Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

New Full Formulary Listing Effective September 1, 2014:

- **colesevelam HCl, tablet, 625mg (Lodalis-VAE)**

Change from Exception Drug Status Listing to Full Formulary Benefit:

- **insulin glulisine, solution for injection, 100U/mL (5x3mL) (10mL); 100U/mL, pre-filled pen SoloStar (3mL) (Apidra-AVT)**

New Exception Drug Status (EDS) Listings Effective September 1, 2014 according to the following criteria:

ivacaftor, tablet, 150 mg (Kalydeco-VER)

For treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene.

Renewal Criteria:
The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.
The patients will be considered to have responded to treatment if either:
a) The patient's sweat chloride test falls below 60mmol/litre; OR
b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmol/litre, the patient will be considered to have responded to treatment if either
c) The patient's sweat chloride test falls by at least 30%; OR
d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria.

Note: Coverage may be approved for up to 150mg every 12 hours for 6 months. Patients will be limited to receiving a one-month supply per prescription.

Revised Exception Drug Status Criteria:

- **fingolimod hydrochloride, capsule, 0.5mg (Gilenya-NVO)**

Exception Drug Status was revised to reflect additional initial therapies. Please refer to Appendix D on the Drug Plan website, http://formulary.drugplan.health.gov.sk.ca/FormularyAppxIndOther.aspx for details.

- **natalizumab, injection solution, 20mg/ml (Tysabri-BGN)**

Exception Drug Status was revised to reflect additional initial therapies. Please refer to Appendix D on the Drug Plan website, http://formulary.drugplan.health.gov.sk.ca/FormularyAppxIndOther.aspx for details.

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