

### Galexos (simeprevir)

#### Galexos (simeprevir) – General Information

**Approvals:** *Federal/Canada:* Yes

*BC's PharmaCare:* Yes, in combination with peginterferon/ribavirin (PR)

**Targeted Genotype:** 1 a/b

**DAA Class:** Galexos is a NS3/4A protease inhibitor (PI). NS3/4A PIs work by blocking a viral enzyme (protease) that enables the hep C virus to survive and replicate in host cells – the liver in this case.

#### Galexos + peginterferon/ribavirin (PR)

**Dose:** 1 pill daily + peginterferon once weekly + ribavirin twice daily

**Approx. SVR:** 84% (without the Q80K genetic mutation)

**Length of Treatment:** 12 weeks Galexos with additional 12 weeks PR – total of 6 months avg.

**Common Side Effects:** Tiredness, headache, flu-like symptoms (associated with interferon), and skin rash, increased bilirubin levels in one's blood, constipation, and sensitivity to sunlight (photosensitivity) (associated with Galexos)

#### BC's PharmaCare Eligibility for Galexos + PR

To qualify for **Galexos in combination with peginterferon/ribavirin**, patients must have:

- Never tried to treat their hep C **OR**
- Tried treatment but the virus came back (*relapsed*) **OR**

- Tried treatment but weren't cured (*non-responder*)

#### **AND have ALL of the following:**

- Lab-confirmed hepatitis C genotype 1
- A prescription for the treatment from a qualified healthcare provider
- Detectable levels of hep C in the last 6 months
- Recent lab-confirmation of NS3 Q80K polymorphism negative for patients with hep C genotype 1a subtype or genotype 1 with indeterminate subtype. Retesting is required for all those who had their genotype tested **before May 1, 2012.**
- A liver fibrosis stage F2 or greater
- Special Authority request completed by a specialist or experienced physician

#### **BUT**

- Who have **NOT** been or **ARE NOT** being treated with a protease inhibitor or a NS5A/NS5B inhibitor.

#### **Galexos: Bioadvance Program**

The *Galexos: Bioadvance Program*, is a patient support program designed to provide health information and reimbursement assistance for patients who have been prescribed Galexos. For more information please call 1-855-512-3740.

Please see <http://www.pacifichepc.org/hepctip/> for more information. *This information is meant as a resource only and is not intended to replace qualified medical attention.*