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# 2020 General Hepatitis C Treatment Coverage Determination Request

**Page 1 of 4**

**(You must complete all 4 pages.)**

**Fax completed form to: 1-800-408-2386** **For urgent requests, please call: 1-800-414-2386**

| **Patient information** | | **Prescriber information** | |
|---|---|---|---|
| Patient name | | Today's date | Physician specialty |
| Patient insurance ID number | | Physician name | NPI/DEA number |
| Patient address, city, state, ZIP | | Physician address, city, state, ZIP | |
| Patient home telephone number | | M.D. office telephone number | |
| Gender ☐ Male ☐ Female | Patient date of birth | M.D. office fax number | |

| **Requested regimen: (check all that apply)** | Please indicate if this is a new start or continuation of therapy and specify the requested duration of therapy. **If continuation of therapy, please indicate start date.** | | | | |
|---|---|---|---|---|---|
| **Medication** | **Dose/Frequency** | **New start** | **Continuation** | **Initial start date** | **Duration of therapy** |
| ☐ Daklinza® (daclatasvir) | | ☐ | ☐ | | |
| ☐ Epclusa® (sofosbuvir/velpatasvir)-requesting **brand** | | ☐ | ☐ | | |
| ☐ sofosbuvir/velpatasvir 400mg;100 mg tablet-requesting **generic** | | ☐ | ☐ | | |
| ☐ Harvoni® (ledipasvir/sofosbuvir)-requesting **brand** | | ☐ | ☐ | | |
| ☐ ledipasvir/sofosbuvir 90mg;400mg tablet-requesting **generic** | | ☐ | ☐ | | |
| ☐ Intron-A® (interferon alfa-2b) | | ☐ | ☐ | | |
| ☐ Mavyret® (glecaprevir/pibrentasvir) | | ☐ | ☐ | | |
| ☐ Pegasys® (pegylated interferon alfa-2a) | | ☐ | ☐ | | |
| ☐ Peg-Intron® (pegylated interferon alfa-2a) | | ☐ | ☐ | | |
| ☐ ribavirin *prior authorization (PA) not required | | ☐ | ☐ | | |
| ☐ Sovaldi® (sofosbuvir) | | ☐ | ☐ | | |
| ☐ Sylatron® (pegylated interferon alfa-2b) | | ☐ | ☐ | | |
| ☐ Technivie® (ombitasvir/paritaprevir/ritonavir) | | ☐ | ☐ | | |
| ☐ Viekira Pak® (ombitasvir/paritaprevir/ritonavir/ dasabuvir) | | ☐ | ☐ | | |
| ☐ Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) | | ☐ | ☐ | | |
| ☐ Zepatier® (elbasvir/grazoprevir) | | ☐ | ☐ | | |
| ☐ Other: _____ | | ☐ | ☐ | | |

(continued on page 2)

**Diagnosis and medical Information**

**Diagnosis** ***(If treatment experienced, list all components of previous treatment regimens and describe outcome)***

☐ Chronic hepatitis C treatment naive ☐ Chronic hepatitis C treatment experienced ☐ Other diagnosis/(ICD10): _____

☐ **Yes** ☐ **No** **Has the diagnosis of chronic hepatitis C virus (HCV) infection been confirmed by the presence of HCV RNA in the serum prior to starting treatment?**

**Please provide HCV RNA viral load:** _____ **Date:** _____

**What is the patient's HCV genotype?**

☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other (specify): _____

**Medical history** ***(Please check all boxes that apply and include office notes)***

☐ **Yes** ☐ **No** Hepatitis B coinfection ☐ **Yes** ☐ **No** HIV coinfection ☐ **Yes** ☐ **No** End stage renal disease

☐ **Yes** ☐ **No** Hepatocellular carcinoma ☐ **Yes** ☐ **No** Received a liver transplant ☐ **Yes** ☐ **No** Received a kidney transplant

**Which of the following TESTS were used to determine LIVER STAGE?** ***(Please check all boxes that apply and include medical records as supporting documentation)***

☐ Liver biopsy ☐ Metavir ☐ Fibroscan ☐ APRI ☐ ARFI ☐ SWEI ☐ Other (specify): _____

**What is the patient's FIBROSIS STAGE?**

☐ **F1** ☐ **F2** ☐ **F3** ☐ **F4**

**Which of the following best describe patient's liver disease, based on liver staging tests (liver biopsy, Metavir, Fibroscan, etc.), radiological imaging, physiologic or clinical findings? (*Please check box that best describe patient's liver disease and include medical records as supporting documentation)***

**Fibrosis stage F1, F2, or F3**: ☐ No cirrhosis **Fibrosis stage F4**: ☐ Compensated cirrhosis **OR** ☐ Decompensated cirrhosis

**Was testing for the presence of virus with NS5A resistance-associated polymorphisms performed?** ☐ Yes ☐ No

**If testing was done, does the patient have NS5A resistance-associated polymorphism at amino acid positions 28, 30, 31, or 93?** ☐ Yes ☐ No

If testing was not done, provide a reason for why testing was not done:

_____

_____

**Has patient been screened for the presence of virus with the NS3 Q80K polymorphism at baseline?** ☐ Yes ☐ No

**If screening was done, does patient have Q80K polymorphism?** ☐ Yes ☐ No

If screening was not done, provide a reason for why screening was not done:

_____

_____

(continued on page 3)

**Please check all boxes that apply:**

1. ☐ **All covered Part D drugs on any tier of the plan's formulary would not be as effective for the enrollee as the requested formulary drug and/or would likely have adverse effects for the enrollee.**

2. ☐ **Yes** ☐ **No** **Is the prescriber a gastroenterologist, hepatologist or infectious disease specialist OR did the prescriber obtain a consult from one of these specialists? If NO, complete section below:**

**Please complete this section below only if your patient does not meet the standard requirements listed above.**

Please explain why your patient should be considered for exception although not meeting the plan's suggested PA criteria. Statement should include specifically which requirement is not met and why patient should be exempt from meeting this requirement. (Please note any information that is incomplete or illegible will delay the review process.)

_____

_____

3. **For TREATMENT EXPERIENCED patients, please complete this section:**

☐ **Yes** ☐ **No** **Has patient been treated with ribavirin and/or peginterferon alfa?**

**If yes, list all components of previously treated regimen below and check the box that best describe treatment outcome**:

| HCV regimen | Treatment duration/dates | Treatment outcome |
|---|---|---|
| | | ☐ Relapsed<br>☐ Partial responder<br>☐ Non-responder<br>☐ Toxicities<br>☐ Discontinued therapy prior to completing full course<br>☐ Other: _____ |
| | | ☐ Relapsed<br>☐ Partial responder<br>☐ Non-responder<br>☐ Toxicities<br>☐ Discontinued therapy prior to completing full course<br>☐ Other: _____ |

☐ **Yes** ☐ **No** **Has patient been treated with regimens containing Epclusa®, Incivek®, Harvoni®, Victrelis®, Olysio®, Sovaldi®, Zepatier®, Daklinza®, Technivie®, Mavyret®, Vosevi® or Viekira® Pak?**

**If yes, list all components of previously treated regimen below and check the box that best describe treatment outcome.**

| HCV regimen | Treatment duration/dates | Treatment outcome |
|---|---|---|
| | | ☐ Relapsed<br>☐ Partial responder<br>☐ Non-responder<br>☐ Toxicities<br>☐ Discontinued therapy prior to completing full course<br>☐ Other: _____ |
| | | ☐ Relapsed<br>☐ Partial responder<br>☐ Non-responder<br>☐ Toxicities<br>☐ Discontinued therapy prior to completing full course<br>☐ Other: _____ |

(continued on page 4)

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**Please check all boxes that apply *(continued)*:**

**4. Will patient be taking ribavirin with the requested regimen?**

☐ Yes (ribavirin is covered without PA) ☐ No, patient is intolerant/ineligible for ribavirin

**5. ☐ Other supporting information**

*NOTE: All exception requests require prescriber supporting statements. Additionally, requests that are subject to prior authorization (or any other utilization management requirement), may require supporting information. Please attach supporting information, as necessary, for your request.

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 documentation supporting this information is available for review if requested by the health plan sponsor, or, if applicable, a state or federal regulatory agency. I understand that any person who knowingly makes or causes to be made a false record or statement that is material to a claim ultimately paid by the United States government or any state government may be subject to civil penalties and treble damages under both the federal and state False Claims Acts. See, e.g., 31 U.S.C. §§ 3729-3733. By signing this form, I represent that I have obtained patient consent as required under applicable state and federal law, including but not limited to the Health Information Portability and Accountability Act (HIPAA) and state re-disclosure laws related to HIV/AIDS.

| **Prescriber signature** | **Date** |
|---|---|
| | |