| | 4/1/16 | <p>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.</p> <p>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.</p> |
| WA | | <ul style="list-style-type: none"> Amerigroup will follow the Washington Health Care PDL for Coverage Provide indefinite coverage for all members regardless of formulary status ONLY IF PREVIOUSLY PRESCRIBED |
| MD | | <ul style="list-style-type: none"> Maryland behavioral health is state carve out |

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. 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: December 31, 2015.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015. Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.