

September 28, 2017

Dear Prescribers, Pharmacy Owners, Managers and Pharmacists,

Re: Changes to Exception Drug Status (EDS) Approval Process and Expiry Dates

Effective October 1, 2017, many Part 3 drugs will no longer require Exception Drug Status (EDS) renewal for coverage under Manitoba's Provincial Drug Programs (PDP) and the Employment and Income Assistance Drug Program (EIA).

All Part 3 EDS drugs will still require initial approval, but for many drugs, if coverage approval is granted, this approval will be indefinite and prescribers will no longer need to reapply for extending or renewing this coverage. Any patient that has an active EDS approval (as of October 1, 2017) for any of the drugs affected by this change will automatically have the approval extended indefinitely.

This change will help to ensure that there is no interruption of benefit coverage for drugs that are prescribed for certain chronic conditions to clients who meet the established Part 3 EDS criteria as recommended by an expert committee of health professionals.

This change will affect only products identified in the attached List of Designated Drugs with Indefinite EDS Approval. This List, which may be updated from time to time, can be found online at:
<http://www.gov.mb.ca/health/pharmacare/healthprofessionals.html>.

As a general reminder, please review the following information about EDS Requests:

For New EDS Requests:

- The prescriber must contact the EDS Office to obtain the necessary approval for benefit coverage before a client's prescription is filled.
- ☐ Prescriptions purchased prior to the effective date of Part 3 approval will not be covered by PDP or EIA. No exceptions.
- ☐ **If a client meets Part 3 EDS criteria for one of the products identified in the List of Designated Drugs with Indefinite EDS Approval, benefit coverage will be granted indefinitely.**
- ☐ **The client will receive an initial approval letter which confirms indefinite EDS approval.**
- ☐ Only the lowest generic cost as listed in the Manitoba Drug Interchangeability Formulary is considered eligible.
- ☐ If the request for benefit coverage is not approved, the client is responsible for the full cost of the treatment.

For Renewal EDS Requests:

- If a client has an active EDS approval for a product identified in the List of Designated Drugs with Indefinite EDS Approval – as of October 1, 2017, this coverage will be grandfathered indefinitely; **no renewal will be required.**
- ☐ **The client will not be sent a letter to confirm their continued EDS approval.**

Please note that some private and extended health insurance providers require their clients to have the EDS approval before they agree to cover any part of the prescription cost. It is the clients' responsibility to contact their private drug plan directly for further information.

Additionally, many clients contact Manitoba's Pharmacare Help Desk to request a copy of their "EDS Renewal Letter" for the purpose of their third party insurer. Effective October 1, 2017, the Department will not supply this letter to patients for any drugs that are (a) a renewal and (b) a drug on the List of Designated Drugs with Indefinite Exception Drug Status Approval.

The EDS Office will continue to receive EDS requests **exclusively by fax, indefinitely**. Please fax your EDS requests to **204-942-2030**, or our toll free number at **1-877-208-3588**. Our usual processing time is one to two business days. The EDS Office triages all requests and prioritizes urgent requests. **Urgent requests received during regular business hours will usually be processed within 24 hours.**

Please visit the "Information for Health Professionals" page of our website at <http://www.gov.mb.ca/health/pharmacare/healthprofessionals.html> for updates to our policies, forms, and procedures regularly. Thank you for your continued support and patience as we continue to review and modify processes and procedures.

Sincerely,

(Original signed by)

Patricia Caetano, PhD
Executive Director, Provincial Drug Program

List of Designated Drugs with Indefinite Exception Drug Status Approval

Drug Category	Product Name (Brand)	Product Name (Generic)	Effective Date
Antidiabetics	Actos	pioglitazone	October 1, 2017
	Amaryl	glimepiride	October 1, 2017
	Gluconorm	repaglinide	October 1, 2017
	Janumet (Janumet XR)	sitagliptin/metformin	October 1, 2017
	Januvia	sitagliptin	October 1, 2017
	Jardiance	empagliflozin	October 1, 2017
	Jentaducto	linagliptin/metformin	October 1, 2017
	Forxiga	dapagliflozin	October 1, 2017
	Invokana	canagliflozin	October 1, 2017
	Komboglyze	saxagliptin/metformin	October 1, 2017
	Onglyza	saxagliptin	October 1, 2017
	Trajenta	linagliptin	October 1, 2017
	Xigduo	dapagliflozin/metformin	October 19, 2017
Synjardy	empagliflozin/metformin	May 31, 2019	
COPD Treatments	Anoro Ellipta	umeclidinium/vilanterol	October 1, 2017
	Duaklir Genuair	aclidinium/formoterol	October 1, 2017
	Incruse Ellipta	umeclidinium	October 1, 2017
	Inspiolto Respimat	olodaterol/tiotropium	October 1, 2017
	Seebri Breezhaler	glycopyrronium	October 1, 2017
	Spiriva	tiotropium	October 1, 2017
	Spiriva Respimat	tiotropium	October 1, 2017
	Tudorza Genuair	aclidinium	October 1, 2017
	Ultibro Breezhaler	glycopyrronium/indacaterol	October 1, 2017
Urinary Antispasmodics	Oxytrol	oxybutynin	October 1, 2017
	Trosec	trosipium	October 1, 2017