Drug Plan and Extended Benefits
Saskatchewan Ministry of Health

Pharmacy Information Bulletin No. 663
April 13, 2018

EXCEPTION DRUG STATUS LISTING UPDATE - HEPATITIS C MEDICATIONS

Effective April 1, 2018, the Saskatchewan Formulary includes expanded clinical eligibility criteria for the following hepatitis C medications as Exception Drug Status (EDS) benefits, as well as the addition of a new direct-acting antiviral:

- **Daklinza** (daclatasvir);
- **Epclusa** (sofosbuvir/velpatasvir);
- **Harvoni** (ledipasvir/sofosbuvir);
- **Ibavyr** (ribavirin);
- **Sovaldi** (sofosbuvir);
- **Vosevi** (sofosbuvir/velpatasvir/voxilaprevir); and
- **Zepatier** (elbasvir/grazoprevir)

Note: While Holkira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir) and Moderiba (ribavirin) remain listed under EDS, these medications will only be considered for patients in whom the other listed oral hepatitis C treatment alternatives are not appropriate. Requests for these medications should provide details of why the listed alternatives are not appropriate, as well as indicate how the patient meets the listed EDS criteria.

Exception Drug Status Coverage for Hepatitis C Medications

- EDS coverage for hepatitis C medications will be approved based on the published criteria (see April 1, 2018 Formulary bulletin #170 at: http://formulary.drugplan.ehealthsask.ca/SaskFormularyBulletins.aspx.
- Designated Prescribers or authorized clinic staff can request EDS for these agents on behalf of their patients by:
  - Completing the designated application form (http://formulary.drugplan.ehealthsask.ca/AppForms.aspx); or
  - Calling the EDS phone line at 306-787-8744 (Regina) or 1-800-667-2549 (toll-free).
- Qualifying patients will pay for hepatitis C medications according to their current coverage(s), deductible, and/or copayment.

Designated Prescribers

- Prescribers interested in becoming a Designated Prescriber can contact the Drug Plan and Extended Benefits Branch at 306-787-8744, 1-800-667-2549, or DPEB@health.gov.sk.ca to receive a copy of the prescriber agreement.

Direct Observed Therapy

- Designated Prescribers may identify patients who will benefit from Direct Observed Therapy (DOT).
- With DOT, a pharmacist witnesses the administration of medication for eligible patients.
- Designated Prescribers will notify a community pharmacist that DOT is requested for a specific patient directly on the hepatitis C therapy prescription.
- For more details, refer to the DOT Policy Document available on the secure Drug Plan WEB page (https://www.drugplan.health.gov.sk.ca).

Pharmacist Checklist

- Check the patient's Pharmaceutical Information Program (PIP) profile to confirm EDS is approved.
- If requested by the Designated Prescriber, provide the patient's daily dose through Direct Observed Therapy (DOT).
- Submit claims for the medication and DOT fee according to instructions below.
- Review the patient's coverage:
  - Request reassessment of Special Support, if applicable; or
  - Request Emergency Assistance if Special Support is not already in place; and/or
  - Provide information or application forms for Special Support or Seniors' Drug Plan.

Prescription Claim Submission Instructions

- All claims should be submitted online (paper claims will not be accepted).
- Prescription claims will be subject to a patient's coverage (deductible and/or copayment).
- The DOT Fee will be 100% covered by the Drug Plan for eligible patients.

Part 1: Prescription claim for a listed hepatitis C medication:

- Due to the high cost of these medications, pharmacists may only dispense a **7-day or 14-day supply** at one time. This may be submitted in **one or two** separate claims.
- The pharmacist must dispense a 7-day or 14-day supply for hepatitis C medications for all patients by:
  - Submitting ONE claim with a quantity for 7 days every 7 days; OR
  - Submitting TWO claims on the same day with a quantity for 7 days every 14 days; OR
  - Submitting ONE claim with a quantity for 14 days every 14 days.
- Submissions of daily or monthly claims are not permitted**.**

Part 2: DOT fee (pseudoDIN 00951106) may be claimed only if patient is referred by their prescriber:

The pharmacist:

- Must submit the DOT fee online once weekly (paper claims will not be accepted).
- Must witness the daily administration of the hepatitis C medication(s).
- Must document the patient interaction on the Direct Observed Therapy Form posted on the secure Drug Plan WEB page (https://www.drugplan.health.gov.sk.ca).
- Must provide information to the Drug Plan for verification upon request.
- May submit $3.50 per day to a maximum of $24.50 per week.
  NOTE: Pharmacists may only submit ONE DOT fee for a combination or twice-daily drug regimen. Separate DOT fees for each medication in the regimen are NOT allowed.
- **Refer to Pharmacy Bulletin #582 (April 1, 2015) for more details on billing DOT fees.**

Reminders:

- **Hepatitis C medications must be dispensed in a regular 7-day or 14-day supply.**
- **Eligible patients will pay according to their current coverage(s), deductible, and/or copayment.**
- **Review patient coverage and encourage applications for Special Support, Seniors' Drug Plan, or request a reassessment of Special Support coverage for eligible patients.**

If you or your patients have any questions regarding:

- EDS, contact: 306-787-8744 or 1-800-667-2549
- Claims submission, contact: 306-787-3317 or 1-800-667-7581

Information is also available:

- Visit http://formulary.drugplan.ehealthsask.ca
- On the secure Drug Plan web page at https://www.drugplan.health.gov.sk.ca for previous bulletins and information.