Government of Saskatchewan

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SASKATCHEWAN FORMULARY BULLETIN

Interim Measures Related to Exception Drug Status (EDS) During COVID-19 Pandemic

Health system challenges resulting from the current COVID-19 pandemic may create difficulty in routinely accessing certain medical tests. One such example is pulmonary function tests (PFTs), which are required to fulfil EDS criteria for some medications.

To avoid EDS lapses for approved patients during this time, the Drug Plan will extend EDS duration for drugs requiring follow-up PFTs for renewal. Additionally, certain medications for Chronic Obstructive Pulmonary Disease (COPD) will have EDS criteria modified on an interim basis to allow approval when PFTs may not be accessible.

The duration of these changes will be informed by the timeframe of pandemic resolution in Saskatchewan. Any interim EDS changes will be noted in Appendix A of the Saskatchewan Formulary, as well as through Formulary Bulletins to prescribers and pharmacists. Please continue to monitor the Formulary website and bulletins for additional EDS updates during the COVID-19 pandemic.

The Drug Plan reminds dispensing pharmacy staff that **automatic Online EDS Adjudication (OEA) is available for select EDS medications, and adjudication should be attempted prior to contacting the Drug Plan**. This may prevent the need for a manual EDS application.

Listings with extended EDS durations for patients requiring renewal:

- dornase alfa, inhalation solution, 1mg/mL (Pulmozyme-HLR)
- nintedanib, capsule, 100mg, 150mg (OFEV-BOE)
- pirfenidone, capsule, 267mg; tablet, 267mg, 801mg (Esbriet-HLR)

***NOTE: Once PFT services become accessible, prescribers are encouraged to submit renewal requests as soon as possible in order to minimize EDS processing delays.*

Listings with modified criteria when EDS is requested (Note that automatic Online EDS Adjudication is available for some of these drugs and adjudication should be attempted prior to contacting the Drug Plan):

- In the event that PFT/spirometry is temporarily unavailable, the diagnosis of moderate to severe COPD for EDS purposes will not require the use of these assessment tools for the following:
    - aclidinium bromide, powder for inhalation, 400ug (Tudorza Genuair-ACL)
    - aclidinium bromide/formoterol fumarate dihydrate, powder for inhalation, 400ug/12ug (Duaklir Genuair-AST)

- glycopyrronium bromide, inhalation powder capsule, 50ug/dose (Seebri Breezhaler-NVR)
- indacaterol/glycopyrronium, inhalation powder capsule, 110UG/50UG (Ultibro Breezhaler- NVR)
- tiotropium bromide monohydrate, inhalation solution, 2.5ug (Spiriva Respimat-BOE) powder capsule, 18ug/dose (Spiriva-BOE)
- tiotropium bromide monohydrate/olodaterol HCl, inhalation solution, 2.5ug/2.5ug (Inspiolto Respimat-BOE)
- umeclidinium bromide, powder for inhalation, 62.5UG (Incruse Ellipta-GSK)
- umeclidinium bromide/vilanterol trifenatate, powder for inhalation, 62.5/25UG (Anoro Ellipta- GSK)

Listings with added OEA functionality:

- dornase alfa, inhalation solution, 1mg/mL (Pulmozyme-HLR) – initial approval only

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