September 9, 2021

Re: Hepatitis C Prior Authorization Criteria

Dear Drug Utilization Review Board:

This letter is submitted on behalf of the Virginia Hepatitis Coalition, a newly formed coalition of patients, providers, and community members coming together to realize the elimination of viral hepatitis in the Commonwealth of Virginia.

While the Commonwealth has made great progress in increasing access to treatment for hepatitis C virus (HCV) by simplifying the prior authorization process, prior authorizations continue to be a significant barrier to accessing HCV treatment. Utilization management strategies, including prior authorization, are commonly used to facilitate guideline-adherent therapy of complex and costly therapies. However, as currently employed, they disproportionately restrict access to care for and unintentionally perpetuate stigma against the very communities who need treatment most. **As such, we are requesting that the DUR Board consider removing prior authorizations for preferred direct acting antivirals (DAAs).**

As Virginia continues its fight against the SARS-COV-2 virus, we must not neglect the pre-existing public health crisis of HCV that has been augmented by the opioid epidemic. Governor Northam remains committed to combating the opioid crisis within the Commonwealth. Recent provisional data by the CDC found that the rate of reported drug related deaths in Virginia surpassed the national average by 12.5 percent. Additionally, the Virginia Electronic Disease System (VEDSS) data as of 2020 shows increased acute HCV trends since 2009.[1] To uphold this commitment, infectious diseases associated with injection drug use, like HCV, must not have barriers to treatment. If the Commonwealth is to reduce these rates, access to treatment must be streamlined for all stakeholders.

Fortunately, prescribing HCV treatment for non-cirrhotic and compensated cirrhotic patients has been made easy with the adoption of the *American Association for the Study of Liver Disease* and the *Infectious Disease Society of America* (AASLD/IDSA*) Simplified Treatment Algorithm*. This systematic process walks prescribers step-by-step through evidence-based eligibility criteria, pretreatment assessments, and recommended regimens. The simplicity of the guidelines and pan-genotypic nature of preferred agents makes prior authorizations redundant and obsolete. One study found that when clinical pharmacists managed HCV therapy, sustained viral response (SVR) rates were 95.1%. Pharmacists were able to identify adverse drug reactions and manage 798 drug interactions in 596 patients.[2] This suggests that maximizing upon the clinical expertise of an interdisciplinary team can improve medication safety and clinical outcomes.

[1] Virginia Department of Health. Viral Hepatitis C Rates. https://www.dmas.virginia.gov/media/1386/hepatitis-c-webinar_90820-final.pdf. Published September 8, 2020. Accessed July 19, 2021

[2] Koren DE, Zuckerman A, Teply R, Nabulsi NA, Lee TA, Martin MT. Expanding Hepatitis C Virus Care and Cure: National Experience Using a Clinical Pharmacist-Driven Model. Open Forum Infect Dis. 2019;6(7):ofz316. doi:10.1093/ofid/ofz316

Prior authorizations place an undue administrative burden on prescribers, which takes away time and resources from other life-saving care. A study in Rhode Island found that the complete prior authorization process from prescription to DAA acquisition took 45-120 minutes per patient, longer with a protracted denial and appeals process.[3] Additionally, a 2019 study by the University of Virginia cited the need to have dedicated staff to complete prior authorizations.[4] However, not all healthcare facilities have the resources to allocate staff to this time-consuming task. Ultimately, prior authorizations delay time-sensitive medications for our most vulnerable residents thereby increasing the risk of hepatocellular carcinoma, liver failure, and death.

The current Virginia Medicaid DMAS prior authorization process continues to be confusing for providers as prior authorization criteria vary by insurance plan. Virginia Medicaid Fee-for-Service (FFS) and Managed Care Organization (MCO) plans require submission of a prior authorization form with information about the patient, prescriber, drug, and diagnosis (see pages 4 and 5 for FFS form). Some MCOs also require specific labs, such as a genotype – despite the availability of pan-genotypic medications (see pages 6 through 8 for United Healthcare Community Plan form) – and clinic notes (see pages 9 and 10 for Optima Health form) to be submitted with the prior authorization form. Plans also have differing eligibility requirements. For example, although FFS plans do not restrict who can prescribe HCV treatment, Virginia Premier requires that medications be prescribed by or in consultation with a gastroenterologist, hepatologist, transplant specialist, or infectious disease specialist (see page 132 of the Virginia Premier Prior Authorization Criteria). It is concerning that MCOs are not meeting the legal requirement to provide equal or better care by ensuring that policies are not more restrictive than those set forth by the Commonwealth.

Furthermore, the inconsistency in eligibility and documentation requirements increases the likelihood that the prior authorizations may be denied, further delaying treatment. Fortunately, prior authorizations have been safely removed for preferred HCV medications in 8 state Medicaid plans including California, Indiana, Louisiana, Michigan, New York, Rhode Island, Washington, and Wisconsin. These states recognize that reducing this administrative burden allows prescribers to dedicate more time to clinical services and instead leverage pharmacists' clinical knowledge and drug-drug interaction software used daily for other chronic conditions to confirm the appropriateness of therapy.

Ultimately, the World Health Organization (WHO) has committed to eliminating viral hepatitis globally by 2030. To meet this goal, every nation and every state must remove unnecessary barriers to treatment for an otherwise curable disease. Therefore, we ask this Board to strongly consider removing prior authorizations for preferred DAAs in accordance with the AASLD/IDSA Simplified Treatment Algorithm.

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[3] Duryea P, Habchi J, Sprecht-Walsh S, Thomas AM, Bratberg J, et.al. A Modifiable Barrier to Hepatitis C Virus Elimination in Rhode Island: The Prior Authorization Process for Direct-Acting Antiviral Agents. R I Med J. 2020;103(5):41-44. http://rimed.org/rimedicaljournal/2020/06/2020-06-41-hcv-duryea.pdf. Access July 21, 2021.

[4] Sherbuk J, McManus K, Kemp Knick T, et.al. Disparities in Hepatitis C Linkage to Care in the Direct Acting Antiviral Era: Findings From a Referral Clinic With an Embedded Nurse Navigator Model. Frontiers in Public Health. 2019;7:392. doi:10.3389/fpubh.2019.00362.

We appreciate your actions to date and your attention to this matter. We would welcome the opportunity to discuss these matters further. Please direct all communication to the Virginia Hepatitis Coalition Organizing Committee (vhc-organizing-committee@googlegroups.com).

Sincerely,

Virginia Hepatitis Coalition

CC: Dr. Chethan Bachireddy
Pharmacy & Therapeutics Committee

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

HEPATITIS C ANTIVIRALS: PREFERRED

Preferred Drugs include Mavyret® and sofosbuvir/velpatasvir

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

MEMBER INFORMATION

Last Name:

First Name:

Medicaid ID Number:

Date of Birth: ___ – ___ – ____

Gender: ☐ **Male** ☐ **Female**

Member Age: _____

PRESCRIBER INFORMATION

Last Name:

First Name:

NPI Number:

Phone Number: ___ – ___ – ____

Fax Number: ___ – ___ – ____

DRUG INFORMATION

***The preferred hepatitis C drugs listed below can be prescribed by a generalist without specialty consultation.**

☐ **Mavyret®** ☐ **sofosbuvir/velpatasvir**

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

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Member's Last Name:

Member's First Name:

DIAGNOSIS

☐ Acute or chronic hepatitis C ☐ Compensated cirrhosis ☐ Hepatocellular carcinoma

☐ Decompensated cirrhosis (Child-Pugh score class B or C) ☐ Status post-liver transplant

Choose One: ☐ Treatment initiation ☐ Continuation of therapy, current week: _____

(For your information only) Hepatitis C complexity review: If a patient meets any of these criteria, they may benefit from specialty consultation.

- Patient is coinfected with Hepatitis B
- Patient is pregnant, breastfeeding, or planning to breastfeed
- Patient is taking atazanavir or rifampin
- Patient has severe kidney problems or is on dialysis
- Patient has HIV
- Patient has severe decompensated liver cirrhosis or a Child-Pugh score class B or C

_____ _____

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.
Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services.

The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:
Magellan Medicaid Administration / ATTN: MAP
11013 W. Broad Street, Glen Allen, VA 23060

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UnitedHealthcare Community Plan

Prior Authorization Request Form
Fax Back To: (866) 940-7328
Phone: (800) 310-6826

Specialty Medication Prior Authorization Cover Sheet

(This cover sheet should be submitted along with a Pharmacy Prior Authorization Medication Fax Request Form. Please refer to www.uhcprovider.com for medication fax request forms.)

Patient Information

Patient's Name:

Insurance ID: Date of Birth: Height: Weight:

Address: Apartment #:

City: State: Zip Code:

Phone Number: Alternate Phone: Sex: ☐ Male ☐ Female

Provider Information

Provider's Name: Provider ID Number:

Address: City: State: Zip Code:

Suite Number: Building Number:

Phone Number: Fax number:

Provider's Specialty:

Medication Information

Medication: Quantity: ICD10 Code:

Directions: Diagnosis: Refills:

Physician Signature**: Initial here if DAW:

Physician Signature**: By signing above, the physician is providing the specialty pharmacy with a prescription that can be used to facilitate the dispensing and/or coordination of delivery for the requested medication.

Medication Instructions

Has the patient been instructed on how to **Self-Administer**? ☐ Yes ☐ No

Is this medication a **New Start**? ☐ Yes ☐ No

If continuation please provide the following: Initiation Date: / / Date of Last Dose: / /

Is there documentation of positive clinical response to current therapy? ☐ Yes ☐ No

****Please attach any pertinent clinical information that would pertain to support stated diagnosis. Additional clinical information may be needed depending on your patients plan, including medication(s) previously tried and failed.**

Delivery Instructions

Note: Delivery coordination requires a "**Physician Signature**" above and complete "**Provider Information**" and "**Patient Information**"

Note: All necessary ancillary supplies are provided free of charge to the patient at the time of delivery

Ship to: Physician's Office ☐ Patient's Address ☐ Date medication is needed: / /

Medication Administered: Home Health ☐ Self-Administered ☐ LTC ☐ Physician's Office ☐

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UnitedHealthcare Community Plan

Preferred Hepatitis C Medications - Virginia
PRIOR AUTHORIZATION REQUEST FORM

Please complete this **entire** form and fax it to: **866-940-7328**. If you have questions, please call **800-310-6826.**
This form contains multiple pages. Please complete all pages to avoid a delay in our decision.
Allow at least 24 hours for review.

Section A – Member Information

First Name:	Last Name:	Member ID:
Address:		
City:	State:	ZIP Code:
Phone:	DOB:	Allergies:
Primary Insurance:	Policy #:	Group #:

Is the requested medication □ New or □ Continuation of Therapy? If continuation, list start date: _____
Is this patient currently hospitalized? □ Yes □ No If recently discharged, list discharge date: _____

Section B - Provider Information

First Name:		Last Name: M.D./D.O.		
Address:		City:	State:	ZIP code:
Phone:	Fax:	NPI #:	Specialty:	
Office Contact Name / Fax attention to:				

Section C - Medical Information ***(This form is for Hepatitis C Medications only; for all other drugs please submit a new form)***

Medication 1:	**Strength:**
Directions for use (Include length of therapy):	**Quantity:**
Medication 2:	**Strength:**
Directions for use (Include length of therapy):	**Quantity:**
Diagnosis (Please be specific & provide as much information as possible)**:**	**ICD-10 CODE:**

Is this member pregnant? □ Yes □ No If yes, what is this member's due date? _____

THIS SECTION MUST BE COMPLETED FOR ALL PATIENTS WITH HEPATITIS C
All supporting labs and chart documentation is required for medical review of this request.

Genotype (Must submit supporting lab documentation)
□ Genotype 1 □ Genotype 2 □ Genotype 3 □ Genotype 4 □ Genotype 5 □ Genotype 6
□ Other Genotype (Must Specify): _____

UnitedHealthcare Community Plan

Preferred Hepatitis C Medications - Virginia
PRIOR AUTHORIZATION REQUEST FORM

Member First name:	Member Last name:	Member DOB:

Clinical and Drug Specific Information

□ **Yes** □ **No**	**Has the provider assessed the patient to indicate if they meet the following diagnoses (provider must document what diagnoses the patient meets)?** *(If yes, check which applies)* □ Chronic hepatitis C □ Hepatocellular carcinoma □ Compensated cirrhosis □ Decompensated cirrhosis □ Status post liver transplant
□ **Yes** □ **No**	**Has the provider reviewed the patient readiness criteria below?** • Patient compliance to treatment regimen • Patient does not have Hepatitis B • Patient is not pregnant, breastfeeding or planning to breastfeed • Patient is not taking atazanavir or rifampin • Patient does not have severe kidney problems or is not on dialysis • Patient does not have HIV • Patient does not have severe liver cirrhosis or a Child-Push score class B or C

Physician Signature: _____ **Date:** _____

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OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request.** All other information may be filled in by office staff**; fax to 1-800-750-9692**. No additional phone calls will be necessary **if** all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization will be delayed.**

Hepatitis C Antivirals (PREFERRED)

***The preferred hepatitis C drugs listed below can be prescribed by a generalist without specialty consultation.**

Drug Requested: Select below the drug that applies	
❑ **Mavyret™** (glecaprevir/pibrentasvir)	❑ **sofosbuvir/velpatasvir**

DRUG INFORMATION: Authorization will be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Quantity per Day: _____ **ICD Code, if applicable:** _____

Member Age: _____

CLINICAL CRITERIA: Check below all that apply. All criteria and diagnoses must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Note: The preferred Hepatitis C drugs listed below can be prescribed by a generalist without specialty consultation.

DIAGNOSIS:		
❑ **Acute or Chronic Hepatitis C**	❑ **Compensated cirrhosis**	❑ **Hepatocellular carcinoma**
❑ **Status post-liver transplant**	❑ **Decompensated cirrhosis (Child Pugh score class B or C)**	
❑ **Severe renal impairment (eGFR < 30mL/min/1.73m^2) or end stage renal disease requiring hemodialysis**		

Choose One below:

❑ Treatment initiation ❑ Continuation of therapy, current week: _____

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

(For your information only) Hepatitis C Complexity Review: If a patient meets any of these criteria, they may benefit from specialty consultation.

- Patient is coinfected with Hepatitis B
- Patient is pregnant, breastfeeding, or planning to breastfeed
- Patient is taking atazanavir or rifampin
- Patient has severe kidney problems or is on dialysis
- Patient has HIV
- Patient has severe decompensated liver cirrhosis or a Child-Pugh score class B or C

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***REVISED/UPDATED:** ~~12/27/2017;~~ ~~6/15/2018;~~ ~~8/27/2018;~~ ~~6/14/2019;~~ ~~8/13/2019;~~ ~~12/4/2019;~~ ~~10/26/2020;~~ **12/21/2020**