Government of Saskatchewan

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch

Exception Drug Status Request
Hepatitis C Therapy

Please ensure all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information		Section 2 – Patient Information	
First Name **Last Name**		**First Name** **Last Name**	
Mailing Address		**Date of Birth:** ____/____/_____ (day/month/year)	**Gender** ☐ **Male** ☐ **Female**
Telephone No.	**Fax No.**	**Health Services Number**	

Section 3 – Requested Drug Regimen (see Appendix A for specific criteria)

Select <u>all</u> components of the prescribed treatment regimen:

- ☐ asunaprevir (Sunvepra-BMY)
- ☐ daclatasvir (Daklinza-BMY)
- ☐ elbasvir/grazoprevir (Zepatier-MRK)
- ☐ ledipasvir/sofosbuvir (Harvoni-GSI)
- ☐ ombitasvir/paritaprevir/ritonavir and dasabuvir (Holkira Pak-ABV*)
- ☐ ribavirin (Ibavyr-GSI, Moderiba-ABV*)
- ☐ sofosbuvir (Sovaldi-GSI)
- ☐ sofosbuvir/velpatasvir (Epclusa-GSI)

Length of therapy: _____ weeks

**Requests for Holkira Pak and/or Moderiba must be accompanied by documentation to support why other listed oral hepatitis C treatment alternatives are not appropriate for the patient. Refer to criteria in Appendix A of the Saskatchewan Formulary for more details.*

Section 4 – Clinical Information

Confirmed diagnosis of chronic hepatitis C infection: ☐ Yes ☐ No

Laboratory-confirmed hepatitis C virus (HCV) genotype and subtype: _____

Quantitative HCV RNA: _____ IU/mL Date (day/month/year): ____/____/_____ ***(must be tested within the last six months)***

Fibrosis Stage (Metavir score or equivalent): _____ **Indicate below which acceptable method for determining fibrosis was used:**

☐**AST-to-Platelet Ratio Index (APRI)** ☐**FibroScan** ☐**Fibrosis-4 (FIB-4)** ☐**FibroTest** ☐**Liver biopsy**

Liver cirrhosis: ☐ Yes ☐ No **If cirrhotic, provide the Child Pugh Score:** _____ (A = 5-6; B or C = 7 or above)

Relevant Medical History:

- ☐ HIV co-infection
- ☐ HBV co-infection
- ☐ Co-existent liver disease with diagnostic evidence of fatty liver disease (include method of diagnosis): _____
- ☐ Transplanted organ: _____ Date of transplant (day/month/year): ____/____/_____
- ☐ Extra-hepatic manifestation: _____
- ☐ Chronic kidney disease stage: _____
- ☐ Diabetes treated with anti-diabetic drugs
- ☐ Woman of childbearing age who is planning pregnancy, or may become pregnant within the next 12 months

Chronic Hepatitis C Treatment History: ☐ Treatment-naïve ☐ Treatment-experienced

If treatment-experienced, list drug(s) tried and dates of therapy:_____

_____

Response to prior treatment: ☐ Null response ☐ Relapse ☐ Virologic breakthrough or rebound ☐ Intolerance

Please submit the completed form and required additional information by:

- Fax to 306-798-1089; or
- Email to DPEB@health.gov.sk.ca; or
- Mail to the Drug Plan and Extended Benefits Branch, 2nd floor, 3475 Albert Street, Regina, SK S4S 6X6

If you have any questions, please call 306-787-8744 (in Regina) or 1-800-667-2549 (toll-free).

Section 5 – Additional Clinical Information (Optional)

This section is optional and may be completed if there are additional clinical details which may assist in the consideration of exceptional requests.

Section 6 – Direct Observed Therapy

Based on the patient's individual situation and regular access to a community pharmacy, the prescriber has evaluated the decision for the patient to receive Direct Observed Therapy (DOT).

With DOT, the patient will visit their pharmacy on a daily basis to take their oral hepatitis C medication doses as a means of encouraging treatment adherence. Pharmacists will follow up with prescribers to discuss patient non-adherence.

☐ Direct Observed Therapy Recommended
(leave blank if not recommended)

NOTE: Please indicate on the patient's prescription if DOT is recommended.

Section 7 – Patient Consent

Patient to check and initial as reviewed.

☐ _____ I am aware of the requirement for adherence to my prescribed hepatitis C drug treatment protocol. Missed doses of my hepatitis C medication will lessen my chances of a successful treatment outcome, and may increase the risk of viral resistance.

☐ _____ I understand the Saskatchewan Drug Plan will receive data specific to my treatment from my physician for medication effectiveness monitoring purposes. I understand my personal health information will be kept secure and confidential and will not be disclosed for an additional purpose.

I also understand my participation is voluntary but required for eligibility of Exception Drug Status coverage from the Saskatchewan Drug Plan. I may withdraw my consent at any time, but once I do, drug coverage for this treatment may also be withdrawn.

If you have any questions please contact the Ministry of Health's Chief Privacy Officer at 306-787-2137.

Patient name (printed): _____ **Date:** ____/____/_____
(day/month/year)

Patient signature (required): _____

Prescriber's Signature (Required)	**Date:** ____/____/_____ (day/month/year)

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