

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"/> 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 (Please also fill out brand form) | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ | |
| <input type="checkbox"/> Sofosbuvir/Velpatasvir 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"/> Mavvyret 3 tablets 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 400-100-100mg once daily | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ | |
| <input type="checkbox"/> Other: _____ | <input type="checkbox"/> 12 weeks | <input type="checkbox"/> 24 weeks | <input type="checkbox"/> 16 weeks | <input type="checkbox"/> Other: _____ | |

2. For ribavirin requests, please answer the following questions:

a. Is the member or their partner pregnant? **Yes or No**

b. Is the member or their partner of childbearing age? **Yes or No**

- If **Yes**, has the member been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy? **Yes or No**

3. What is the member's weight? _____ lbs _____ kg

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)? _____

- 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. Is the member HIV positive? **Yes or No**

10. 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).**

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

*If yes, date of transplant _____ Which organ? _____

Physician office's signature* _____ Print Name _____

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12. 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

13. 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.**

14. 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.

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

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

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

<p><u>Zepatier</u></p> <ul style="list-style-type: none"><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., Prezcoibx, 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	<p><u>Mavyret</u></p> <ul style="list-style-type: none"><input type="checkbox"/> Moderate or Severe hepatic impairment (CTP Class B or C)<input type="checkbox"/> History of prior hepatic decompensation<input type="checkbox"/> Atazanavir (e.g., Evotaz, Reyataz)<input type="checkbox"/> Atorvastatin<input type="checkbox"/> Carbamazepine<input type="checkbox"/> Darunavir (e.g., Prezcoibx, 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"/> Nevirapine (Viramune)<input type="checkbox"/> Phenytoin<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 (Hypericum perforatum)<input type="checkbox"/> NONE	<p><u>Harvoni</u></p> <ul style="list-style-type: 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"/> St. John's Wort (Hypericum perforatum)<input type="checkbox"/> Tipranavir (Aptivus) together with Ritonavir (e.g., Kaletra, Norvir, Viekira Pak)<input type="checkbox"/> NONE
<p><u>Ribavirin</u></p> <ul style="list-style-type: none"><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	<p><u>Epclusa</u></p> <ul style="list-style-type: none"><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) together with Ritonavir (e.g., Kaletra, Norvir, Viekira Pak)<input type="checkbox"/> Topotecan<input type="checkbox"/> NONE	<p><u>Vosevi</u></p> <ul style="list-style-type: none"><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 (Hypericum perforatum)<input type="checkbox"/> Tipranavir (e.g., Aptivus) together with Ritonavir (e.g., Kaletra, Norvir, Viekira Pak)<input type="checkbox"/> NONE

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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, which are contraindicated.

Sovaldi

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

Pegasys, 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)
- Alfuzosin
- Apalutamide
- Atorvastatin
- Carbamazepine, phenytoin, phenobarbital
- Cisapride
- Colchicine in patients with renal and/or hepatic impairment
- Dronedarone (Multaq)
- Darunavir/ritonavir 600/100mg twice daily in treatment experienced members with at least one darunavir resistance associated substitution or with no baseline resistance information
- Efavirenz (e.g., Atripla, Sustiva, Symfi, Symfi Lo)
- Ergotamine, dihydroergotamine, methylergonovine
- Ethinyl estradiol-containing medications (e.g., combined oral contraceptives)
- Everolimus, sirolimus, tacrolimus
- Gemfibrozil
- Ketoconazole >200mg/day
- Known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome)
- Lopinavir/ritonavir (e.g., Kaletra)
- Lomitapide
- Lurasidone (Latuda)
- Lovastatin, simvastatin
- Omeprazole >40mg/day
- Pimozide (Orap)
- Ranolazine
- 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

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