AHDC PRIOR AUTHORIZATION PROTOCOL FOR HEPATITIS C TREATMENT

ZEPATIER™ (50mg elbasvir/ 100mg Grazoprevir): tablet (PREFERRED AGENT)

EPCLUSA® (400mg sofosbuvir/100mg velpatasvir)
HARVONI™ (90mg ledipasvir/400mg sofosbuvir)
SOVALDI ™ (sofosbuvir)
OLYSIO™ (simeprivir)
PEG-INTRON™ (peginterferon alfa-2b)
VIEKIRA PAK™ (Ombitasvir 12.5mg , paritaprevir 75mg, ritonavir 50mg tablets and dasabuvir 250mg)
VIEKIRA XR™ (Ombitasvir 12.5mg , paritaprevir 75mg, ritonavir 50mg tablets and dasabuvir 250mg)
TECHNIVIE™ (Ombitasvir 12.5mg , paritaprevir 75mg, ritonavir 50mg tablets)
DAKLINZA™ (Daclatasvir)
RIBAVIRIN tablets or capsules
PEGASYS™ (peginterferon alfa-2a)
ANY OTHER NEWLY MARKETED AGENT for treatment of Hepatitis C

NOTE: WHERE APPLICABLE AND APPROPRIATE FOR GENOTYPE, if the request is for a treatment regimen that includes any other direct acting antiviral (DAA) other than ZEPATIER the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, etc.) for not using ZEPATIER. (Please see TREATMENT SUMMARY BELOW)

All Initial requests MUST meet the following requirements:

1. Patient Age 18 or older, **AND**
2. Patient has **one** of the following:
   - History of liver transplant,

   OR
   - A Metavir fibrosis score of F2-F4 documented by a liver biopsy, **OR**
   - A Metavir fibrosis score of F2-F4 documented by Fibroscan, **OR**
   - A Metavir fibrosis score of F2-F4 documented by a blood test, **AND**
3. Lab testing required before starting treatment (copy of results required):
   - Genotype
   - For Zepatier Genotype 1a requests: testing for the presence of virus with NS5A resistance-associated variant polymorphisms (RAV's) to determine appropriate therapy, **AND**

   within three (3) months of starting treatment (copy of results required):
   - ALT/AST
   - Detectable HCV RNA viral load
   - CBC **(for treatment regimens with interferon or ribavirin, and for ribavirin requests hemoglobin is at least 10g/dL)**
   - GFR
   - HIV
   - TSH (**for interferon regimens**)
   - INR
4. Lab testing **within one (1) month** of starting treatment (copy of results required):
   - Pregnancy test in women of childbearing age **(for treatment regimens with ribavirin)**, with patient agreeing to use two or more forms of contraception, and will have monthly pregnancy tests during therapy,
5. The patient has been counseled on barriers to HCV therapy, alcohol, and illicit drug use. **AND**

6. If the patient has a history of failed treatment due to non-adherence, documentation has been provided that the causes of non-adherence have been corrected or addressed, **AND**

7. The dose that has been prescribed for the patient is consistent with the dosing recommendations listed below, and is prescribed by a specialist in hepatology / gastroenterology / infectious disease/ or transplant, **AND**

8. Presence of previous treatment, treatment regimen and response, **AND**

9. If the patient is cirrhotic, there is documentation of compensated or decompensated disease, **AND**

10. Provider has addressed all potential drug interactions with Hepatitis C regimen (including discontinuation of the interacting drug, dose reduction, or counseling of the patient of the risks associated with the use of both medications), **AND**

11. The beneficiary has agreed to participate in Hepatitis C monitoring, educational and counseling program provided by the health plan, and the beneficiary clearly understands that only one course of therapy is allowed in DC Medicaid lifetime, **AND**

12. The request includes the completed DC Medicaid Beneficiary Disclosure and Commitment to Take Hepatitis C Medications form.

13. The provider has a documented plan to monitor HCV-RNA levels at weeks 4, 8 and 12 and SVR12 to review the outcome of therapy or assess any conditions that warrant discontinuation of therapy.

Treatment for patients with Hepatitis C Genotypes 1, 2, 3, or 4 infections with Hepatocellular Carcinoma: All initial requests must meet the following additional requirement

- Documentation of testing confirming the diagnosis of Hepatocellular Carcinoma through either Imaging Testing (such as Ultrasound, Computed Tomography, Magnetic Resonance Imaging), Laparoscopy, or Biopsy.

Treatment of recurrent HCV infection post liver transplant: (Does not require patient to have advanced to severe fibrosis)

- Documentation of liver transplant including date of transplant

APPROVAL CONSIDERATIONS MUST BE REVIEWED BY MEDICAL DIRECTOR FOR MEDICAL NECESSITY Dose and Duration of Therapy: (SEE TREATMENT SUMMARY THAT FOLLOWS)
Approvals of requests will be consistent with package labeling or current guidelines, at FDA approved dosing. These regimens are subject to change as newly marketed agents become available.

ALL regimens are for 28 day supply per fill (See REFILL CONSIDERATIONS BELOW).

Hepatitis C Treatment Summary

Treatment Naïve-No Cirrhosis		
Genotype	**Treatment Option**	**Duration**
Genotype 1a WITHOUT baseline NS5A RAVs or Genotype 1b, GT4	Zepatier	12 weeks
Genotype 1a WITH baseline NS5A RAVs or if NS5A RAV's not submitted with request, or if genotype subtype not provided	Harvoni (VL < 6,000,000) OR Epclusa (VL > 6,000,000)	8 weeks 12 weeks
Genotype 2, 3, 5 or 6	Epclusa	12 weeks

Treatment Naïve-With Cirrhosis		
Genotype	**Treatment Option**	**Duration**
Genotype 1a WITHOUT baseline NS5A RAVs or Genotype 1b, GT4	Zepatier	12 weeks
Genotype 1a WITH baseline NS5A RAVs or if NS5A RAV's not submitted with request, or if genotype subtype not provided	Epclusa	12 weeks
Genotype 2, 3, 5, or 6	Epclusa	12 weeks

Previously treated patients NO CIRRHOSIS			
Genotype	**Failed Regimen**	**Treatment Option**	**Duration**
Genotype 1a WITHOUT baseline NS5A RAVs or Genotype 1b	Peg/Riba	Zepatier	12 weeks
Genotype 1a WITH baseline NS5A RAVs, or if NS5A RAV's not submitted with request, or if genotype subtype not provided	Peg/Riba	Epclusa	12 weeks
Genotype 1	Sovaldi/Ribavirin +/- Peg	Harvoni with weight based ribavirin	12 weeks
Genotype 1	Incivek, Victrelis, or Olysio + Peg/Riba (NS3 Protease inhibitors)	Epclusa	12 weeks
Genotype 1	Sovaldi/Olysio	Defer treatment	Defer treatment
Genotype 1	NS5A inhibitors	Defer treatment	Defer treatment
Genotype 2	Peg/Riba	Epclusa	12 weeks

Genotype 2	Sovaldi/Riba	Epclusa with weight based ribavirin	12 weeks
Genotype 3	Peg/Riba	Epclusa	12 weeks
Genotype 3	Sovaldi/Riba	Epclusa with weight based ribavirin	12 weeks
Genotype 4	Peg/Riba	Epclusa	12 weeks
Genotype 5 and 6	Peg/Riba	Epclusa	12 weeks

Previously treated patients WITH CIRRHOSIS			
Genotype	**Failed Regimen**	**Treatment Option**	**Duration**
Genotype 1a WITHOUT baseline NS5A RAVs or Genotype 1b	Peg/Riba	Zepatier	12 weeks
Genotype 1a WITH baseline NS5A RAVs, or if NS5A RAV's not submitted with request, or if genotype subtype not provided	Peg/Riba	Epclusa	12 weeks
Genotype 1	Sovaldi/Ribavirin +/- Peg	Harvoni with weight based ribavirin	24 weeks
Genotype 1	Incivek, Victrelis, or Olysio + Peg/Riba (NS3 Protease inhibitors)	Zepatier and weight based ribavirin	12-16 weeks* *16 weeks for GT1a WITH baseline NS5A RAVs
Genotype 1	Sovaldi/Olysio	If immediate treatment is required-testing for NS5A and NS3A RAVs must be completed. If nucleoside-based dual DAA therapy is requested (e.g. sofosbuvir), give with weight based ribavirin, and refer to current guidelines	24 weeks
Genotype 1	NS5A inhibitors	Defer treatment If immediate treatment is required-testing for	If immediate treatment is required, refer to current guidelines

		NS5A and NS3A RAVs must be completed. If nucleoside-based dual DAA therapy is requested (e.g. sofosbuvir), give with weight based ribavirin, and refer to current guidelines	
Genotype 2	Peg/Riba	Epclusa	12 weeks
Genotype 2	Sovaldi/Riba	Epclusa with weight based ribavirin	12 weeks
Genotype 3	Peg/Riba	Epclusa with weight based ribavirin	12 weeks
Genotype 3	Sovaldi/Riba	Epclusa with weight based ribavirin	12 weeks
Genotype 4	Peg/Riba	Epclusa	12 weeks
Genotype 5 and 6	Peg/Riba	Epclusa	12 weeks

Decompensated Cirrhosis including Hepatocellular Carcinoma			
Genotype	**Failed Regimen**	**Treatment Option**	**Duration**
Genotype 1 or 4		Epclusa with weight based ribavirin	12 weeks
Genotype 1 or 4 **Ribavirin ineligible**		Epclusa	24 weeks
Genotype 1 or 4	Sovaldi or NS5A based regimen	Epclusa with weight based ribavirin	24 weeks
Genotype 2 or 3		Epclusa with weight based ribavirin	12 weeks

Patients with Renal Impairment, Including Severe Renal Impairment (CrCl , 30mL/min) or ESRD requiring Hemodialysis			
Genotype	**Creatinine Clearance**	**Treatment Option**	**Duration**
All Genotypes	CrCl 30mL/min-80mL/min	No dosage adjustment is required for this level of renal impairment, see charts above	No dosage adjustment is required for this level of renal impairment, see charts above
Genotype 1a, 1b or 4	CrCl < 30ML/min for	Zepatier	12 weeks

	treatment BEFORE kidney transplant		
Genotype 2, 3, 5 or 6	CrCl < 30ML/min for treatment BEFORE kidney transplant	Peg + dose adjusted ribavirin (200mg daily)	

Post-Transplant, Including Compensated Cirrhosis		
Genotype	**Treatment Option**	**Duration**
Genotype 1 or 4 Naïve or Experienced All levels of fibrosis including compensated cirrhosis	Harvoni with weight based ribavirin	12 weeks
Genotype 1 or 4 Treatment Naïve and with compensated disease and are **ribavirin ineligible**	Harvoni	24 weeks
Genotype 2 and 3	Sovaldi and Daklinza with low initial dose ribavirin (600mg and increased as tolerated)	12 weeks
Genotype 2 and 3 **ribavirin ineligible**	Sovaldi and Daklinza with low initial dose ribavirin (600mg and increased as tolerated)	24 weeks

Post-Transplant, Decompensated Cirrhosis		
Genotype	**Treatment Option**	**Duration**
Genotype 1 or 4 Naïve or Experienced All levels of fibrosis and decompensated cirrhosis	Harvoni with low initial ribavirin (600mg and increased as tolerated)	12 weeks
Genotype 1 or 4 Treatment Naïve and with compensated disease and are **ribavirin ineligible**	Harvoni	24 weeks
Genotype 2	Sovaldi and ribavirin (initial dose 600mg/day, increased monthly by 200mg/day as tolerated to weight based dose)	24 weeks

Continuation of therapy to be completed by Health Plan or Case Management

REFILL CONSIDERATIONS:

1. The health plan will reach out to all members approved for treatment, with the intent to educate and ensure successful completion of the regimen.
2. The health plan will guide and reinforce compliance through ongoing interaction with the member.
3. Repeat viral load at treatment week 4, week 8, week 12 and 12 weeks following completion of therapy to establish SVR.
4. For Zepatier requests, repeat ALT/AST should be completed at week 8 if on 12 weeks of therapy, and also at week 12 (if patient is on 16 weeks of therapy).

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