Drug Plan and Extended Benefits
Saskatchewan Ministry of Health

Pharmacy Information Bulletin No. 637
April 6, 2017

Exception Drug Status LISTING UPDATE - HEPATITIS C MEDICATIONS

Effective April 1, 2017, the following drugs used to treat hepatitis C will be eligible for Exception Drug Status (EDS) approval according to the published EDS criteria:

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

Note: While Holkira Pak-ABV (ombitasvir/paritaprevir/ritonavir and dasabuvir) and Moderiba-ABV (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.

Obtaining Exception Drug Status Approval for Hepatitis C Medications

- The hepatitis C medications will be approved based on the published EDS criteria (see April 1, 2017, Formulary bulletin #165 at http://formulary.drugplan.ehealthsask.ca/SaskFormularyBulletins.aspx).
- Only Designated Prescribers may request EDS for these agents on behalf of their patients by submitting the Hepatitis C Therapy – EDS Application Form: http://formulary.drugplan.ehealthsask.ca/AppForms.aspx.
- Qualifying patients will pay for hepatitis C medications according to their current coverage(s), deductible, and/or copayment.

Designated Prescribers:

- Prescribers who wish to be a Designated Prescriber may contact the Drug Plan at 306-787-8744 or 1-800-667-2549 or email DPEB@health.gov.sk.ca to receive a copy of the prescriber agreement.
- Designated Prescribers should indicate on the Hepatitis C Therapy - EDS Application Form and on the patient's prescription if direct observed therapy (DOT) is recommended.

Direct Observed Therapy (DOT)

- Only Designated Prescribers may recommend DOT. With Direct Observed Therapy, a pharmacist witnesses the administration of medication for eligible patients.
- 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 PIP to confirm EDS is approved.
- Provide the daily dose through Direct Observed Therapy (DOT) for approved patients.
- Submit claims for the medication and DOT fee according to instructions on page 2.
- Request reassessment of Special Support, if applicable, or request Emergency Assistance if Special Support is not already in place.
- 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 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 administration of these medications.
- 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:

- **Prescriptions for 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.**
- **Encourage patients to apply for Special Support and/or Seniors' Drug Plan if they are not already enrolled.**
- **Request a reassessment of Special Support coverage for eligible patients.**

If you or your patients have any questions:

- Call the Drug Plan and Extended Benefits Branch at 306-787-3317 (Regina) or 1-800-667-7581
- Visit http://formulary.drugplan.ehealthsask.ca
- Pharmacy professionals may also visit https://www.drugplan.health.gov.sk.ca for more information