Government of Saskatchewan

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# SASKATCHEWAN FORMULARY BULLETIN

## Update to the 62nd Edition of the Saskatchewan Formulary

***New Exception Drug Status (EDS) Listing Effective August 1, 2015 according to the following criteria:***

- **ombitasvir/paritaprevir/ritonavir, 12.5mg/75 mg/50mg, tablets, and dasabuvir 250 mg, tablets (Holkira Pak-ABV)**

For patients that meet the eligibility criteria outlined below, clinicians will be encouraged to use Holkira Pak as one of the preferred therapeutic options over other covered therapies (e.g. interferon-based regimens with NS3/4A protease inhibitors or polymerase inhibitors). This recommendation is based on Holkira Pak's advantages in some patient populations, including potentially higher SVR rates, improved tolerability, no need for concomitant interferon, and shorter course of therapy.

For treatment-naïve and treatment-experienced adult patients with chronic hepatitis C genotype 1 infection, with compensated liver disease, (including compensated cirrhosis)[1] according to the following criteria:

- Prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other physician experienced in treating hepatitis C as determined by the Drug Plan
- Lab-confirmed hepatitis C genotype 1, subtype 1a and 1b required
- Patient has a quantitative HCV RNA value within the last 6 months
- Fibrosis stage F2 or greater (Metavir scale or equivalent)

Duration of therapy reimbursed:

| **Genotype 1 Patient Population** | **Duration of therapy** |
|---|---|
| Treatment naïve and experienced Genotype 1b, non-cirrhotic** | 12 weeks |
| Treatment naïve and experienced Genotype 1a, non-cirrhotic | 12 weeks in combination with RBV |
| Treatment naïve and experienced Genotype1b, cirrhotic | 12 weeks in combination with RBV |
| Treatment naïve and experienced (prior relapsers and prior partial responders) Genotype 1a, cirrhotic | 12 weeks in combination with RBV |
| Treatment experienced Genotype 1a, with cirrhosis, and who have had a previous null response to pegIFN and RBV | 24 weeks in combination with RBV |

***HOLKIRA™ PAK with ribavirin is recommended in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.*

**Exclusion criteria:**

- Patients currently being treated with another HCV antiviral agent
- Patients who have received a previous trial of Holkira Pak (re-treatment requests will **NOT** be considered)
- Decompensated patients
- No funding for other Genotypes except as noted in the above funding criteria for Genotype 1
- Patients who have received previous NS3/4A protease inhibitor-based regimens (i.e. boceprevir, telaprevir, and simeprevir-based regimens)
- Patients who have received previous sofosbuvir-based regimens (i.e. including ledispasvir/sofosbuvir)

**NOTES:**

1. Compensated cirrhosis is defined as cirrhosis with a Child Pugh Score =A (5-6).
2. Treatment experienced patients are defined as those who have previously been treated with PegINF/RBV and did NOT receive adequate response.
3. HIV-HCV co-infected patients with Genotype 1 may be considered as per criteria listed above.

***<u>New Non-Interchangeable Exception Drug Status (EDS) Listing Effective August 1, 2015 according to the following criteria:</u>***

- **ribavirin, tablet, 200mg, 400mg, 600mg (Moderiba-ABV)**

For treatment of chronic hepatitis C genotype 1 infection, who have received Exception Drug Status (EDS) approval of ombitasvir/paritaprevir/ritonavir (Holkira Pak) according to the following condition and schedule:

Duration of therapy reimbursed:

| **Genotype 1 Patient Population** | **Duration of therapy** |
|---|---|
| Treatment naïve and experienced Genotype 1a, non-cirrhotic | 12 weeks in combination with Holkira Pak |
| Treatment naïve and experienced Genotype1b, cirrhotic | 12 weeks in combination with Holkira Pak |
| Treatment naïve and experienced (prior relapsers and prior partial responders) Genotype 1a, cirrhotic | 12 weeks in combination with Holkira Pak |
| Treatment experienced Genotype 1a, with cirrhosis, and who have had a previous null response to pegIFN and RBV | 24 weeks in combination with Holkira Pak |

*Treatment must be prescribed by a hepatologist, gastroenterologist or an infectious disease specialist or other physician experienced in treating hepatitis C as determined by the Drug Plan.*

***<u>Revised Exception Drug Status Criteria:</u>***

- **lansoprazole, orally disintegrating tablet, 15mg, 30mg (Prevacid FasTab-ABB)**
  For patients who require treatment with a proton pump inhibitor, but are unable to swallow or are tube fed.

- **omeprazole, capsule/tablet, 10mg (Losec-AST) (and listed generics)**
  For pediatric patients requiring treatment with a proton pump inhibitor where the full Formulary options are not appropriate.

***Revised Exception Drug Status Criteria (see bold italicized portion):***

- **ledipasvir/sofosbuvir, tablet, 90mg/400mg (Harvoni-GSI)**

  For patients that meet the eligibility criteria outlined below, clinicians will be encouraged to use Harvoni as ***one of*** the preferred therapeutic option***s*** over other covered therapies (e.g. interferon-based regimens with NS3/4A protease inhibitors or polymerase inhibitors). This recommendation is based on Harvoni's advantages in some patient populations, including potentially higher SVR rates, improved tolerability, no need for concomitant interferon or ribavirin therapy, shorter course of therapy, and once daily dosing.

  (All other criteria remain unchanged.)

***Change from Exception Drug Status Listing to Full Formulary Benefit Listing effective August 1, 2015:***

- amoxicillin trihydrate/potassium clavulanate, oral suspension, 40mg/5.3mg/mL (Clavulin-GSK); oral suspension, 80mg/11.4mg/mL; 25mg/6.25mg; 50mg/12.5mg/mL; tablet, 250mg/125mg, 500mg/125mg; tablet, 875mg/125mg (Clavulin-GSK) (and listed generics)
- cyproterone acetate, injection, 100mg/mL (Androcur-PMS); tablet, 50mg (Androcur-PMS) (and listed generics)
- diclofenac sodium, ophthalmic solution, 0.1% (Voltaren Ophtha-ALC)
- lansoprazole, delayed release capsule, 15mg; 30mg (Prevacid-ABB) (and listed generics)
- midodrine HCl, tablet, 2.5mg, 5mg (Apo-Midodrine-APX)
- minocycline HCl, capsule, 50mg, 100mg (listed generics)
- minoxidil, tablet, 2.5mg, 10mg (Loniten-PFI)
- nimodipine, tablet, 30mg (Nimotop-BAY)
- sodium cromoglycate, capsule, 100mg (Nalcrom-AVT)
- ursodiol, tablet, 250mg (Urso-AXC), 500mg (Urso DS-AXC) (pms-Ursodiol C-PMS)
- zuclopenthixol, acetate injection, 50mg/mL (Clopixol-Acuphase-AVT)
- zuclopenthixol decanoate injection, 200mg/mL (Clopixol-Depot-AVT)
- zuclopenthixol dihydrochloride tablet, 10mg, 25mg, (Clopixol-AVT)

**Saskatchewan Ministry of Health**
**Drug Plan and Extended Benefits Branch**
**2nd Floor, 3475 Albert Street**
**Regina, Saskatchewan S4S 6X6**
**(306) 787-3317**
**1-800-667-7581**