denotes change in current criteria
denotes new criteria

Adbry

Adbry *(Tralokinumab) is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.*

CRITERIA FOR APPROVAL:

1. Prescribed by or in consultation with an allergist, immunologist or dermatologist; **AND**

2. Documented diagnosis of moderate to severe Atopic Dermatitis (AD). Documentation must include the affected BSA, areas of involvement and severity of symptoms; **AND**

3. The patient must be within the age range as recommended by the FDA label and indication; **AND**

4. Affected body surface area is greater than or equal to 10%; **AND**

5. Patient has failed to find relief of symptoms after a minimum of 30-day trials of two agents from the following list in the last 12 months:
    a. Medium to High potency topical corticosteroid*
    b. Elidel
    c. Eucrisa
    d. Tacrolimus

*Trial of medium to high potency topical steroid is required unless the affected area involves sensitive areas such as the face, skin folds or genitals. However, a trial of two other agents among the list above, are still required prior to Adbry approval.

Approval Duration:

Initial approval will be for 3 months.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**
2. Documentation of satisfactory patient response (including current affected BSA and severity of symptoms) has been provided.

Continuation of therapy will be granted for 12 months.

Eprontia (topiramate solution)

Eprontia requires medical reasoning beyond convenience or enhanced compliance as to why the medical need cannot be met by using the preferred Topamax (topiramate) sprinkle capsules.

ANTICONVULSANTS

CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered.

For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.

In situations where AB-rated generic equivalent products are available, "Brand Medically Necessary" must be hand-written by the prescriber on the prescription for the brand name product to be reimbursed.

ADJUVANTS

carbamazepine carbamazepine ER CARBATROL (carbamazepine) DEPAKOTE SPRINKLE (divalproex) divalproex divalproex ER divalproex sprinkle EPITOL (carbamazepine) EQUETRO (carbamazepine) GABITRIL (tiagabine) LAMICTAL (lamotrigine) LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) LAMICTAL XR (lamotrigine) lamotrigine levetiracetam IR levetiracetam ER levetiracetam IR suspension oxcarbazepine tablets QUDEXY XR (topiramate ER) TEGRETOL SUSPENSION (carbamazepine) TEGRETOL XR (carbamazepine) TOPAMAX SPRINKLE CAPS (topiramate) TRILEPTAL SUSPENSION (oxcarbazepine) topiramate IR tablet	APTIOM (eslicarbazepine) BANZEL (rufinamide) BRIVIACT (brivaracetam) carbamazepine oral suspension DEPAKOTE (divalproex) DEPAKOTE DR (divalproex DEPAKOTE ER (divalproex) DIACOMIT CAPSULE/POWDER PACK (stripentol)** ELEPSIA XR (levetiracetam) EPRONTIA SOLUTION (topiramate)**** felbamate FELBATOL (felbamate) FINTEPLA (fenfluramine) SOLUTION***** FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA SOLUTION (levetiracetam) KEPPRA XR (levetiracetam) lamotrigine dose pack lamotrigine ER lamotrigine ODT oxcarbazepine suspension OXTELLAR XR (oxcarbazepine) rufinamide oral suspension, tablets SABRIL (vigabatrin)	*Topiramate ER will be authorized after a thirty (30) day trial of topiramate IR. **Diacomit may only be approved as adjunctive therapy for diagnosis of Dravet Syndrome when prescribed by, or in consultation with, a neurologist AND requires a thirty (30) day trial of valproate and clobazam unless one (1) of the exceptions on the PA form is present. Diacomit must be used concurrently with clobazam. *** Trokendi XR are only approvable on appeal. *****Full PA criteria for Fintepla may be found on the PA Criteria page by clicking the hyperlink. ****Eprontia requires medical reasoning beyond convenience or enhanced compliance as to why the medical need cannot be met by using the preferred Topamax (topiramate) sprinkle capsules.

topiramate ER* valproic acid VIMPAT (lacosamide) zonisamide	SPRITAM (levetiracetam) TEGRETOL TABLETS (carbamazepine) tiagabine TOPAMAX TABLETS (topiramate) topiramate IR sprinkle caps topiramate ER sprinkle caps (generic Qudexy) TRILEPTAL TABLETS (oxcarbazepine) TROKENDI XR (topiramate)*** vigabatrin tablet/powder pack XCOPRI (cenobamate)	

BARBITURATES/AB

Oral and topical contraceptives

:

Class PA Criteria:

Non-preferred agents require a trial with three (3) preferred contraceptive products including a trial with a preferred product with the same route of administration as the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present.

Phexxi may be approvable when it is prescribed for the prevention of pregnancy; **AND** reasoning is provided as to why the clinical need cannot be met with a preferred agent. Phexxi will not be approved for use by patients who are also using hormonal contraceptive vaginal rings.

Atypical Antipsychotics

Current class criteria:

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

Proposed class criteria:

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. ~~All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.~~ When determining requests for non-preferred products, any trial utilizing a preferred agent whose dose or duration was limited due to adverse effects or clear lack of efficacy will be considered complete only if the agent was being taken within the FDA-approved therapeutic range*

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

*According to manufacturer dosing recommendations

Hepatitis C

Criteria for Approval

1) If all the following are met, a consult is not required*: Patient is 18 years of age or older, treatment-naïve, non-cirrhotic, HBV-negative, HIV negative, and non-pregnant. ***While a consult is not required, it is highly recommended that the prescriber is educated in the treatment and diagnosis of Hepatitis C through an academic/training mentorship program such as Project ECHO and/or WVHAMP.**

   Therapy requested for a patient who does not meet all the above criteria, for re-treatment or for a patient experiencing cirrhosis must be prescribed by, or in conjunction with, a gastroenterologist, hepatologist or infectious disease physician. For these patients, consults are permitted, including those through Project ECHO and WVHAMP, however the date of the consult and the contact information for all physicians involved must be submitted with the request for prior authorization; **AND**

2) Both the prior authorization form and the patient-prescriber agreement must be fully completed and signed by the prescriber. Failure to complete any portion of these required documents will result in a denial of the request; **AND**

3) Patient must be diagnosed with hepatitis C and meet all clinical and age requirements specified in the package label; **AND**

4) All requests must supply a fibrosis score and at least one detectable HCV viral level, both obtained within 6 months prior to the start of therapy; **AND**

5) Documentation must be submitted indicating the patient has (or is) receiving vaccination for HepA & HepB or is currently immune; **AND**

6) The patient and prescriber agree that an SVR12 will be collected and submitted to WV Medicaid to confirm therapy success. **Failure to do so may result in disqualification of the patient from future coverage; AND**

7) Patients scheduled to receive an HCV NS3 protease inhibitor (ie, grazoprevir, voxilaprevir, glecaprevir) should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score.
   Patients with current or prior history of decompensated liver disease or with a current CTP score ≥7 should not receive treatment with regimens that contain NS3 protease inhibitors due to increased blood levels and/or lack of safety data.

8) FDA-approved pediatric formulations of direct acting antivirals (DAA), and DAAs approved for pediatric use, may be granted a prior authorization for those under the age of 18 only when used in strict-accordance with current AASLD guidelines based indication and age/weight. Preferred regimens for treatment naïve or interferon-experienced children and adolescents without cirrhosis or with compensated cirrhosis may be found listed in Attachment B near the end of this document. **Prior authorization is STILL required.**

Duration of Approval

- A list of preferred agents and treatment durations for adults with chronic Hepatitis C therapy may be found in Attachment A, located at the end of this document. Attachment B contains a list of preferred regimens for selected pediatric patients. Requests for any regimen not listed in Attachment A or B should be accompanied with a brief clinical justification explaining the choice of therapy.

- Initial approvals will be for the entire regimen, as long as the regimen is listed in Attachment A or B.

- Additional therapy beyond the intended regimen may be requested by completing the Prior Authorization Continuation Request Form.

- Emergency fills will NOT be granted under any circumstance.

Prior Authorization May Be Denied For The Following Reasons

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

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

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

5) Lost or stolen medication replacement requests will not be authorized.

Additional Criteria For Re-Treatment Or Re-Infection

Re-infection OR Re-treatment may be covered at the discretion of the Medical Director and only on a case-by-case basis. In addition to meeting initial criteria for approval, the following questions MUST be addressed in a written appeal letter (please note additional information may be required):

1) Is retreatment necessary due to treatment failure or re-infection?

2) Was the patient compliant to previous therapy (few to no missed doses)? If not, why?

3) Were there any additional factors that led to treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.

4) *Has the patient received education regarding risk behaviors associated with HCV infection?*

5) *Please briefly outline a therapeutic plan for the patient including frequency of clinic visits (in-person or telehealth), adherence counseling, planned duration of therapy and follow-up requirements which are intended to prevent future non-compliance.*

The prescriber shall attest to the following to the best of their knowledge:

1) *The patient is willing and able to comply with the requirements of the proposed retreatment plan;* ***AND***

2) *Any factors that may have led to noncompliance with previous treatment(s) have been addressed*

ATTACHMENT A: HepC Treatment Algorithm and Preferred Regimens

Preferred Regimens Listed Below *(not all regimens available are listed; most cost-effective regimens listed below)*

NOTE: Adult Guidelines have changed substantially; most recommendations are largely genotype non-specific; exceptions are noted in red

ADULT: Treatment naïve (includes those treated in the past with IFN/RBV or IFN + 1st generation protease inhibitors)
No cirrhosis ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks (for GT5/6 and/or HIV/HCV co-infection, 12 weeks is recommended) ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
Compensated cirrhosis, HIV negative ❑ Mavyret 100/40 mg, three (3) tablets daily for 8 weeks ❑ sofosbuvir/velpatasvir 400/100, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
Compensated cirrhosis, HIV positive ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks (for GT3, add weight based RBV if Y93H positive)
ADULT: Treatment experienced (with or without compensated cirrhosis)
Sofosbuvir-based regimen ❑ Mavyret 100/40 mg, three (3) tablets daily for 16 weeks
NS3/4 protease inhibitor inclusive regimen (e.g. Zepatier) ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks (for GT3, if cirrhosis, add weight based RBV if not contraindicated)
Mavyret ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks (if compensated cirrhosis, add weight based RBV)
Vosevi or sofosbuvir + Mavyret ❑ Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 24 weeks
GT 3 only: sofosbuvir/NS5A (e.g. Harvoni) ❑ Vosevi 400/100/100 mg, one tablet daily + weight based RBV for 12 weeks
ADULT: Re-infection of Allograft Liver after Transplant
DAA-treatment naïve, no decompensated cirrhosis ❑ Mavyret 100/40 mg, three (3) tablets daily for 12 weeks ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily for 12 weeks
DAA-treatment experienced, no decompensated cirrhosis ❑ Vosevi 400/100/100 mg, one tablet daily for 12 weeks **IF multiple negative baseline characteristics, consider** ❑ Vosevi 400/100/100 mg, one tablet daily + low dose RBV# for 12 weeks
Treatment naïve, decompensated cirrhosis ❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV# for 12 weeks

Treatment experienced, decompensated cirrhosis (Child-Pugh B or C ONLY)
❑ sofosbuvir/velpatasvir 400/100 mg, one tablet daily + low dose RBV[#] for 24 weeks
ADULT: Decompensated Cirrhosis
No prior sofosbuvir or NS5A failure
❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 12 weeks (low dose RBV[#] recommended for Child-Pugh class C cirrhosis)
❑ sofosbuvir/velpatasvir 400/100 mg daily for 24 weeks (will be approved only for patients with documented ineligibility for RBV)
Prior sofosbuvir or NS5A failure
❑ sofosbuvir/velpatasvir 400/100 mg + weight-based RBV daily for 24 weeks (low dose RBV if Child-Pugh C)

[#] ***low dose ribavirin = 600 mg/day and increase as tolerated***

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

ATTACHMENT B - The following regimens relate ONLY to treatment naïve or interferon-experienced children and adolescents without cirrhosis or with compensated cirrhosis. Please see current AASLD guidelines for other patient types. **Wherever appropriate, brand Mavyret or generic Epclusa (sofosbuvir/pibrentasvir) are the preferred regimens.**

GT	Age (years)	Weight (kg)	Drug/Dose	Weeks
Any	≥3	< 20	Oral pellets: (Mavyret) glecapravir 150/pibrentasvir 60 mg daily	8
		≥20 to <30	Oral pellets: (Mavyret) glecapravir 200/pibrentasvir 80 mg daily	8
		≥20 to <45	Oral pellets: (Mavyret) glecapravir 250 mg/ pibrentasvir 100 mg	8
	≥12 OR	≥45	Oral pellets: (Mavyret) glecapravir 300/pibrentasvir 120 mg/day	8
Any	≥3	<17	Oral pellets: (Epclusa) sofosbuvir 150 mg/velpatasvir 37.5 mg once daily	12
		17 to <30	Oral pellets: (Epclusa) sofosbuvir 200 mg/velpatasvir 50 mg once daily	12
		>30	Oral pellets: (Epclusa) sofosbuvir 400 mg/velpatasvir 100 mg once daily	12

Patient-Provider Agreement – Hepatitis C

I, _____, have been counseled by my healthcare provider on the following:

☐ The importance of not drinking alcohol or using illicit drugs during and after my treatment for Hepatitis C and that I may be required to submit to a drug screen at the discretion of my healthcare provider.

☐ How to avoid being re-infected with Hepatitis C during and after my treatment.

☐ If the patient has been diagnosed with a Substance Use Disorder, the prescriber has counseled/recommend/encouraged the patient to enroll in a treatment program

☐ (**Male**) The importance of using a barrier method of birth control and encouraging my partner to also use birth control.

☐ (**Female**) The importance of using two forms of birth control (one of which must be a barrier method) while being treated. I agree to have pregnancy tests as ordered by my healthcare provider. I also understand that I must tell my healthcare provider if I do become pregnant.

☐ I agree to complete the entire course of treatment, as well as all associated laboratory tests during and after treatment, as ordered by my healthcare provider.

☐ **I agree to IMMEDIATELY notify my prescriber if for any reason I feel that I should stop my treatment. I understand that failure to complete my full course of therapy solely due to actions on my part may result in loss of future coverage through Medicaid.**

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☐ **(Prescriber)** I understand that an SVR12 is requested to verify treatment success and that failure to provide these results to Medicaid may result in disqualification of my patient from future coverage.

☐ ~~**(Prescriber) – FOR PATIENTS with SUD (Substance Use Disorder)** I have confirmed to the best of my ability that my patient is "stable" and actively enrolled in an SUD recovery program.~~

X _____ _____

Your prior authorization request for Aimovig has been approved for 3 months. Additional

therapy may be approved only with clinical documentation showing a 50% reduction in either the number of headache days per month or the overall symptom severity (as measured by MIDAS or HIT-6) compared to baseline.

Patient Signature Date

X _____ _____