STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Prior Authorization Criteria (PDL drugs)

- ***Namenda XR*** **–** Namenda XR will only be authorized with documentation indicating why immediate-release products cannot be used.
- ***Cresemba*** **–** ***(****See criteria below)*
- ***Aristada*** **–** *(See criteria below)* Must be stabilized for 90 days on an aripiprazole product; Aristada will be approved with one concurrent prescription of oral aripiprazole during the initiation of the script **This product does not yet appear on the PDL**
- ***Cosentyx*** **–** New indications added for Psoriatic Arthritis and Ankylosing Spondylitis; a trial of Humira will be required for these indications as well as for plaque psoriasis.
- ***Zepatier*** **–** ***(****See criteria below).* Non-preferred and must have demonstrated renal deficiencies that would contraindicate preferred medications for the specific genotype; **This product does not yet appear on the PDL**
- ***Non-preferred Hypoglycemics –*** All classes now have language specifying the path from preferred to non-preferred (except SGLT2s which have no preferred product). The following classes did not have language specifying how to get a non-preferred agent:
    - **HYPOGLYCEMICS, INCRETIN MIMETICS/ENHANCERS:** A ninety (90) day trial of each chemically distinct preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.
    - **HYPOGLYCEMICS, INSULIN AND RELATED AGENTS**: A ninety (90) day trial of a pharmacokinetically similar agent is required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.
    - **HYPOGLYCEMICS, MEGLITINIDES** : A ninety (90) day trial of each chemically distinct preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.
    - **HYPOGLYCEMICS, TZD** : A ninety (90) day trial of each chemically distinct preferred agent will be required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.
- ***IBS Agents (Amitiza, Linzess and Movantik)*** **–** Removed requirement for bulk-forming laxative. We can only require trials of medications covered by Medicaid. Besides the laxatives listed on the PDL, we currently cover the OTC laxatives Milk of Magnesia and Miralax. All covered laxatives are hyperosmotics.
- ***Kynamro*** **-** Requires a 24-week trial of Repatha
- ***Juxtapid*** **–** Requires a 24-week trial of Repatha; Now listed under “Lipotropics, Other (Non-Statins) - MTP inhibitor” as a non-preferred agent
- ***Repatha*** **–** *Board voted to postpone the review of Repatha until May’s DUR Board meeting.*

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Office of Pharmacy Service
Prior Authorization Criteria

CRESEMBA®
(isavuconazonium sulfate**)**
Effective 4/1/2016

Prior Authorization Request Form

CRESEMBA is an azole antifungal indicated for use in the treatment of invasive aspergillosis and invasive mucormycosis.

Criteria for Approval

1) Diagnosis of invasive aspergillosis OR invasive mucormycosis; **AND**
2) Patient is ≥ 18 years of age; **AND**
3) ONE of the two:
    a. Patient has a documented side-effect, allergy, contraindication to, or is intolerant of or failed voriconazole if the diagnosis is aspergillosis or Noxafil® (posaconazole) if the diagnosis is mucormycosis; **OR**
    b. Patient is completing a course of therapy with the requested medication that was initiated in the hospital.

References

1) Cresemba package insert revised 6/2015
2) Lexi-Comp Clinical Application 02/17/2016
3) Treatment of Aspergillosis: Clinical Practice Guidelines of the Infectious Diseases Society of America (http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/Aspergillosis.pdf)
4) http://www.uptodate.com/contents/pharmacology-of-azoles
5) http://www.uptodate.com/contents/mucormycosis-zygomycosis?source=machineLearning&search=mucormycosis&selectedTitle=1%7E68&sectionRank=1&anchor=H18#H18
6) http://www.uptodate.com/contents/treatment-and-prevention-of-invasive-aspergillosis?source=machineLearning&search=invasive+aspergillis&selectedTitle=1%7E150&sectionRank=2&anchor=H5#H5

V2016.2a – created 02-17-2016 (BMT)
Approved 2-24-16 by WV DUR Board

STATE OF WEST VIRGINIA
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Office of Pharmacy Service
Prior Authorization Criteria

ARISTADA®
(aripiprazole lauroxil)
Effective 2/24/2016

Prior Authorization Request Form

ARISTADA is an extended-release intramuscular injectable suspension of the atypical antipsychotic aripiprazole and is indicated for the treatment of schizophrenia.

Criteria for Approval

4) Diagnosis of schizophrenia; **AND**
5) Patient must be between 18 and 65 years of age; **AND**
6) Stabilized on at least 90 days of therapy with another aripiprazole product.
7) Aristada must be initiated in conjunction with the patient's currently stabilized dose of oral aripiprazole for 21 consecutive days.

References

7) Aristada package insert revised 1/2016
8) Lexi-Comp Clinical Application 02/17/2016

V2016.2a – created 02-17-2016 (BMT)
Approved 2-24-16 by WV DUR Board

STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services Prior Authorization Criteria

ZEPATIER™ (elbasvir and grazoprevir)

Effective 2/24/2016

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form

Preferred HepC Regimens (Attachment A)

Zepatier™ is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.

Criteria for Approval

1) **All requests for Zepatier must clearly indicate why the patient cannot take a preferred medication indicated for their HCV genotype (See Attachment A for a list of preferred regimens per genotype); AND**

2) All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**

3) Patient must have a documented **fibrosis level ≥ F3**; **AND**

4) Patient must be eighteen (18) years of age or older; **AND**

5) Zepatier must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

6) Patient must be diagnosed with chronic Hepatitis C Genotype 1 or 4; **AND**

7) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**

8) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level (*See Table 1 for the list of accepted regimens)*.

- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Table 1 Accepted Regimens and Treatment Duration for HCV Therapy

Diagnosis		Approved Regimen	Duration
Genotype 1a	- Treatment-naïve or PegIFN/RBV-experienced[1] without baseline NS5A polymorphisms[2]	Zepatier	12 weeks
Genotype 1a	- Treatment-naïve or PegIFN/RBV-experienced[1] with baseline NS5A polymorphisms[2]	Zepatier + ribavirin	16 weeks
Genotype 1b	- Treatment-naïve or PegIFN/RBV-experienced[1]	Zepatier	12 weeks
Genotype 1a/1b	- PegIFN/RBV/PI-experienced[3]	Zepatier + ribavirin	12 weeks
Genotype 4	- Treatment-naïve	Zepatier	12 weeks
Genotype 4	- PegIFN/RBV-experienced[1]	Zepatier + ribavirin	16 weeks

[1]Peginterferon alfa + ribavirin
[2]Polymorphisms at amino acid positions 28, 30, 31 or 93.
[3]Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.

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ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS

Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging (MRI, ultrasound, or CT)
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/µL), and coagulopathy (INR > 2)

Criteria for Denial

1) Requests submitted with incomplete documentation will be denied.

2) Failure to report a fibrosis score.

3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.

4) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.

5) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.

2) For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Zepatier.

3) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

4) Lost or stolen medication replacement request will not be authorized.

5) Zepatier was granted breakthrough therapy designation for the treatment of chronic HCV genotype 1 infection in patients with end stage renal disease on hemodialysis and for the treatment of chronic HCV genotype 4 infection. Breakthrough therapy designation is a program designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

References

1) Zepatier [package insert]. Merck, January, 2016.
2) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 16, 2016.
3) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.
4) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician.* 2006 Sep 1;74(5):756-762.