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This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to {{COMPANY_NAME}} at {{CLIENT_PAG_FAX}}. Please contact {{COMPANY_NAME}} at {{CLIENT_PAG_PHONE}} with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of {{DRUGNAME}}.

Patient's Name: {{MEMFIRST}} {{MEMLAST}} **Date**: {{TODAY}}
Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}} **Patient Phone:** <<MEMPHONE>>
Specialty: _____ **NPI#:** _____
Physician Office Telephone: {{PHYSICIANPHONE}} **Physician Office Fax:** {{PHYSICIANFAX}}
Physician Office Address: <<PHYADDRESS1>> <<PHYADDRESS2>> <<PHYCITY>>, <<PHYSTATE>> <<PHYZIP>>
Drug Name: {{DRUGNAME}}

Quantity: _____ **Frequency:** _____ **Strength:** _____
Route of Administration: _____ **Expected Length of Therapy:** _____
Diagnosis: <<DIAGNOSIS>> **ICD Code**: <<ICD9>>

1. What is the prescribed drug regimen?
   Indicate ALL drugs for this course of treatment.
   - ❑ Epclusa monotherapy (sofosbuvir and velpatasvir)
   - ❑ Harvoni (ledipasvir and sofosbuvir) monotherapy
   - ❑ Sovaldi + Pegasys + ribavirin
   - ❑ Viekira Pak monotherapy
   - ❑ Zepatier monotherapy
   - ❑ Vosevi monotherapy
   - ❑ Mavyret monotherapy
   - ❑ Epclusa (sofosbuvir and velpatasvir)
   - ❑ Harvoni (ledipasvir and sofosbuvir) + ribavirin
   - ❑ Sovaldi + ribavirin
   - ❑ Viekira Pak + ribavirin
   - ❑ Zepatier + ribavirin
   - ❑ Vosevi + ribavirin
   - ❑ Mavyret + Sovaldi + ribavirin
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. What is the diagnosis?
   - ❑ Chronic hepatitis C virus (HCV) infection
   - ❑ Acute HCV infection
   - ❑ Systemic mastocytosis
   - ❑ Hairy cell leukemia
   - ❑ Chronic myeloid leukemia in pregnancy
   - ❑ Erdheim-Chester disease
   - ❑ Adult T-cell leukemia/lymphoma
   - ❑ Mycosis fungoides/Sezary syndrome
   - ❑ Chronic hepatitis B, including hepatitis D virus (HDV) co-infection
   - ❑ Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk myelofibrosis)
   - ❑ Primary cutaneous CD30+ T-cell lymphoproliferative disorders
   - ❑ Other _____
4.. What is the patient's weight? _____ kg

Section A: Pegasys Requests

1. Is Pegasys being prescribed as a component of a treatment regimen for hepatitis C virus (HCV) infection?
   If Yes, skip to Section B. ❑ Yes ❑ No

2. *If the diagnosis is Chronic hepatitis B virus (HBV) infection, including hepatitis D virus (HDV) co-infection,* Is the patient currently receiving treatment with the requested regimen?
   ❑ Yes ❑ No *no further questions.* ❑ NA - diagnosis not applicable

3. How many weeks of therapy has the patient already completed with the requested regimen? Please do not indicate the planned duration of therapy. ❑ Less than 48 weeks ❑ 48 weeks or more *No further questions*

4. *If the diagnosis is myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk-myelofibrosis), systemic mastocytosis, mycosis fungoides/Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, or chronic myeloid leukemia in pregnancy*, is this a request for continuation of therapy with Pegasys?
   ❑ Yes ❑ No ❑ N/A, diagnosis is not listed above *If No or NA, no further questions.*

5. *If the diagnosis is myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower risk-myelofibrosis),* has the patient experienced benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis, etc.)?
   If Yes or No, no further questions. ❑ Yes ❑ No ❑ NA - diagnosis not applicable

6. *If the diagnosis is systemic mastocytosis,* has the patient experienced benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., reduction in serum and urine metabolites of mast cell activation, improvement in cutaneous lesions, skeletal disease, bone marrow mast cell burden, etc.)?
   If Yes or No, no further questions. ❑ Yes ❑ No ❑ NA - diagnosis not applicable

7. *If the diagnosis is mycosis fungoides/Sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, or chronic myeloid leukemia in pregnancy*, is there evidence of unacceptable toxicity or disease progression on the current regimen?
   ❑ Yes ❑ No ❑ NA - diagnosis not applicable

Section B: All Requests

1. What was the patient's treatment status prior to the requested regimen? *Indicate all that apply.*
   List continues on next page.
   ❑ Treatment-naïve, *skip to #14*
   ❑ Failed prior treatment with a direct-acting antiviral (DAA)
   ❑ Failed prior treatment with PEG-IFN (with or without an HCV protease inhibitor [e.g., Victrelis, Incivek, Olysio]) with or without ribavirin
   ❑ Failed prior treatment with PEG-IFN and ribavirin
   ❑ Failed prior treatment with Olysio + PEG-IFN + ribavirin
   ❑ Failed prior treatment with Victrelis + PEG-IFN + ribavirin
   ❑ Failed prior treatment with Incivek + PEG-IFN + ribavirin
   ❑ Failed prior treatment with an interferon-based regimen with or without ribavirin
   ❑ Failed prior treatment with a sofosbuvir-based regimen
   ❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen (e.g., NS5A- or sofosbuvir-containing regimen [e.g., Epclusa, Harvoni, Mavyret, Technivie with or without ribavirin, Sovaldi with PEG-IFN and ribavirin, Zepatier])
   ❑ Failed prior treatment with Mavyret
   ❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen other than Mavyret (e.g., NS5A- or sofosbuvir-containing regimens [e.g., Epclusa, Harvoni, Technivie with or without ribavirin, Sovaldi with PEG-IFN and ribavirin, Zepatier])
   ❑ Failed prior treatment with a direct-acting antiviral (DAA) regimen (e.g., NS5A- or sofosbuvir-containing regimen [e.g., Daklinza and Sovaldi with or without ribavirin, Epclusa with or without ribavirin, Sovaldi with ribavirin])
   ❑ Failed prior treatment with a regimen containing an NS5A inhibitor other than Mavyret (e.g., Daklinza, Epclusa, Harvoni, Viekira Pak, Viekira XR, Zepatier)
   ❑ Failed prior treatment with a regimen containing sofosbuvir (Sovaldi)
   ❑ Failed prior treatment with Vosevi
   ❑ Failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), excluding Mavyret, without prior treatment with an NS3/4A protease inhibitor

❑ Failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), excluding Mavyret, without prior treatment with an NS3/4A protease inhibitor
❑ Failed prior treatment with PEG-IFN + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor
❑ Failed prior treatment with Sovaldi + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor
❑ Failed prior treatment with Sovaldi + PEG-IFN + ribavirin without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor
❑ Failed prior treatment with an interferon-based regimen
❑ Failed prior treatment with an interferon-based regimen + ribavirin
❑ Failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni), excluding Mavyret, without prior treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio, Incivek, Victrelis)
❑ Failed prior treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio, Incivek, or Victrelis in combination with peginterferon and ribavirin; Olysio with Sovaldi) without prior treatment with a regimen containing an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni)
❑ Failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa])
❑ Failed 16 weeks of therapy with sofosbuvir (Sovaldi) and Mavyret
❑ Failed prior treatment with PEG-IFN (with or without ribavirin)
❑ Failed prior treatment with PEG-IFN and ribavirin without an HCV protease inhibitor (Olysio, Incivek, or Victrelis)
❑ Other: _____

2. Will the requested drug be prescribed by or in consultation with a prescriber specializing in one of the following: A) infectious disease, B) gastroenterology, C) hepatology, or D) transplant?
❑ Yes - Infectious disease ❑ Yes - Gastroenterology ❑ Yes - Hepatology
❑ Yes - Transplant ❑ No - None of the above

3. What is the patient's hepatitis C virus (HCV) genotype?
❑ Genotype 1 ❑ Genotype 2 ❑ Genotype 3 ❑ Genotype 4 ❑ Genotype 5 ❑ Genotype 6
❑ Unknown genotype/genotype could not be determined

4. What is the patient's Metavir/fibrosis score? ❑ F0 ❑ F1 ❑ F2 ❑ F3 ❑ F4 ❑ Unknown

5. Has the patient been screened for Hepatitis B virus (HBV)? ❑ Yes ❑ No ❑ Unknown

6. Has the patient been evaluated for alcohol and substance abuse using a validated screening tool?
❑ Yes ❑ No

7. Does the patient have a recent history (within the past 6 months) of alcohol or substance abuse?
❑ Yes ❑ No *If No, skip to #9*

8. Has the patient received alcohol or substance abuse counseling, completed or is participating in a recovery program, or currently seeing an addiction specialist? ❑ Yes ❑ No

9. Has the patient been counseled on the importance of adherence, confirmed readiness for treatment or retreatment and agrees to be compliant with regimen? ❑ Yes ❑ No

10. *If the patient is currently receiving treatment with the requested regimen,* what is the SPECIFIC date the patient started this current course of therapy?
Indicate in mm/dd/yyyy. Please specify. _____ ❑ NA - not applicable

11. What is the **SPECIFIC** date (mm/dd/yyyy) the patient is expected to start or has started this course of therapy? Indicate in mm/dd/yyyy. Please do not state "as soon as possible (ASAP)" if treatment will be delayed after approval, please specify.
❑ Any date, please specify. _____

12. Is the patient treatment-naive? *If Yes, skip to #15* ❑ Yes ❑ No

13. What previous treatment has the patient received? Please specify the regimen, dates, and duration (number of weeks) of previous therapy.
    ❑ Any regimen, date, and duration, please specify _____
    ❑ Unknown, *no further questions.*

14. What is the reason for retreatment?
    ❑ Non-compliance ❑ Reinfection ❑ Treatment failure ❑ Other _____

15. Prior to treatment, has hepatitis C virus (HCV) been confirmed by the presence of a viral load (HCV RNA) in the serum? ❑ Yes ❑ No

16. What is the patient's pretreatment hepatitis C virus (HCV) RNA level?
    ❑ Less than 6 million IU/mL ❑ Greater than or equal to 6 million IU/mL ❑ Unknown

17. What is the planned duration of therapy?
    ❑ Up to 8 weeks ❑ Up to 12 weeks ❑ Up to 16 weeks ❑ Up to 24 weeks ❑ Up to 48 weeks

18. How many weeks of therapy has the patient already completed with the requested regimen? Please do not indicate the planned duration of therapy.
    ❑ Less than 8 weeks ❑ 8 weeks or longer ❑ Less than 12 weeks ❑ 12 weeks or longer
    ❑ Less than 16 weeks ❑ 16 weeks or longer ❑ Less than 24 weeks ❑ 24 weeks or longer
    ❑ Less than 48 weeks ❑ 48 weeks or longer

19. Does the patient have any of the following conditions?
    ❑ Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)
    ❑ Moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C)
    ❑ None of the above

20. Please indicate which, if any, of the following applies to the patient.
    ❑ Has received a kidney transplant
    ❑ Received liver transplant from hepatitis C virus (HCV)-viremic donor
    ❑ Received non-liver organ transplant from HCV-viremic donor
    ❑ Has recurrent hepatitis C virus (HCV) infection post liver transplantation
    ❑ Has compensated cirrhosis
    ❑ Has human immunodeficiency virus (HIV) co-infection
    ❑ Has received an NS3/4A protease inhibitor or NS5A inhibitor
    ❑ None of the above

20. Has the patient failed prior treatment with a direct-acting antiviral (DAA)? ❑ Yes ❑ No

Complete the following section based on the prescribed regimen if applicable.

Section C: Harvoni (ledipasvir and sofosbuvir)+/- ribavirin

Harvoni monotherapy

1. Does the patient have decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)?
   ❑ Yes ❑ No

2. Does the patient have documented anemia? ❑ Yes ❑ No *If No, skip to #4*

3. What is the patient's baseline hemoglobin (Hgb) level?
   If less than 10 g/dL, no further questions. ❑ Less than 10 g/dL ❑ Greater than or equal to 10 g/dL

4. Is the patient ineligible to receive ribavirin? ❑ Yes ❑ No *If No, no further questions.*

5. Please indicate the reason for ribavirin ineligibility. *Indicate below and no further questions.*
   ❑ Intolerance to ribavirin
   ❑ Patient is a pregnant female or male whose female partner is pregnant
   ❑ Hemoglobinopathy
   ❑ Coadministration with didanosine
   ❑ History of significant or unstable cardiac disease
   ❑ Other: _____

Harvoni + ribavirin

6. Does the patient have recurrent hepatitis C virus (HCV) infection post liver transplantation? ❑ Yes ❑ No

7. Does the patient have decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)?
   ❑ Yes ❑ No

Section D: Epclusa (sofosbuvir and velpatasvir) +/- ribavirin

Epclusa monotherapy

1. Has the patient received a liver or non-liver organ transplant from a hepatitis C virus (HCV)-viremic donor?
   ❑ Yes ❑ No

2. Does the patient have documented anemia? ❑ Yes ❑ No *If No, skip to #4*

3. What is the patient's baseline hemoglobin (Hgb) level?
   If less than 10 g/dL, no further questions. ❑ Less than 10 g/dL ❑ Greater than or equal to 10 g/dL

4. Is the patient ineligible to receive ribavirin? ❑ Yes ❑ No *If No, skip to #6*

5. Please indicate the reason for ribavirin ineligibility.
   ❑ Patient is a pregnant female or male whose female partner is pregnant
   ❑ History of significant or unstable cardiac disease ❑ Coadministration with didanosine
   ❑ Intolerance to ribavirin ❑ Hemoglobinopathy ❑ Other: _____

6. Which, if any, of the following characteristics does the patient have?
   ❑ Human immunodeficiency virus (HIV) and the patient is on a tenofovir disoproxil fumarate (TDF)-containing regimen with an estimated glomerular filtration rate (eGFR) less than 60 mL/min
   ❑ HBsAG positive
   ❑ Current pregnancy
   ❑ Known or suspected hepatocellular carcinoma
   ❑ Prior liver transplantation
   ❑ None of the above

Epclusa (sofosbuvir and velpatasvir) + ribavirin

7. Has laboratory testing for presence of NS5A inhibitor resistance-associated substitutions been performed?
   ❑ Yes ❑ No ❑ Unknown *If No or Unknown no further questions.*

8. Was the Y93H substitution associated with velpatasvir resistance detected? ❑ Yes ❑ No

Section E: Vosevi +/- ribavirin

Vosevi monotherapy

1. Does the patient have cirrhosis? ❑ Yes ❑ No

2. Has laboratory testing for the presence of NS5A inhibitor resistance-associated substitutions been performed?
   ❑ Yes ❑ No ❑ Unknown *If No or Unknown no further questions.*

3. Was the Y93H substitution associated with velpatasvir resistance detected? ❑ Yes ❑ No

Section F: Mavyret +/- Sovaldi +/- ribavirin

Mavyret monotherapy

1. *If patient received non-liver organ transplant from HCV-viremic donor*, will treatment be initiated in the first week after transplant? ❑ Yes ❑ No

2. Is the patient co-infected with human immunodeficiency virus (HIV)? ❑ Yes ❑ No

3. Has the patient had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier])? ❑ Yes ❑ No

4. Has the patient received an NS3/4A protease inhibitor or NS5A inhibitor? ❑ Yes ❑ No

5. Does the patient have sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa])? ❑ Yes ❑ No

6. Has the patient had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g.,

elbasvir/grazoprevir [Zepatier])? ❑ Yes ❑ No

7. Has the patient received an NS3/4A protease inhibitor or NS5A inhibitor? ❑ Yes ❑ No
8. Has the patient had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier])? ❑ Yes ❑ No
9. Has the patient received treatment with a regimen containing an NS3/4A protease inhibitor (e.g., Olysio, Incivek, Victrelis) or an NS5A inhibitor (e.g., Daklinza, Epclusa, Harvoni)? ❑ Yes ❑ No
10. Which, if any, of the following characteristics does the patient have? *List continues on next page.*
    ❑ Human immunodeficiency virus (HIV) in a patient on a tenofovir disoproxil fumarate (TDF)-containing regimen with an estimated glomerular filtration rate (eGFR) less than 60 mL/min
    ❑ Hepatitis B surface antigen (HBsAG) positive
    ❑ Current pregnancy
    ❑ Known or suspected hepatocellular carcinoma
    ❑ Prior liver transplantation
    ❑ None of the above

Mavyret + Sovaldi + ribavirin

11. Does the patient have an extremely difficult case (e.g., genotype 3 with cirrhosis)? ❑ Yes ❑ No

Section G: Sovaldi + ribavirin

1. Is the request for a patient with hepatocellular carcinoma awaiting liver transplantation?
   ❑ Yes ❑ No *If No, skip to #3*
2. Does the patient meet the MILAN criteria defined as the following: A) tumor size 5 centimeters (cm) or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3 cm or less in diameter with multiple tumors, AND B) no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor? ❑ Yes ❑ No
3. Does the patient have documented interferon (INF) ineligibility? ❑ Yes ❑ No *If No, no further questions.*
4. Please indicate the reason for interferon (IFN) ineligibility.
   ❑ Intolerance to IFN
   ❑ Autoimmune hepatitis and other autoimmune disorders
   ❑ Hypersensitivity to PEG-IFN or any of its components
   ❑ Major uncontrolled depressive illness
   ❑ A baseline neutrophil count less than 1,500/mcL
   ❑ A baseline platelet count less than 90,0000/mcL
   ❑ A baseline hemoglobin count less than 10g/dL
   ❑ History of pre-existing cardiac disease
   ❑ Other: _____

Section H: Zepatier +/- ribavirin

1. Was the patient tested for baseline NS5A resistance-associated substitutions (RASs)/polymorphisms?
   ❑ Yes ❑ No ❑ Unknown
2. Is one or more baseline NS5A resistance-associated substitution (RAS)/polymorphism present?
   ❑ Yes ❑ No

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

_____

Prescriber (Or Authorized) Signature and Date