HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Generic	Brand	HICL	GCN	Exception/Other
BREXPIPRAZOLE	REXULTI	42283		
CARIPRAZINE	VRAYLAR	42552		

NOTE: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at point of service with a message indicating that prior authorization (PA) is required.

Members who do not meet the step therapy criteria at point of service will need to submit a Medication Request Form (MRF) to MedImpact for clinical review. First level drug therapy required include the following:

- Aripiprazole, asenapine, clozapine, iloperidone, lurasidone, olanzapine, quetiapine (IR or XR), risperidone, ziprasidone,
- Lookback is 365 days,
- Lookback will also include brand name agents and look for itself.

CUSTOMER SERVICE REPRESENTATIVE (CSR)
PA COORDINATOR (PAC)

This is a Rhode Island (RI) member or prescriber determination for behavioral health and substance abuse requests:

1. Does the member live in Rhode Island **or** is the prescribing provider's office located in Rhode Island?

   If yes, continue to #2.
   If no, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.

2. Is the requested medication non-formulary?

   If yes, continue to review using the clinical determination criteria below. For Customer Service, all other requests require a Medication Request Form (MRF) be submitted for review.

   If no, **approve for 12 months by HICL.**

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ATYPICAL ANTIPSYCHOTIC MEDICATIONS

CLINICAL DETERMINATION CRITERIA

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

GUIDELINES FOR USE

1. Is the member already being treated with Rexulti or Vraylar (excluding treatment initiated with provider samples) and is responding well?

   If yes, continue to #10.
   If no, continue to #2.

2. Is the request for Rexulti for a member 18 years of age or older?

   If yes, continue to #3.
   If no, continue to #5.

3. Is the request for a member with the diagnosis of schizophrenia?

   If yes, continue to #6.
   If no, continue to #4.

4. Is the request for a member with the diagnosis of depression?

   If yes, continue to #7.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Atypical Antipsychotic guideline, Rexulti is only covered for members at least 18 years of age who are diagnosed with either schizophrenia or major depressive disorder (MDD). Your provider did not indicate that you have one of these conditions and therefore your request was not approved.

5. Is the request for Vraylar for a member at least 18 years of age with one of the following diagnoses: schizophrenia or bipolar disorder (manic or mixed episodes associated w/ bipolar I disorder)?

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (for Vraylar): Per your health plan's Atypical Antipsychotic guideline, Vraylar is covered for members at least 18 years of age with a diagnosis of schizophrenia or manic or mixed episodes associated w/ bipolar I disorder. Your provider did not indicate that you have one or more of these conditions and therefore your request was not approved.

   DENIAL TEXT (for Rexulti): Per your health plan's Atypical Antipsychotic guideline, Rexulti is only covered for members at least 18 years of age. Your provider did not indicate that you are at least 18 years of age and therefore your request was not approved.

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ATYPICAL ANTIPSYCHOTIC MEDICATIONS

INITIAL CRITERIA (CONTINUED)

6. Has the member tried and failed therapy with at least two alternative atypical antipsychotics, one of which must be aripiprazole (Abilify)?

   If yes, continue to #10.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (for Vraylar): Per your health plan's Atypical Antipsychotic guideline, Vraylar is only covered for members at least 18 years of age with a diagnosis of schizophrenia or manic or mixed episodes associated with bipolar I disorder who have first tried at least two alternative antipsychotic medications, one of which must be aripiprazole (Abilify). Your provider did not indicate that you have tried at least two alternative medications and therefore your request was not approved.

   DENIAL TEXT (for Rexulti): Per your health plan's Atypical Antipsychotic guideline, Rexulti is only covered for members at least 18 years of age with a diagnosis of schizophrenia or major depressive disorder who have first tried at least two alternative antipsychotic medications, one of which must be aripiprazole (Abilify). Your provider did not indicate that have tried at least two alternative medications and therefore your request was not approved.

7. Has the member tried and failed therapy with at least two antidepressant medications?

   If yes, continue to #8.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Atypical Antipsychotic guideline, a previous trial with at least two different antidepressant medications, such as sertraline (Zoloft), fluoxetine (Prozac) or desvenlafaxine (Effexor), is required prior to approval of Rexulti. Your provider did not indicate that you previously tried at least two antidepressant medications and therefore your request was not approved.

8. Will the member be taking this medication adjunctively with an antidepressant medication?

   If yes, continue to #9.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Atypical Antipsychotic guideline, approval of Rexulti requires that you will take it in combination with an antidepressant medication. Your provider did not indicate that you will be taking Rexulti with an antidepressant medication and therefore your request was not approved.

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ATYPICAL ANTIPSYCHOTIC MEDICATIONS

INITIAL CRITERIA (CONTINUED)

9. Has the member tried and failed therapy with at least two alternative antipsychotic medications?

   If yes, continue to #10.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Atypical Antipsychotic guideline, a trial with at least two alternative antipsychotic medications used for the treatment of depression, such as aripiprazole (Abilify), olanzapine (Zyprexa) or quetiapine (Seroquel), is required prior to approving coverage of Rexulti for depression. Your physician did not indicate that you have first tried and failed at least two alternative antipsychotic medications and therefore your request was not approved.

10. **Approve for 12 months by HICL as follows:** (The quantity is hard-coded for one tablet per day) Please use status code #056.

    Requests for products on formulary with a restriction, please use the approval text provided.
    APPROVAL TEXT for Rexulti: Your request for Rexulti has been approved for a 12-month period for a quantity of 30 tablets per 30 days.

    APPROVAL TEXT for Vraylar: Your request for Vraylar has been approved for a 12-month period for a quantity of 30 capsules per 30 days.

    Requests for products not on formulary, please use the approval text provided.
    APPROVAL TEXT for Rexulti: Your request for Rexulti has been approved for a quantity of 30 tablets per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

    APPROVAL TEXT for Vraylar: Your request for Vraylar has been approved for a quantity of 30 capsules per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RENEWAL CRITERIA

1. Has the provider noted improvement while on therapy?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Atypical Antipsychotic guideline, authorization for renewal requires that you have experienced improvement while on therapy. Your provider did not indicate your condition has improved while on therapy and therefore your request was not approved.

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ATYPICAL ANTIPSYCHOTIC MEDICATIONS

RENEWAL CRITERIA (CONTINUED)

2. **Approve for 12 months by HICL as follows:** (The quantity is hard-coded for one tablet per day) Please use status code #056.

   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT for Rexulti: Your request for Rexulti has been approved for a 12-month period for a quantity of 30 tablets per 30 days.

   APPROVAL TEXT for Vraylar: Your request for Vraylar has been approved for a 12-month period for a quantity of 30 capsules per 30 days.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT for Rexulti: Your request for Rexulti has been approved for a quantity of 30 tablets per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   APPROVAL TEXT for Vraylar: Your request for Vraylar has been approved for a quantity of 30 capsules per 30 days for a 12-month period at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RATIONALE
To encourage the use of first line and generic antipsychotic agents whenever possible.

FDA APPROVED INDICATIONS
REXULTI is an atypical antipsychotic indicated for:
- Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD)
- Treatment of schizophrenia

VRAYLAR is an atypical antipsychotic indicated for:
- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder.

REFERENCES
- Highlights of Prescribing Information [database online]. Atlanta, GA. Available at: http://www.otsuka-us.com/Products/Documents/Rexulti.PI.pdf [Accessed: August 26, 2015].
- Highlights of Prescribing Information. Parsippany, NJ. Available at http://www.allergan.com/assets/pdf/vraylar_pi. Accessed July 18, 2016.

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