

Ontario Public Drug Programs

Notice from the Executive Officer: Interim Extension of the Temporary Facilitated Access Mechanism (Rheumatology)

December 31, 2018

This is an update to the original notice dated December 14, 2017.

This notice provides an update to pharmacies about the claims submission process under the Temporary Facilitated Access Mechanism (TFA Rheumatology) using the Health Network System (HNS).

To ensure ongoing timely drug access, the TFA Rheumatology for Ontario Drug Benefit (ODB) program recipients aged 24 years and under that was scheduled to end on December 31, 2018 has been **extended until further notice**.

Overview

On January 1, 2018, the Temporary Facilitated Access mechanism for rheumatology (TFA Rheumatology) was implemented for certain biologics for select indications such that when prescribed by approved prescribers for their patients aged 24 years and under who are eligible to receive benefits under the ODB program, an Exceptional Access Program (EAP) request was not required.

During the extension, the TFA Rheumatology mechanism will continue according to existing policy. Under this mechanism, **approved TFA Rheumatology prescribers do not need to submit an application to the Exceptional Access Program** if the drug is being used to treat the specified indication and if the prescriber determines that the patient's circumstances meet the EAP reimbursement criteria. The following drug products are eligible for access through TFA Rheumatology.

Indication	Drugs Covered Under TFA Rheumatology
Polyarticular juvenile idiopathic arthritis (pJIA)	Actemra, Enbrel*, Humira**, Orenzia, Remicade
Systemic juvenile idiopathic arthritis (sJIA)	Actemra, Kineret (disease onset must be before age of 16 even if patient is currently over 16 years of age)
Juvenile spondyloarthritis or enthesitis-related arthritis (JSpA/ERA)	Enbrel, Remicade (disease onset must be before age of 16 even if patient is currently over 16 years of age)
Uveitis/non-infectious ocular inflammatory disease (OID)	Remicade, Humira

*Reminder that the biosimilar Erelzi (etanercept) is funded on the ODB Formulary as a Limited Use (LU) product for pJIA for etanercept naïve patients. Please visit the ODB eFormulary for details on the LU criteria:

<https://www.formulary.health.gov.on.ca/formulary/>

**Humira for pJIA – patients under 10 years of age are to be funded by the manufacturer

Authorized prescribers are only permitted to use the TFA Rheumatology mechanism if the posted online EAP criteria are met for the indication specified, as further explained below

(http://www.health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf).

- Patients stable on a biologic who require ongoing coverage must have met the initial criteria prior to starting the biologic and any renewal criteria must be met before the TFA Rheumatology mechanism can be used to provide ongoing coverage on or after January 1, 2018.
- For new patients starting on a biologic after January 1, 2018, the TFA Rheumatology mechanism can be used if the initial EAP approval criteria are met.
- The TFA Rheumatology mechanism can also be used for renewals for existing EAP patients as long as the applicable renewal criteria are met.
- Only the standard dosing regimen for the patient's age and weight is allowed, as posted online for the specific indications or according to the product monograph.

If the applicable EAP criteria are met, then the authorized prescriber's prescribing of the therapy will be deemed to satisfy the requirements in section 16 of the *Ontario Drug Benefit Act* for an EAP approval. An approved EAP request will NOT be required.

Further details on TFA Rheumatology including prescriber and pharmacist requirements can be found at:

http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/notices/exec_office_20171214.pdf

Additional Information:

For pharmacies:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282