STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN Morgantown, WV 26506
Fax: 1-800-531-7787 Phone: 1-800-847-3859

Office of Pharmacy Services Prior Authorization Criteria for Chronic Hepatitis C Virus (HCV) Therapy

Effective 10/01/2019

Patient - Prescriber Agreement Form
Prior Authorization Request Form
Prior Authorization Continuation Request Form
HepC Treatment Algorithm (Attachment A) and Preferred Regimens

Criteria for Approval

1) Must be prescribed by, or in conjunction* with, a gastroenterologist, hepatologist or infectious disease physician;
   *Consults are permitted, including those through Project Echo, however contact information for all physicians involved must be submitted with the request for prior authorization.
   AND

2) All prior authorization documentation, including the Patient-Prescriber Agreement must be complete or the request will be denied; **AND**

3) Patient must meet the minimum FDA approved age requirement as specified in the package label; **AND**

4) If the patient has been newly diagnosed with chronic hepatitis C in the past 12 months, then the diagnosis must be confirmed by submitting the results of two (2) viral RNA tests taken at least 6 months apart with the prior authorization request. ALL patients must have at least one viral RNA test result documented within 6 months of the start of therapy; **AND**

5) Prescriber must attest that to the best of their knowledge the patient has abstained from the use of illicit drugs (excluding marijuana) and has not abused alcohol for a minimum of **three (3) months**; **AND**

6) Documentation must be submitted indicating the patient has (or is) receiving vaccination for HepA & HepB.

7) 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.**

Duration of Approval

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in Attachment A located at the end of this document. Initial approvals will be for a maximum of 12 weeks and require submission of the starting HCV RNA level.

- Additional therapy beyond 12 weeks may be requested by completing the Prior Authorization Continuation Request Form and is approvable only after receipt of a viral load indicating treatment efficacy as suggested by AASLD guidelines*.

- Emergency fills will NOT be granted under any circumstance.

***** AASLD guidelines recommend that quantitative HCV viral load testing be done after 4 weeks of therapy (TW4). If HCV RNA is detectable at week 4 of treatment, repeat quantitative HCV RNA viral load testing is recommended after 2 additional weeks of treatment. If the quantitative HCV viral load has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended.

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PRIOR AUTHORIZATION MAY BE DENIED FOR THE FOLLOWING REASONS

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

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

3) Evidence exists that the patient has abused any illicit substance (excluding marijuana) or alcohol in the past three (3) months. Significant alcohol consumption should be noted and addressed before requesting coverage.

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

5) Requests for continuation of coverage beyond 12 weeks will be denied if the patient's HCV RNA level has increased by greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week 6 (or thereafter) or if the prescriber has not submitted a viral load prior to treatment week 12. **Denial of continuation due to lack of efficacy does not prevent the approval of an alternative regimen if indicated by AASLD guidelines.**

6) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable quantitative HCV RNA levels measured at 12 weeks following completion of therapy (SVR12). If RNA levels have not been submitted, then it will be assumed that therapy was successful.
Re-infection will not be covered except at the discretion of the Medical Director and only on a case-by-case basis.

7) Lost or stolen medication replacement request will not be authorized.

ATTACHMENT A: HepC Treatment Algorithm and Preferred Regimens

(not all regimens available are listed; most cost-effective regimens listed below)

❑	**Genotype 1a**
	❑ Treatment naïve, no cirrhosis, HCV viral load < 6 million copies/ml→ Regimen 1 or 12 (HIV negative only) or 7 (only if negative for NS5A resistance associated polymorphisms) or 5
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥ 6 million→ Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic→ Regimen 1 or 7 (only if negative for NS5A resistance associated polymorphisms) or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin +NS3 protease inhibitor, no prior NS5A, no sofosbuvir), no cirrhosis → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor, no prior NS5A, no sofosbuvir), compensated cirrhosis, Child-Pugh A ONLY → Regimen 9 (only if negative for NS5A resistance associated polymorphisms¥) or 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 2
	❑ Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY →Regimen 3 or 10

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	❑ Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier), dasabuvir (Viekira), pibrentasvir (Mavyret) and daclatasvir (Daklinza), including those given with a NS3/4A protease inhibitor, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 10
	❑ Re-infection of allograft liver after transplant, no cirrhosis →Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	**Genotype 1b**
	❑ Treatment naïve, no cirrhosis, HCV viral load <6 million copies/ml → Regimen 1 or12 (HIV negative only) or 7 or 5
	❑ Treatment naïve, no cirrhosis, HCV viral load ≥6 million → Regimen1 or 7 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 2 or 7 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), not cirrhotic → Regimen 1 or 7 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin ONLY), compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 7 or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, no cirrhosis → Regimen 9 or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin + protease inhibitor), no prior NS5A, no prior sofosbuvir, compensated cirrhosis, Child-Pugh A ONLY → Regimen 9 or 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), no cirrhosis → Regimen 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin +/- PEG-IFN OR simeprevir, no NS5A), compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced, any NS5A inhibitor but NO NS3/4A protease inhibitor (prior therapy ONLY with daclatasvir+sofosbuvir, ledipasvir+sofosbuvir or sofosbuvir +velpatasvir), no cirrhosis or compensated cirrhosis, Child-Pugh A ONLY → Regimen 3 or 10
	❑ Treatment experienced, any NS5A inhibitor (ledipasvir (Harvoni), velpatasvir (Epclusa/Vosevi), elbasvir (Zepatier), dasabuvir (Viekira), pibrentasvir (Mavyret) and daclatasvir (Daklinza), including those given with a NS3/4A protease inhibitor, non-cirrhotic or compensated cirrhosis (Child-Pugh A ONLY)→ Regimen 10
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	**Genotype 2**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (sofosbuvir + ribavirin) → Regimen 5 or 2
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 or if RBV ineligible**ONLY→ Regimen 4
	❑ Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis, → Regimen 15 or 6 or 2
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
❑	**Genotype 3**

	❑ Treatment naïve, no cirrhosis→ Regimen 1 or 5
	❑ Treatment naïve, with cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H neg → Regimen 5 or 3
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis, Y93H positive → Regimen 6 or 3
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY → Regimen 6 or 3, if RBV ineligible only** → Regimen 8
	❑ Treatment experienced (any direct acting antiviral including NS5A), no or compensated cirrhosis, Child-Pugh A ONLY → Regimen 10; if prior NS5A AND cirrhosis → Regimen 11
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A failure → Regimen 6 or, if RBV ineligible ONLY** **→ Regimen 4
	❑ Decompensated cirrhosis, prior sofosbuvir or NS5A failure → Regimen 16 (low dose ribavirin if Child-Pugh C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis → Regimen 15 or 6 or 2
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis → Regimen 15 or 6
❑	**Genotype 4**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 7 or 5
	❑ Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 7 or 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), no cirrhosis → Regimen 1 or 7 (only if prior virologic relapse after PEG-IFN therapy) or 5
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis, Child-Pugh A ONLY→ Regimen 5 or 7 (only if prior virologic relapse after PEG-IFN therapy) or Regimen 2
	❑ Treatment experienced (any direct acting antiviral including NS5A), with or without compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A →Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
❑	**Genotype 5**
	❑ Treatment naive, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis, Child-Pugh A ONLY → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (any DAA including NS5A), with no or compensated cirrhosis (Child-Pugh A ONLY) → Regimen 10
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A →Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
	❑ Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
	❑ Re-infection of allograft liver after transplant, no cirrhosis → Regimen 2
	❑ Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
	❑ Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14
❑	**Genotype 6**
	❑ Treatment naïve, no cirrhosis → Regimen 1 or 5
	❑ Treatment naïve, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (PEG-IFN + ribavirin), without cirrhosis → Regimen 1 or 5
	❑ Treatment experienced (PEG-IFN + ribavirin), compensated cirrhosis (Child-Pugh A ONLY) → Regimen 5 or 2
	❑ Treatment experienced (any direct acting antiviral, including NS5A) with or without compensated cirrhosis (Child-Pugh A

	ONLY)→ Regimen 10
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A→Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	Decompensated cirrhosis, no prior sofosbuvir or NS5A, ribavirin ineligible**→ Regimen 4
❑	Decompensated cirrhosis, prior treatment with sofosbuvir or NS5A → Regimen 6 (low dose ribavirin if Child-Pugh Class C)
❑	Re-infection of allograft liver after transplant, no cirrhosis Regimen 2
❑	Re-infection of allograft liver after transplant, compensated cirrhosis (Child-Pugh A ONLY) → Regimen 13
❑	Re-infection of allograft liver after transplant, decompensated cirrhosis (Child-Pugh B and C only) → Regimen 14

Preferred REGIMENS Key for HepC Treatment Algorithm (Attachment A):

1. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 56 days (8 weeks) ☐
2. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 84 days (12 weeks) ☐
3. Mavyret (glecaprevir/pibrentasvir) 100/40 mg; three (3) tablets daily for 112 days (16 weeks) ☐
4. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 168 days (24 weeks) ☐
5. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily for 84 days (12 weeks) ☐
6. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
7. Zepatier (elbasvir/grazoprevir) 50/100 mg daily for 84 days (12 weeks) ☐
8. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + sofosbuvir 400 mg daily for 84 days (12 weeks) ☐
9. Zepatier (elbasvir/grazoprevir) 50/100 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
10. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily for 84 days (12 weeks) ☐
11. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) 400/100/100 mg, one tablet daily + weight-based ribavirin for 84 days (12 weeks) ☐
12. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily for 56 days (8 weeks) ☐
13. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + weight-based ribavirin for 84 days (12 weeks) ☐
14. Harvoni (ledipasvir/sofosbuvir) 90/400 mg daily + low dose ribavirin for 84 days (12 weeks) ☐
15. Daklinza^(daclatasvir) 60 mg plus Sovaldi (sofosbuvir) 400 mg daily + low initial dose of ribavirin for 84 days (12 weeks) ☐
16. Epclusa (sofosbuvir/velpatasvir) 400/100 mg daily + weight-based ribavirin for 168 days (24 weeks) ☐

^ Dose of Daklinza (daclatasvir) MUST BE ADJUSTED with certain co-administered drugs (reduced to 30 mg daily with concurrent CYP3A4 inhibitors and increased to 90 mg daily with concurrent moderate CYP3A4 inducers)
# low dose ribavirin = 600 mg/day and increase as tolerated
¥ Genotype 1a polymorphisms at amino acid positions 28, 30, 31, or 93

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

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General Mechanism of Action for Available Agents

- **Daklinza** (daclatasvir) is an HCV NS5A inhibitor.
- **Epclusa** (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor and velpatasvir, an HCV NS5A inhibitor.
- **Harvoni** (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor.
- **Mavyret** (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of patients with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult patients with HCV **genotype 1** infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. **(NOTE: GT1 is the only genotype that can be retreated with Mavyret after previous NS5A or NS3/4A protease inhibitor therapy)**
- **Olysio** (simeprevir) is an HCV NS3/4A protease inhibitor.
- **Sovaldi** (sofosbuvir) is an HCV nucleotide analog NS5B polymerase inhibitor.
- **Technivie** (ombitasvir/paritaprevir) is a fixed-dose combination of ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.
- **Viekira XR** (dasabuvir/ombitasvir/paritaprevir) includes dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor, ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.
- **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, and is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:
    - genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
    - genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.

    *** **Additional benefit of VOSEVI over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor**.
- **Zepatier** (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor.

References

1) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://hcvguidelines.org/ Accessed September 05, 2017.
2) LexiComp Clinical Drug Information – Accessed November 22, 2016.
3) Epclusa [package insert]. Foster City, CA; Gilead, June 2016.
4) Viekira XR™ [package insert]. Abbvie, Revised 7/2016
5) Daklinza [package insert]. Bristol-Myers Squibb Company, Feb 2016.

6) Sovaldi [package insert]. Foster City, CA; Gilead, August 2015.
7) Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. April 2015.
8) Technivie® [package insert]. Abbvie, Revised 7/2015
9) Viekira Pak™ [package insert]. Abbvie, Revised 4/2016
10) Zepatier [package insert]. Merck, January, 2016.
11) Harvoni [package insert]. Foster City, CA; Gilead, February 2016.
12) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.
13) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician.* 2006 Sep 1;74(5):756-762.
14) Mavyret [package insert]. Abbvie. August, 2017.

Attachment A Change Log:

Ver 2016.3C Created by Laureen Biczak (GHS) and edited by BMT 6/7/2016
Ver 2016.4D Created by Laureen Biczak (CHC)
Ver 2016.4E Created by Laureen Biczak (CHC)
Ver 2017.1G Created by Laureen Biczak (CHC) 08/31/2017
Ver 2017.2H_1b_V3 Created by Laureen Biczak (CHC) 10/09/2017 and edited by BMT 11/16/2017
Ver 2018.1A Edited by Laureen Biczak (CHC) 12/20/17
Ver 2019.3b Created by Brian Thompson (BMS) 9/06/2019 (Major changes below)

1) Removed fibrosis requirement
2) Require contact info for consults. All requests must be from a specialist or in consult with a specialist.
3) Excluded marijuana from drug abstinence requirement.
4) Require 2 RNA tests to prove chronic HepC if the patient has been diagnosed in the last 12 months. At least one test within 6 months of the start of therapy for all patients.
5) Require HepA and HepB vaccinations to be started if the patient doesn't already have them.