Pharmacy Benefit Determination Policy

Policy Subject:	Hepatitis C Agents	**Dates:**	
Policy Number:	SHS PBD38	**Effective Date:**	June 26, 2014
Classification:	Anti-virals: Hepatitis C	**Revision Date:**	March 21, 2018
Policy Type:	☐ **Medical** ☒ **Pharmacy**	**Approval Date:**	February 27, 2019
Department:	Pharmacy	**Next Review Date:**	February 2020

Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Hepatitis C Agents through the Medical/Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

NA

Clinical Determination Guidelines:

Document the following with chart notes

A. Hepatitis C
   1. Age > 18 years
   2. Prescribing physician: Infectious disease, gastroenterologist, hepatologist
   3. Diagnosis and severity
      a. Detectable HCV RNA
      b. Documented genotype
      c. Fibrosis score:
         - METAVIR score: F1 and above
   4. Patient lifestyle
      a. Negative urine and blood drug screening (10 panel) within a month of treatment initiation
      b. Alcohol abstinence attestation

5. Treatment option(s)
   a. Preferred: Meets below (go to https://www.hcvguidelines.org/)
      - FDA approved for specific genotype, treatment history and cirrhosis status
      - Preferred agent based on current Pharmacy and Therapeutics Committee recommendation.
   b. Non-preferred: Contraindication to preferred treatment option(s)
6. Dosage regimen (go to https://www.hcvguidelines.org/)

B. Exclusions
1. General: Non-FDA approved indications, dosage, frequency, duration, or routes of administration
2. Renal impairment:
   a. CrCl < 30 ml/min: Sovaldi
   b. CrCl < 20 ml/min: Harvoni
3. Hepatic impairment
   a. Moderate to severe hepatic impairment (Child-Pugh class B or C): Zepatier, Viekira Pak, Technivie
   b. Severe hepatic impairment (Child-Pugh class C): Epclusa, Mavyret
4. Contraindicated drug interactions (go to https://www.hep-druginteractions.org/)
5. Drug specific: Ribavirin
   a. Pregnancy: pregnant/breast-feeding women, men with pregnant female partners
   b. Comorbid or history of disease: severe pre-existing cardiac disease, severe hepatic dysfunction or decompensated cirrhosis; hemoglobinopathies

Appendix I: METAVIR Fibrosis Score & Activity Score

Fibrosis	Score	Activity	Score
No fibrosis	F0	No activity	A0
Portal fibrosis without septa	F1	Mild activity	A1
Few Septa	F2	Moderate activity	A2
Numerous septa w/o cirrhosis	F3	Severe activity	A3
Cirrhosis	F4		

Appendix II: Monitoring & Patient Safety

Drug	Adverse Reaction	Monitoring Parameters	REMS
Daklinza (daclatasvir) Epclusa (sofosbuvir + velpatasvir Harvoni (ledipasvir + sofosbuvir) Mavyret (glecaprevir + pibrentasvir) Zepatier (elbasvir + grazoprevir)	• CNS: Fatigue (11-18%) HA (9-17%) • GI: Nausea (6-11%)	• Labs: LFT, Cr (Pre,during), HCV-RNA (pre & post)	None needed
Viekira Pak	• CNS: Fatigue (34%), insomnia (5-26%) • Derm: Hypersensitivity rxns (7-24%), pruritus (7%-18%) • GI: nausea (7-18%) • Neuro/MSK: Weakness (4-14%)	• Labs: ALT/SGPT (baseline & during), HCV-RNA (pre & post)	None needed
Technivie (ombitasvir, paritaprevir, ritonavir)	• CNS: Fatigue (7-15%), Asthenia 25-29%), insomnia (5-13%) • GI: nausea (9-14%)	• Labs: ALT/SGPT (baseline & during), HCV-RNA (pre & post)	None needed
Sovaldi (sofosbuvir)	• CNS: Fatigue (30-59%), HA (24-44%), Insomnia (15-29%) • Derm: Pruritus (11-27%), skin rash (8-18%) • GI: Nausea (22-34%), diarrhea (9-12%) • Hem/Onc:↓Hgb (6-23%), anemia (6-21%) • Neuro/MSK: Weakness (5-21%), myalgia (6-14%) • Resp: Flu-like Sx (6-16%) • Misc: Fever (4-18%),	• Labs: LFT, Cr (Pre,during), HCV-RNA (pre & post) • Pregnancy test: pre & monthly < 6 mons post d/c	None Needed

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References and Resources:

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3. Ombitasvir + paritaprevir plus ritonavir w or w/o ribavirin in treatment-naive and treatment-experienced patients with genotype 4 chronic hepatitis C virus infection (PEARL-I): a randomized, open-label trial. Lancet. 2015.
4. Diagnosis of cirrhosis by transient elastography (FibroScan). *Gut* 2006;55:403-408.
5. AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on March 2018
6. Zepatier oral tablets (elbasvir/grazoprevir) Package Insert. Merck & Co. Inc. 2016.
7. Practice of FibroTest for Hepatitis C Accessed from BioPredictive site on 2/9/17 http://www.biopredictive.com/intl/physician/fibrotest-for-hcv/view?set_language=en
8. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations; Department of Veterans Affairs National Hepatitis C Resource Center and the HIV, Hepatitis and Related Conditions Program in the Office of Specialty Care Services October 18, 2017
9. University of Liverpool HEP Drug Interactions: https://www.hep-druginteractions.org/ accessed March 2018

Approved By:

2/27/19

Peter Graham, MD – PHP Executive Medical Director — Date

4/27/19

Human Resources (Kurt Batteen) — Date