DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Glecaprevir and Pibrentasvir (Mavyret™) tablets

PRIOR AUTHORIZATION PROGRAM Request Form- Initial Request (12 weeks maximum)

CLIENT'S NAME: _____ ADAP ID:_____

CLIENT'S DATE OF BIRTH_____ ADAP Pharmacy:_____

DC ADAP Policy: Mavyret™ (Glecaprevir and pibrentasvir) is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor and a HCV NS5A inhibitor (pibrentasvir). Mavyret™ is a co-formulated, immediate release bilayer tablet for oral administration that contains glecaprevir 100 mg and pibrentasvir 40 mg in a single tablet.

Mavyret™ requires prior approval for coverage. Allow up to 96 hours for completion of request.

Physician will provide the client's HCV RNA quantitative results 12 weeks after completion of therapy to DC ADAP upon request.

Please Fax (1) Supportive medical letter of necessity (2) Applicable diagnostic test results and (3) Patient signed acknowledgement and Commitment letter (4) Indicate Jurisdiction of ADAP Approval □DC □ MD □VA □WVA

Indication for Use:

MAVYRET™ is a fixed- dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection genotype 1,2,3, 4, 5 or 6 without cirrhosis and with cirrhosis Child Pugh A. It is also indicated in adult patients who have been previously treated with a regimen containing an HCV NS5A inhibitor or a NS3/4A protease inhibitor, but not both.

Criteria for use: ***Please complete and respond to all that apply***

1. Medical Provider is experienced in the care of HIV/hepatitis C infection, or in consultation with an infectious disease specialist or gastroenterologist.

   YES □ NO □
2. Does client have adherence issues with antiretrovirals or other medications?

   YES □ NO □
3. Client is not being treated with medications that are not recommended for use with or contraindicated with glecaprevir or pibrentasvir (refer to product labeling).

   YES □ NO □
4. Client is currently receiving received atazanavir.

   YES □ NO □
5. Client has confirmed clinical diagnosis of HIV co-infection with chronic Hepatitis C.

   YES □ NO □ Hepatitis C genotype_____
6. Client has decompensated liver disease.

   YES □ NO □
7. Client has cirrhosis.

   YES □ NO □
8. Client has had a positive hepatitis C viral load taken within the last 6 months.

   YES □ NO □

9. Client has a FibroSure score of _____. Date of test_____ or biopsy proven fibrosis score of _____, Date _____.
10. Client is treatment naïve

    YES □ NO □
11. Has client been previously treated with NS5A inhibitor without prior treatment with NS3/4A protease inhibitor?

    YES □ NO □
12. Has client been previously treated with NS3/4A protease inhibitor without prior treatment with NS5A inhibitor?

    YES □ NO □
13. Client's anticipated start date of Mavyret™ is_____.
14. Client's anticipated duration of HCV treatment is _____ weeks.

Recommended dosage and administration: The recommended dosage* of Mavyret™ (glecaprevir 100 mg and pibrentasvir 40 mg) is three tablets taken orally once daily with or without food. Treatment duration is based on patient characteristics as described in the following table.

Glecaprevir and Pibrentasvir Treatment Durations based on Patient Characteristics (Reference Only)

	Treatment Duration	
Patient Population	**No cirrhosis**	**Compensated cirrhosis (Child-Pugh A)**
Genotypes 1,2,3,4,5 or 6	8 weeks	12 weeks

	Treatment Duration		
HCV Genotype	**Previously treated with regimen containing**	**No Cirrhosis**	**Compensated cirrhosis (Child-Pugh A)**
1	NS5A inhibitor without prior treatment with NS3/4A protease inhibitor	16 weeks	16 weeks
	NS3/4A protease inhibitor without prior treatment with NS5A inhibitor	12 weeks	12 weeks
1,2,4,5 or 6	PRS[3]	8 weeks	12 weeks
3	PRS[3]	16 weeks	16 weeks

[3]PRS equates with prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin and/or sofosbuvir, but no prior treatment with an HCV NS5A inhibitor or NS3/4A PI

Physician's signature:_____ Date:_____

Physician's Name (Print):_____Phone #:_____Fax #:_____

Fax Completed Form to Clinical Pharmacy Associates, Inc.

Fax: 1 (888) 971-7229 Phone: 1 (800) 745-0434 ext. 150 Attention: Prior Approval Program

Approval: YES □ NO □ Date_____ Initials_____Office use only

Reason for denial_____