

Ontario Public Drug Programs

Notice from the Executive Officer: Temporary Facilitated Access Mechanism (Rheumatology) for Ontario Drug Benefit Recipients aged 24 years and under

December 14, 2017

Effective January 1, 2018, the Ontario Public Drug Programs (OPDP) will implement a Temporary Facilitated Access mechanism for rheumatology (TFA Rheumatology) that will provide coverage for certain biologics for select indications when prescribed by approved prescribers for their patients aged 24 years and under who are eligible to receive benefits under the Ontario Drug Benefit (ODB) program, without the need for an Exceptional Access Program (EAP) request.

The following drug products are eligible for access through TFA Rheumatology. Under this mechanism, approved TFA Rheumatology prescribers do not need to submit an application to 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 approval criteria.

Indication	Drugs Covered Under TFA Rheumatology
Polyarticular juvenile idiopathic arthritis (pJIA)	Actemra, Enbrel*, Humira**, Oencia, 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

*Note that Enbrel will only be eligible through TFA Rheumatology for patients who were stabilized on etanercept for pJIA prior to December 21, 2017. Effective December 21, 2017, the biosimilar Erezli (etanercept) is funded on the ODB Formulary as a Limited Use (LU) product for pJIA.

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

Authorized prescribers will only be 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).

- For patients currently stable on a biologic who require ongoing coverage, they 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.

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.** The TFA Rheumatology mechanism can be used from January 1st, 2018 until December 31st, 2018.

Prescribing Requirements

The authorized prescriber must be a physician identified on the TFA Rheumatology List of Authorized Prescribers maintained by the Ontario Rheumatology Association, which is responsible for determining prescriber eligibility. For more information on TFA Rheumatology prescriber eligibility, please contact the ORA at admin@ontariorheum.ca.

Rheumatologists granted TFA are expected to:

1. Only use the TFA Rheumatology mechanism if prescribing a drug product used to treat the specified indication on this list for an ODB eligible recipient aged 24 years and under.
2. Ensure that new patients meet the posted initial criteria prior to starting the biologic. For patients currently stable on a biologic, ensure they met the initial criteria prior to starting the biologic and currently meet renewal criteria. In the case of renewals, any renewal criteria must be met. All criteria are posted online (http://www.health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf).
3. Write a prescription and ensure the following are included:
 - a. the drug
 - b. the indication
 - c. the dose and frequency of administration (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)
 - d. quantity to be dispensed and/or repeats
 - e. The words "Temporary Facilitated Access" or "TFA"
 - f. Their College of Physicians and Surgeons of Ontario (CPSO) Registration/License Number
4. Sign and date the prescription

Pharmacist Requirements

A pharmacist is required to validate that the drug and prescriber are eligible under the TFA Rheumatology mechanism.

Note: If the patient currently has a prescription for a biologic eligible for the TFA Rheumatology mechanism on file, effective January 1, 2018, they can refill the prescription under the TFA Rheumatology mechanism if the prescription is from an authorized prescriber on the TFA Rheumatology List of Authorized Prescribers. If a patient has an existing EAP approval for the biologic, the duration of the existing approval will continue to be valid. Additionally, the same prescription may also be dispensed using the TFA Rheumatology mechanism.

List of DINs/PINs for Eligible Drugs

Drug and Indication	Dosage and DIN/PIN
Abatacept (Orencia) for: <ul style="list-style-type: none"> • Polyarticular juvenile idiopathic arthritis (pJIA) 	250mg/15mL injection 02282097
Adalimumab (Humira) for: <ul style="list-style-type: none"> • Polyarticular juvenile idiopathic arthritis (pJIA) • Uveitis/non-infectious ocular inflammatory disease (OID) 	40mg/0.8mL prefilled syr 02258595 40mg/0.8mL prefilled pen 09857294 (PIN) 40mg/0.8mL vial for pediatric use 09854785 (PIN)
Anakinra (Kineret) for: <ul style="list-style-type: none"> • Systemic juvenile idiopathic arthritis (sJIA) 	150mg/mL 02245913
Etanercept (Enbrel) for: <ul style="list-style-type: none"> • Juvenile spondyloarthritis or enthesitis-related arthritis (JSpA/ERA) • Renewals of Polyarticular juvenile idiopathic arthritis (pJIA) 	25mg 02242903 50mg 02274728 SureClick 50mg/mL Pref Autoinj 09857394 (PIN)
Infliximab (Remicade) for: <ul style="list-style-type: none"> • Polyarticular juvenile idiopathic arthritis (pJIA) • Juvenile spondyloarthritis or enthesitis-related arthritis (JSpA/ERA) • Uveitis/non-infectious ocular inflammatory disease (OID) 	100mg/vial 02244016 09852956 (compounding PIN)
Tocilizumab (Actemra) for: <ul style="list-style-type: none"> • Polyarticular juvenile idiopathic arthritis (pJIA) • Systemic juvenile idiopathic arthritis (sJIA) 	80mg/4mL single use vials 02350092 200mg/10mL single use vials 02350106 400mg/20mL single use vials 02350114

TFA Rheumatology List of Authorized Prescribers

The TFA Rheumatology List of Authorized Prescribers which indicates which prescribers are authorized to use the TFA Rheumatology mechanism effective January 1, 2018 will be communicated directly to pharmacies through OneMail. This list will be updated on an ongoing basis.

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