

Member Name: \_\_\_\_\_ Member ID: \_\_\_\_\_ Member DOB: \_\_\_\_\_

Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

**Horizon NJ Health**  
***Hepatitis C Treatment – Medical Necessity Request***

1. Which drugs are being requested (please include the requested dose, directions and length of therapy for each)?

- |   |                                   |                                   |                                   |                                       |                                       |
|---|-----------------------------------|-----------------------------------|-----------------------------------|---------------------------------------|---------------------------------------|
| <input type="checkbox"/> Pegasys: _____               | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> PegIntron: _____             | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Ribavirin: _____             | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Sovaldi 400mg once daily     | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Harvoni 90-400mg once daily  | <input type="checkbox"/> 8 weeks  | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks     | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Viekira Pak                  | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Daklinza 60mg once daily     | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Zepatier 50-100mg once daily | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Epclusa 400-100mg once daily | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Mavyret 300-120mg daily      | <input type="checkbox"/> 8 weeks  | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks     | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Vosevi                       | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |
| <input type="checkbox"/> Other: _____                 | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ |                                       |

2. What is the member's weight? \_\_\_\_\_ lbs \_\_\_\_\_ kg

3. What is the member's height? \_\_\_\_\_ feet \_\_\_\_\_ inches

4. What is the diagnosis?  **Hepatitis C** - Please indicate genotype:  1a  1b  2  3  4  5  6  **Other:** \_\_\_\_\_

*\*Please submit lab documentation of genotype.*

5. What date did the member start or is planning to start therapy? \_\_\_\_\_

6. Has the member previously been treated for Hepatitis C? **Yes or No**

- If yes, what drugs was the member treated with and what dates were they filled (if dates unavailable, provide length of therapy)? \_\_\_\_\_

- Please indicate member's treatment response:

Null-responder  Relapser  Partial Responder  Other (please specify): \_\_\_\_\_

- Please provide the HCV RNA levels in IU/mL from previous therapy: \_\_\_\_\_

- Is the member currently in the middle of therapy? **Yes or No** - If yes, how many weeks has the member received? \_\_\_\_\_

7. Does member have cirrhosis?  No cirrhosis

Compensated cirrhosis

Decompensated cirrhosis

- What is the Child Turcotte Pugh (CTP) class:  A (5-6 points)  B (7-9 points)  C (10-15 points)

8. For members with cirrhosis, please provide the following scores regarding the member's level of fibrosis. *\*Please fax over biopsy/lab documentation.*

• Metavir fibrosis score:  0 (No fibrosis)  1  2  3  4

• Fibroscan score: \_\_\_\_\_

• FibroSURE score: \_\_\_\_\_

• APRI score: \_\_\_\_\_

• FIB-4 (Fibrosis-4 index): \_\_\_\_\_

9. Has the member been tested for the Hepatitis B virus? **Yes or No** *\*Please fax over lab documentation of Hepatitis B testing that assesses Hepatitis B surface antigen (HBsAg), Hepatitis B surface antibody (anti-HBs), and antibodies to Hepatitis B core antigen (anti-HBc).*

10. Has the member had an organ transplant? **Yes or No**

*\*If yes, date of transplant \_\_\_\_\_ Which organ? \_\_\_\_\_*

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

**\*Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: \_\_\_\_\_ Member ID: \_\_\_\_\_ Member DOB: \_\_\_\_\_

Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

11. Does the member have hepatocellular carcinoma?

**Yes – Please answer the following:**

- Is the member awaiting liver transplantation? **Yes or No**

- What date is the liver transplant scheduled for: \_\_\_\_\_

**No**

12. Which specialist is prescribing the medication(s):  Gastroenterology,  Infectious Disease,  Hepatology,  Liver Transplant,

Other: \_\_\_\_\_

13. What is the member's estimated glomerular filtration rate (eGFR) \_\_\_\_\_ (ml/min)?

*\*Please submit documentation from within the past 30 days*

14. Please provide the current HCV RNA level taken within the past 90 days and date taken.

- Level: \_\_\_\_\_ IU/ml

Date Taken: \_\_\_\_\_

*\*Please fax over lab report confirming this level.*

15. Is the member eligible to receive ribavirin?

**Yes**

**No** – Please provide the specific reason why the member cannot take ribavirin. Please submit a copy of lab work from within the past 30 days if applicable for the reason provided.

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16. **Please submit a copy of all resistance testing results** (e.g., NS5A resistance-associated substitutions (RAS), Y93H, Q80 polymorphism, etc.)

17. Please fax over any additional labs or clinical information pertaining to the member's diagnosis.

*Continued on p. 3*

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

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Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

**24. For each drug being requested, please indicate if member has any of the listed conditions or is taking any of the listed drugs.**

<u>Zepatier</u>	<u>Mavyret</u>	<u>Harvoni</u>
<input type="checkbox"/> Moderate/severe hepatic impairment (CTP Class B/C) <input type="checkbox"/> Atazanavir (e.g., Evotaz, Reyataz) <input type="checkbox"/> Atorvastatin >20mg/day <input type="checkbox"/> Bosentan <input type="checkbox"/> Carbamazepine, phenytoin <input type="checkbox"/> Cobicistat (Stribild, Evotaz, Prexcobix, Genvoya, Tybost) <input type="checkbox"/> Cyclosporine <input type="checkbox"/> Darunavir (e.g., Prezcobix, Prezista) <input type="checkbox"/> Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo) <input type="checkbox"/> Etravirine (e.g., Intelence) <input type="checkbox"/> Fosamprenavir (e.g., Lexiva) <input type="checkbox"/> Indinavir (e.g., Crixivan), <input type="checkbox"/> Oral Ketoconazole <input type="checkbox"/> Lopinavir (e.g., Kaletra) <input type="checkbox"/> Modafinil <input type="checkbox"/> Nafcillin <input type="checkbox"/> Nelfinavir (e.g., Viracept), <input type="checkbox"/> Nevirapine (e.g., Viramune, Viramune XR) <input type="checkbox"/> Rifampin <input type="checkbox"/> Ritonavir (e.g., Kaletra, Norvir, Technivie, Viekira Pak, Viekira XR) <input type="checkbox"/> Rosuvastatin >10mg/day <input type="checkbox"/> Saquinavir (e.g., Fortovase, Invirase) <input type="checkbox"/> St. John's Wort <input type="checkbox"/> Tipranavir (e.g., Aptivus) <input type="checkbox"/> NONE	<input type="checkbox"/> Severe hepatic impairment (CTP Class C) <input type="checkbox"/> Atazanavir (e.g., Evotaz, Reyataz) <input type="checkbox"/> Atorvastatin <input type="checkbox"/> Carbamazepine <input type="checkbox"/> Darunavir (e.g., Prezcobix, Prezista) <input type="checkbox"/> Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo) <input type="checkbox"/> Ethinyl estradiol (e.g., combined oral contraceptives) <input type="checkbox"/> Etravirine (e.g., Intelence) <input type="checkbox"/> Lopinavir (e.g., Kaletra) <input type="checkbox"/> Lovastatin <input type="checkbox"/> Requiring stable doses of Cyclosporine >100mg/day <input type="checkbox"/> Rifampin <input type="checkbox"/> Ritonavir (e.g., Kaletra, Norvir, Technivie, Viekira Pak, Viekira XR) <input type="checkbox"/> Rosuvastatin >10 mg/day <input type="checkbox"/> Simvastatin (e.g., Juvisync, Vytorin, Zocor) <input type="checkbox"/> St. John's wort ( <i>Hypericum perforatum</i> ) <input type="checkbox"/> NONE	<input type="checkbox"/> Amiodarone without cardiac monitoring <input type="checkbox"/> Carbamazepine <input type="checkbox"/> Elvitegravir/cobicistat/emtricitabine/ tenofovir disoproxil fumarate (Stribild) <input type="checkbox"/> H2-antagonists that exceed doses comparable to Famotidine >40mg twice daily (i.e., Cimetidine >1600mg /day, Nizatidine >300mg/day, Ranitidine >600mg/day) <input type="checkbox"/> Oxcarbazepine <input type="checkbox"/> Phenobarbital <input type="checkbox"/> Phenytoin <input type="checkbox"/> Proton Pump Inhibitors that exceed doses comparable to Omeprazole >20mg daily (i.e., Dexlansoprazole >60mg/day, Lansoprazole >30mg/day, Pantoprazole >40mg/day, Esomeprazole >40mg/day, Rabeprazole >20mg/day) <input type="checkbox"/> Rifabutin, rifampin, or rifapentine <input type="checkbox"/> Rosuvastatin (Crestor) <input type="checkbox"/> Simeprevir (Olysio) <input type="checkbox"/> St. John's Wort ( <i>Hypericum perforatum</i> ) <input type="checkbox"/> Tipranavir (Aptivus) <input type="checkbox"/> NONE
<u>Ribavirin</u> <input type="checkbox"/> Pregnancy <input type="checkbox"/> Member with pregnant partner <input type="checkbox"/> Hemoglobinopathies (e.g., thalassemia major, sickle-cell anemia) <input type="checkbox"/> Didanosine (Videx, Videx EC) <input type="checkbox"/> Stavudine (Zerit, Zerit XR) <input type="checkbox"/> Zidovudine (Retrovir, Combivir, Trizivir) <input type="checkbox"/> Autoimmune Hepatitis (Rebetol only) <input type="checkbox"/> Creatinine Clearance <50ml/min (Rebetol only) <input type="checkbox"/> NONE	<u>Epclusa</u> <input type="checkbox"/> Amiodarone without cardiac monitoring <input type="checkbox"/> Carbamazepine, phenytoin, phenobarbital, oxcarbazepine <input type="checkbox"/> Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo) <input type="checkbox"/> Etravirine (i.e, Intelence) <input type="checkbox"/> Famotidine >40mg twice daily, Cimetidine >1600mg /day, Nizatidine >300mg/day, Ranitidine >600mg/day <input type="checkbox"/> Nevirapine <input type="checkbox"/> Proton Pump Inhibitor: provide name and strength: _____ <input type="checkbox"/> Rifabutin, rifampin, rifapentine <input type="checkbox"/> Rosuvastatin >10mg/day <input type="checkbox"/> St. John's Wort <input type="checkbox"/> Tenofovir disoproxil fumarate (e.g., Atripla, Complera, Stribild, Truvada, Viread) if eGFR is <60mL/min <input type="checkbox"/> Tipranavir (e.g., Aptivus) <input type="checkbox"/> Topotecan <input type="checkbox"/> NONE	<u>Vosevi</u> <input type="checkbox"/> Amiodarone without cardiac monitoring <input type="checkbox"/> Atazanavir (e.g., Evotaz, Reyataz) <input type="checkbox"/> Carbamazepine, phenytoin, phenobarbital, oxcarbazepine <input type="checkbox"/> Cyclosporine <input type="checkbox"/> Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo) <input type="checkbox"/> Etravirine (i.e, Intelence) <input type="checkbox"/> H2-antagonists that exceed doses comparable to Famotidine >40mg twice daily (i.e., Cimetidine >1600mg /day, Nizatidine >300mg/day, Ranitidine >600mg/day) <input type="checkbox"/> Lopinavir (e.g., Kaletra) <input type="checkbox"/> Nevirapine <input type="checkbox"/> Omeprazole >20mg daily <input type="checkbox"/> Pitavastatin <input type="checkbox"/> Pravastatin >40mg/day <input type="checkbox"/> Rifabutin, rifampin, rifapentine <input type="checkbox"/> Rosuvastatin <input type="checkbox"/> St. John's Wort ( <i>Hypericum perforatum</i> ) <input type="checkbox"/> Tipranavir (e.g., Aptivus) <input type="checkbox"/> NONE

Physician office's signature\* \_\_\_\_\_ Print Name \_\_\_\_\_

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Physician Name: \_\_\_\_\_ Physician Phone #: \_\_\_\_\_ Specialty: \_\_\_\_\_

Physician Fax #: \_\_\_\_\_ Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

24, cont'd. For each drug being requested, please indicate if member has any of the listed conditions or is taking any of the listed drugs.

**Sovaldi**

- Amiodarone without cardiac monitoring
- Carbamazepine
- Oxcarbazepine
- Phenobarbital
- Phenytoin
- Rifabutin, rifampin, or rifapentine
- St. John's Wort (Hypericum perforatum)
- Tipranavir (Aptivus)
- NONE

**Pegasys, Peg-Intron, Intron-A**

- Autoimmune Hepatitis
- Hepatic decompensation or decompensated liver disease
- NONE

**Viekira Pak**

- Moderate hepatic impairment (CTP class B)
- Severe hepatic impairment (CTP Class C)
- HIV-coinfected members who are not taking antiretroviral therapy
- Alfuzosin
- Carbamazepine, phenytoin, phenobarbital
- Darunavir (e.g., Prezcobix, Prezista),
- Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo)
- Ergotamine, dihydroergotamine, ergonovine, methylergonovine
- Ethinyl estradiol-containing medications (e.g., combined oral contraceptives)
- Gemfibrozil
- Ketoconazole >200mg/day
- Known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome)
- Lopinavir/ritonavir (e.g., Kaletra)
- Lovastatin, simvastatin
- Omeprazole >40mg/day
- Pimozide (Orap)
- Rifampin
- Rilpivirine once daily (e.g., Complera, Edurant, Juluca, Odefsey)
- Rosuvastatin >10mg/day, Pravastatin >40mg/day
- Salmeterol (e.g., Airduo, Advair, Serevent)
- Sildenafil when dosed as Revatio® for the treatment of PAH
- St. John's Wort (Hypericum perforatum)
- Triazolam; orally administered midazolam
- Voriconazole (unless prescriber states the benefit-to-risk ratio justifies the use of voriconazole)
- NONE

**Daklinza**

- Amiodarone
- Carbamazepine
- Dabigatran (Pradaxa) if CrCl <50ml/min
- Phenytoin
- Rifampin
- St. John's wort (Hypericum perforatum)
- NONE

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