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

Office of Pharmacy Service
Prior Authorization Criteria

Austedo® (deutetrabenazine)

Prior Authorization Request Form

Effective 10/01/2017

AUSTEDO is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

Initial Prior Authorization Criteria:

1. Patient must be at least 18 years of age; **AND**
2. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**
3. Patient must meet the following additional criteria per indication:

I. Treatment of Chorea associated with Huntington's Disease:

1. Request must come from the treating neurologist; **AND**
2. All previous therapies must be documented. Unless contraindicated, the patient must have documented 60-day trials of **amantadine** and **tetrabenazine**; **AND**
3. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT 2 inhibitor.

Initial prior-authorization for this indication will be for 60 days.

Additional coverage requires clinical documentation indicating an improvement or stabilization of symptoms.

II. Treatment of Tardive Dyskinesia (TD):

1. Request must come from the treating neurologist or psychiatrist; **AND**
2. Patient must have a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
   a. Involuntary athetoid or choreiform movements

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

Office of Pharmacy Service
Prior Authorization Criteria

Chantix® (varenicline)

Prior Authorization Request Form

Effective 10/01/2017

CHANTIX is a nicotinic receptor partial agonist indicated for use as an aid to smoking cessation treatment.

Prior authorization criteria:

1. Member is at least 18 years old; **AND**

2. The member is enrolled in an approved smoking cessation program; **AND**

3. The member has had a minimum 30-day trial of either Nicotine Replacement Therapy (NRT) **OR** Zyban (bupropion). The use of combination NRT is covered. Documentation MUST be submitted indicating when therapy occurred; **AND**

4. WV Medicaid will cover the cost of one attempt to quit every 365 days. A quit attempt is expected to consist of a relatively continuous transition between pharmacological agents, therefore no more than 30 days must have lapsed between any pharmacological therapy prior to and including any request for Chantix. Unless contraindicated, NRT **or** bupropion must be trialed every time a quit attempt is initiated.

Prior authorization requests for either NRT or Zyban will be issued for a maximum of ninety (90) days. Initial prior authorization for Chantix will be for 90 days with an additional 90 days available for maintenance therapy if requested. NRT therapy may not be filled concurrently with Chantix.

References

1.) Lexi-Comp drug monograph for Chantix (Reviewed 9/12/2017)
2.) Package insert for Chantix (last update 12/2016)
3.) UpToDate : Overview of Smoking Cessation Management in Adults (reviewed 9/12/2017).
4.) UpToDate: Pharmacotherapy for Smoking Cessation in Adults (reviewed 9/12/2017)

b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
c. Symptom duration lasting at least 8 weeks

AND

3. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam; **AND**

4. Prescriber must submit documentation of all other therapies attempted. Unless contraindicated these therapies must include at least a **60-day trial each** of **clonazepam** and **amantadine**. Patients with documentation of a previous benzodiazepine dependency are not required to trial clonazepam; **AND**

5. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT 2 inhibitor.

Initial prior-authorization for this indication will be for 60 days.

Additional coverage requires clinical documentation indicating significant improvement in symptoms. The results of a current AIMS score must be submitted with every request.

References

1.) Lexi-Comp drug monograph for Austedo (Reviewed 9/12/2017)
2.) Package insert for Austedo (last update 9/2017)
3.) Package insert for Xenazine (last update 6/2015)
4.) Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): cross-scale comparison in assessing tardive dyskinesia. Schizophr Res. 2005 Sep 15;77(2-3):119-28. Gharabawi GM[1], Bossie CA, Lasser RA, Turkoz I, Rodriguez S, Chouinard G.
5.) UpToDate Tardive Dyskinesia: Prevention and Treatment. Article last updated July 24, 2017
6.) American Academy of Neurology Evidence-based guideline: Treatment of tardive syndromes. July 29, 2013.
7.) American Academy of Neurology Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease. August 7, 2012.

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

Office of Pharmacy Service
Prior Authorization Criteria

Eucrisa™ (crisaborole)

Prior Authorization Request Form

Effective 10/01/2017

EUCRISA is a phosphodiesterase 4- inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

Prior authorization requests may be approved for 6 months if the following criteria are met:

1. Diagnosis of atopic dermatitis; **AND**

2. Patient ≥ 2 years old; **AND**

3. Documented 6-week trial and failure of at least one preferred medium to high potency topical corticosteroid (see PDL for a list of preferred agents) **OR** the topical calcineurin inhibitor Elidel (pimecrolimus).

Additional therapy will be available with demonstration of significant improvement since the start of therapy.

References

1.) Lexi-Comp drug monograph for crisaborole (Reviewed 8/22/2017)
2.) UpToDate article: Treatment of atopic dermatitis. Updated July 24, 2017.
3.) Elidel package insert revised 6/2017
4.) Eucrisa package insert revised 12/2016
5.) Pharmacist Letter, Feb 2017 Article: “Explain Where New Eucrisa Fits into Eczema Treatment”

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

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

Office of Pharmacy Services Prior Authorization Criteria for Chronic Hepatitis C Virus (HCV) Therapy

Effective 10/01/2017

Prior Authorization Request Form
Prior Authorization Continuation Request Form
Patient Consent Form
Preferred HepC Regimens (Attachment A)

Criteria for Approval

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

2) Prescriber must submit laboratory evidence confirming that the patient is more likely than not to have a Metavir fibrosis score of F2 or greater; **AND**

3) Patient must meet the minimum FDA approved age requirement as specified in the package label; **AND**

4) Selected treatment regimen must be prescribed by, or in conjunction with, a board-certified gastroenterologist, hepatologist or infectious disease physician; **AND**

5) 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**

6) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 will be collected and made available to WV Medicaid to verify therapy success.

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A located at the end of this document. Initial approvals will be for a maximum of 12 weeks and require submission of the starting HCV RNA level.

- Additional therapy beyond 12 weeks may be requested by completing the Prior Authorization Continuation Request Form and is approvable only after receipt of a viral load indicating treatment efficacy as suggested by AASLD guidelines*.

- Emergency fills will NOT be granted under any circumstance.

***** AASLD guidelines recommend that quantitative HCV viral load testing be done after 4 weeks of therapy (TW4). If HCV RNA is detectable at week 4 of treatment, repeat quantitative HCV RNA viral load testing is recommended after 2 additional weeks of treatment. If the quantitative HCV viral load has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended.

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

Additional Considerations

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

2) Cirrhosis should 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)

3) 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 the selected HCV regimen.

PRIOR AUTHORIZATION MAY BE DENIED FOR THE FOLLOWING REASONS

1) Failure to report a genotype, fibrosis score or other significant omission from required documentation.

2) Any request falling outside the manufacturer guidelines for safe use.

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

4) Patient is taking a concomitant medication that has significant clinical interactions with the requested regimen.

5) Requests for continuation of coverage beyond 12 weeks will be denied if the patient's HCV RNA level has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter) or if the prescriber has not submitted or has not obtained a viral load prior to treatment week 12. **Denial of continuation due to lack of efficacy does not prevent the approval of an alternative regimen if indicated by AASLD guidelines.**

6) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable quantitative HCV RNA levels measured at 12 weeks following completion of therapy (SVR12). 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.

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

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

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

ATTACHMENT A: Accepted Regimens and Treatment Duration for Chronic Hepatitis C Therapy

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml→ Regimen 1 or 12 (HIV negative, non-black only) or 7 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million→ Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7 (only if negative for NS5A resistance associated polymorphisms¥)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms)
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin +NS3 protease inhibitor, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
	❑ Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY → 3 or 10
	❑ Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier), dasabuvir (Viekira), pibrentasvir (Mavyret) and daclatasvir (Daklinza), including those given with a NS3/4A protease inhibitor, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 10
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 13, if ribavirin ineligible** → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	**Genotype 1b**
	❑ Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1 or12 (HIV negative, non-black only) or 7
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen 1 or 7
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1 or 7
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 7 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 9 or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → 9 or 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY → 3 or 10
	❑ Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier),

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

	dasabuvir (Viekira), pibrentasvir (Mavyret) and daclatasvir (Daklinza), including those given with a NS3/4A protease inhibitor, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 10
❑	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 13, if ribavirin ineligible** → Regimen 2
❑	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	**Genotype 2**
❑	Treatment naïve, no cirrhosis → Regimen 1 or 5
❑	Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
❑	Treatment experienced (sofosbuvir + ribavirin) → Regimen 5 or 2
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 or if RBV ineligible**ONLY→ Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
❑	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
❑	Re-infection of allograft liver after transplant, compensated cirrhosis, → Regimen 15 or 6 or 2
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
❑	**Genotype 3**
❑	Treatment naïve, no cirrhosis→ Regimen 1 or 5
❑	Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H neg → Regimen 5 or 3
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 3
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 6 or 3, if RBV ineligible only** → Regimen 8
❑	Treatment experienced (any direct acting antiviral including NS5A), no or compensated cirrhosis, Child-Pugh A ONLY → Regimen 10; if prior NS5A AND cirrhosis → Regimen 11
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 or, if RBV ineligible ONLY** **→ Regimen 4
❑	Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
❑	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
❑	Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 15 or 6 or 2
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
❑	**Genotype 4**
❑	Treatment naïve, no cirrhosis → Regimen 1 or 7
❑	Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 or 2
❑	Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 7 (only if prior virologic relapse after PEG-IFN therapy)
❑	Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY→ Regimen 5 or 7 (only if prior virologic relapse after PEG-IFN therapy) or 2
❑	Treatment experienced (any direct acting antiviral including NS5A), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A →Regimen 6
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
❑	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
❑	**Genotype 5**
	❑ Treatment naive, no cirrhosis → Regimen 1
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (any DAA including NS5A), with no or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A →Regimen 6
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 13, if ribavirin ineligible** → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
❑	**Genotype 6**
	❑ Treatment naïve, no cirrhosis → Regimen 1
	❑ Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 10
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A→Regimen 6
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 13, if ribavirin ineligible** → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14

REGIMENS:

1. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks) ☐
2. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 84 days (12 weeks) ☐
3. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 112 days (16 weeks) ☐
4. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 168 days (24 weeks) ☐
5. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 84 days (12 weeks) ☐
6. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
7. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks) ☐
8. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + sofosbuvir 400 mg daily for 84 days (12 weeks) ☐
9. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight based ribavirin for 84 days (12 weeks) ☐
10. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily for 84 days (12 weeks) ☐
11. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + weight-based ribavirin for 84 days (12 weeks) ☐
12. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks) ☐
13. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose# ribavirin for 84 days (12 weeks) ☐
15. Daklinza^(daclatasvir) 60 mg plus Sovaldi (sofosbuvir) 400 mg daily + low initial dose of ribavirin for 84 days (12 weeks) ☐
16. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight based ribavirin for 168 days (24 weeks) ☐

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

^ Dose of Daklinza (daclatasvir) MUST BE ADJUSTED with certain co-administered drugs (reduced to 30 mg daily with concurrent CYP3A4 inhibitors and increased to 90 mg daily with concurrent moderate CYP3A4 inducers)
# low dose ribavirin = 600 mg/day and increase as tolerated
¥ Genotype 1a polymorphisms at amino acid positions 28, 30, 31, or 93

NOTE: Please provide clinical rationale with the completed PA form if choosing a regimen that is beyond those found within the current guidelines, or if selecting regimens other than those outlined above.

❑ ****Patients who are ribavirin-ineligible must have at least one of the following reasons documented**:

- ❑ History of severe or unstable cardiac disease
- ❑ Pregnant women and men with pregnant partners
- ❑ Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
- ❑ Hypersensitivity to ribavirin
- ❑ Baseline platelet count <70,000 cells/mm3
- ❑ ANC <1500 cells/mm3
- ❑ Hb <12 gm/dl in women or <13 g/dl in men

Patients with CrCl <50 ml/min (moderate or severe renal dysfunction, ESRD, HD) should have dosage reduced

General Mechanism of Action for Available Agents

- **Daklinza** (daclatasvir) is an HCV NS5A inhibitor.
- **Epclusa** (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor and velpatasvir, an HCV NS5A inhibitor.
- **Harvoni** (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.
- **Mavyret** (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult patients with HCV **genotype 1** infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. **(NOTE: GT1 is the only genotype that can be retreated with Mavyret after previous NS5A or NS3/4A protease inhibitor therapy)**
- **Olysio** (simeprevir) is an HCV NS3/4A protease inhibitor.
- **Sovaldi** (sofosbuvir) is an HCV nucleotide analog NS5B polymerase inhibitor.
- **Technivie** (ombitasvir/paritaprevir) is a fixed-dose combination of ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.
- **Viekira XR** (dasabuvir/ombitasvir/paritaprevir) includes dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor, ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.

- **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:
    - genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
    - genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.

    *** **Additional benefit of VOSEVI over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor**.

- **Zepatier** (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

References

1) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://hcvguidelines.org/ Accessed September 05, 2017.
2) LexiComp Clinical Drug Information – Accessed November 22, 2016.
3) Epclusa [package insert]. Foster City, CA; Gilead, June 2016.
4) Viekira XR™ [package insert]. Abbvie, Revised 7/2016
5) Daklinza [package insert]. Bristol-Myers Squibb Company, Feb 2016.
6) Sovaldi [package insert]. Foster City, CA; Gilead, August 2015.
7) Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. April 2015.
8) Technivie® [package insert]. Abbvie, Revised 7/2015
9) Viekira Pak™ [package insert]. Abbvie, Revised 4/2016
10) Zepatier [package insert]. Merck, January, 2016.
11) Harvoni [package insert]. Foster City, CA; Gilead, February 2016.
12) 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.
13) 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.
14) Mavyret [package insert]. Abbvie. August, 2017.

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

Created 3/08/2017 BMT
Approved by WV DUR Board 3/09/2017 – Last Update 9/22/2017 BMT

Attachment A Change Log:

Ver 2016.3C Created by Laureen Biczak (GHS) and edited by BMT 6/7/2016
Ver 2016.4D Created by Laureen Biczak (CHC)
Ver 2016.4E Created by Laureen Biczak (CHC)
Ver 2017.1G Created by Laureen Biczak (CHC) 08/31/2017
Ver 2017.2H Created by Laureen Biczak (CHC) 10/09/2017

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

Office of Pharmacy Service
Prior Authorization Criteria

Ingrezza™ (Valbenazine)

Prior Authorization Request Form

Effective 10/01/2017

INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.

Initial Prior Authorization Criteria:

1. Request must come from the treating neurologist or psychiatrist; **AND**
2. Patient must be at least 18 years of age; **AND**
3. Patient must have a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
    a. Involuntary athetoid or choreiform movements
    b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
    c. Symptom duration lasting at least 8 weeks

    AND
4. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam; **AND**
5. Prescriber must submit documentation of all other therapies attempted. Unless contraindicated these therapies must include at least a 60-day trial each of **clonazepam** and **amantadine**. Patients with documentation of a previous benzodiazepine dependency are not required to trial clonazepam; **AND**
6. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT 2 inhibitor.
7. Patient must not be currently pregnant or lactating.

    Initial prior-authorization will be for 60 days.

    Additional coverage requires clinical documentation indicating significant improvement in symptoms. The results of a current AIMS score must be submitted with every request.

References

1.) Lexi-Comp drug monograph for valbenazine (Reviewed 8/16/2017)
2.) Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): cross-scale comparison in assessing tardive dyskinesia. Schizophr Res. 2005 Sep 15;77(2-3):119-28. Gharabawi GM[1], Bossie CA, Lasser RA, Turkoz I, Rodriguez S, Chouinard G.
3.) UpToDate Tardive Dyskinesia: Prevention and Treatment. Article last updated July 24, 2017
4.) American Academy of Neurology Evidence-based guideline: Treatment of tardive syndromes. July 29, 2013.

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

Office of Pharmacy Service
Prior Authorization Criteria

Korlym® (mifepristone)

Prior Authorization Request Form

Effective 10/01/2017

KORLYM (mifepristone) is a cortisol receptor blocker indicated to control **hyperglycemia** secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. NOTE: Korlym should not be used for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

Prior Authorization Criteria:

1. Patient must have a diagnosis of hyperglycemia secondary to Cushing's Syndrome; **AND**

2. Patient must be at least 18 years of age; **AND**

3. Prior authorization request must be submitted by or in close consultation with an endocrinologist; **AND**

4. Documentation has been submitted that the patient is not pregnant and has been counseled that they must not become pregnant while taking this medication and for at least 1 month after treatment has been stopped; **AND**

5. The patient has failed surgery to treat the condition (e.g., pituitary surgery, adrenal surgery) or is not a candidate for this type of surgery. **AND**

6. Patient must have inadequate results or a contraindication to treatment with metformin, insulin and a GLP-1 agonist (used in combination if necessary).

References

1.) Lexi-Comp drug monograph for Korlym (Reviewed 7/06/2017)
2.) Korlym Package Insert (updated 5/2017)
3.) UpToDate clinical monograph (reviewed 7/6/2017)
4.) Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab (2015) 100 (8): 2807-2831.
5.) Fleseriu, Maria: Recent advances in the medical treatment of Cushing's disease F1000Prime Reports 2014, 6:18 (doi:10.12703/P6-18)
6.) Cuevas-Ramos et al. Update on medical treatment for Cushing's disease. Clinical Diabetes and Endocrinology (2016) 2:16 DOI 10.1186/s40842-016-0033-9

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

Office of Pharmacy Service
Prior Authorization Criteria

Remicade® (infliximab)

Prior Authorization Request Form

Effective 10/01/2017

REMICADE is a tumor necrosis factor (TNF) blocker indicated for:

- Crohn's Disease
- Pediatric Crohn's Disease
- Ulcerative Colitis
- Pediatric Ulcerative Colitis
- Rheumatoid Arthritis (in combination with methotrexate)
- Ankylosing Spondylitis
- Psoriatic Arthritis
- Plaque Psoriasis

Prior authorization requests for Remicade may be approved if the following criteria are met:

1. Patient must be at least 6 years of age; **AND**

2. Request must be for an FDA-approved age and indication; **AND**

3. Request must be made by, or in consultation with, an appropriate specialist; **AND**

4. Patient must have records indicating unsatisfactory clinical results after 90 day trials of Humira, Enbrel and Cosentyx for all FDA-approved indications held in common by these medications. All prior authorization criteria that apply to Humira, Enbrel and Cosentyx must also be satisfied before Remicade will be approved.

References

1.) Lexi-Comp drug monograph for Remicade (Reviewed 7/06/2017)
2.) Remicade Package Insert (updated 10/2015)
3.) UpToDate clinical monograph (reviewed 7/6/2017)

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

Office of Pharmacy Service
Prior Authorization Criteria

Riluzole

Prior Authorization Request Form

Effective 10/01/2017

Riluzole is a glutamate inhibitor indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS)

Initial Prior Authorization Criteria:

1. Patient must have a documented diagnosis of ALS; **AND**
2. Request must be prescribed by, or in consultation with, a neurologist; **AND**
3. Prescription must be for no more than 50 mg every 12 hours; **AND**
4. Patient must have documented baseline complete blood counts (CBC) with differential and liver function tests (LFT) results. (Note: These tests should be repeated monthly for the first 3 months and then every three months thereafter.)

Prior authorizations will be granted for 6 months at a time and require documentation that follow-up monitoring of CBC with differential and LFT has been completed.

References

1.) Lexi-Comp drug monograph for riluzole (Reviewed 7/21/2017)
2.) UpToDate clinical monograph on ALS (reviewed 7/21/2017)
3.) Riluzole package insert (Sanofi-aventis U.S. LLC 2008)
4.) Cochrane Review (2012) Riluzole for amyotrophic lateral sclerosis (ALS)/motor neuron disease (MND)

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

Office of Pharmacy Service
Prior Authorization Criteria

Spinraza® (nusinersen)

Prior Authorization Request Form

Effective 10/01/2017

SPINRAZA is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Spinraza treats spinal muscular atrophy caused by mutations in chromosome 5q that lead to survival motor neuron (SMN) protein deficiency by binding to a specific sequence in the intron downstream of exon 7 of the *SMN2* messenger ribonucleic acid (mRNA) transcript thereby increasing production of full-length SMN protein.

Initial Prior Authorization Criteria:

1. Spinraza must be prescribed by a neurologist experienced in the treatment of SMA or by a physician in close consultation with such a neurologist; **AND**

2. Documentation must be submitted showing the patient has a diagnosis of Spinal Muscular Atrophy (SMA) confirmed by genetic testing; **AND**

3. Documentation must be submitted indicating that the patient has had the following laboratory tests at baseline and prior to each administration: platelet count, prothrombin time; activated partial thromboplastin time, and quantitative spot urine protein testing; **AND**

4. Prescriber must submit documentation of a baseline motor exam using at least one of the following measures of motor function:
   a) Hammersmith Infant Neurologic Exam (HINE)
   b) Hammersmith Functional Motor Scale (HFMSE)
   c) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND).

Initial authorization will be for 6 months.

Criteria for Continuation Approval (Maintenance dosing given every 4 months)

1. Patient must continue to satisfy all criteria required for initial PA approval; **AND**

2. Documented evidence must be submitted showing clinically significant improvement in SMA associated symptoms, such as lack of progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease by submission of medical records with the most recent results (<1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by at least **one of the following** exams:

   a) HINE
   b) HFMSE
   c) CHOP-INTEND

   NOTE: For older individuals (>24 months), alternative means of motor assessment (e.g. Medical Research Council [MRC] strength test, 6 minute walk, upper limb module testing, pulmonary function testing) are appropriate alternatives.

Continuation requests will be authorized for 12 months.

References

1.) Lexi-Comp drug monograph for Spinraza (Reviewed 6/30/2017)
2.) Spinraza Package Insert (updated 5/2017)
3.) UpToDate clinical monograph (reviewed 7/6/2017)

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

Office of Pharmacy Service
Prior Authorization Criteria

Xenazine® (tetrabenazine)

Prior Authorization Request Form

Effective 10/01/2017

XENAZINE is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with chorea associated with Huntington's disease.

Initial Prior Authorization Criteria:

1. Request must come from the treating neurologist; **AND**
2. Patient must be at least 18 years of age; **AND**
3. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**
4. Patient must have a clinical diagnosis of chorea associated with Huntington's Disease; AND
5. All previous therapies must be documented. Unless contraindicated, the patient must have trialed and failed to find improvement in symptoms after at least a **60-day trial** of **amantadine**; **AND**
6. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT 2 inhibitor.

Initial prior-authorization for this indication will be for 60 days.

Additional coverage requires clinical documentation indicating an improvement or stabilization of symptoms.

References

1.) LexiComp drug monograph for tetrabenazine (reviewed 9/1/2017)
2.) Package insert for Xenazine (last update 6/2015)
3.) American Academy of Neurology Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease. August 7, 2012.