

Ontario Public Drug Programs

Notice from the Executive Officer: Extension of the Temporary Facilitated Access Mechanism (Rheumatology) until March 31, 2019

February 13, 2019

This is an update to the notice posted on December 31, 2018.

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).

The government is proposing to change OHIP+ by focusing benefits on children and youth who do not have existing prescription drug benefits. If the proposed changes are approved, OHIP-insured children and youth 24 years of age and under who are NOT covered by private plans would continue to receive coverage for eligible prescription medications through OHIP+.

Children and youth who are covered by private insurance would bill their plans, unless they remain eligible for the Ontario Drug Benefit (ODB) program through an eligibility stream other than OHIP+ (e.g., social assistance, home care). The target implementation date for the proposed changes is April 1, 2019.

Please note that the proposed changes to OHIP+ were posted on Ontario's Regulatory Registry for consultation. Until the proposal is approved by the Lieutenant Governor in Council, the above information about the proposal is subject to change.

The Temporary Facilitated Access Mechanism (TFA Rheumatology) for ODB program recipients aged 24 years and under has been **extended until March 31, 2019**.

The extension of the TFA Rheumatology mechanism will give prescribers additional time to bridge access to eligible biologics/indications using the TFA mechanism and to submit requests to the Exceptional Access Program (EAP) for children and youth who are expected to remain eligible for the ODB program after March 31st. An EAP application will be required as of April 1, 2019, if not submitted already, for both new starts and renewals (or those requiring ongoing

ODB coverage) for children and youth 24 years of age and under who remain eligible for the ODB program (either through OHIP+ or another eligibility stream such as social assistance, home care, etc.). See below for further details.

If an ODB-eligible recipient does not have an Exceptional Access Program approval in place, any claims submitted to the HNS under the TFA Rheumatology mechanism on April 1, 2019 or later will be rejected with the response code “CD – Patient not entitled to drug claimed”.

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 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. As of April 1, 2019, the biologics/indications below will require an approved EAP application for funding through the ODB program.

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

- For patients 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.
- 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. The TFA Rheumatology mechanism can be used **until March 31, 2019**. As of April 1, 2019, **an approved EAP request will be required** for children/youth who remain eligible for the ODB program.

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

Prescribers

For existing patients:

As the ministry will be anticipating a higher volume of requests to the EAP close to the end date of the TFA mechanism (i.e., March 31, 2019), prescribers are encouraged to send in EAP requests several weeks before the end of March for their patients accessing biologics through the TFA Rheumatology mechanism who are expected to remain eligible for the ODB program after March 31st so that the requests can be processed in a timely manner and to prevent delays in patient access to treatment. Specific forms for the above indications can be found on the

Ontario Rheumatology Association (ORA) website at: <https://ontariorheum.ca/drug-forms-and-codes/eap-forms>

Ensure that the forms are complete and evidence of response to therapy is provided. **Only the current EAP renewal criteria need to be met.** EAP reimbursement criteria for the above drugs/indications can be found at:

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

If evidence of response cannot be provided (e.g., if the patient recently started), please provide rationale including the start date of therapy. These will be reviewed on a case-by-case basis.

Please also ensure to indicate that the TFA Rheumatology mechanism was previously used for the patient on the EAP request. If submitting the renewal request on an ORA form, please check off the box “TFA Mechanism Previously Used”. Without this information, ministry assessors will require that prescribers provide further information as to how the patient met the initial EAP reimbursement criteria prior to starting the biologic and also how the patient currently meets the EAP renewal criteria.

For new patients:

For new patients who are expected to remain eligible for the ODB program and who will require one of the above biologics for one of the above indications after March 31st, prescribers are encouraged to submit an EAP request before the end of March. Although the TFA Rheumatology mechanism can be used if the patient meets the EAP reimbursement criteria, this process will end on March 31st.

Pharmacists

Pharmacists are encouraged to inform their patients accessing biologics through the TFA Rheumatology mechanism to speak with their prescribers about submitting an EAP request. Pharmacists are also encouraged to contact these prescribers to send in EAP requests for children and youth who are expected to remain eligible for the ODB program after March 31st as soon as possible to prevent a delay in funding and/or access to treatment.

Claims can continue to be processed in the usual manner under the TFA Rheumatology mechanism until March 31, 2019 without the requirement of an EAP approval.

If a patient continues to be ODB eligible and an EAP request is approved for funding, claims for that patient can be processed without interruption after the TFA Rheumatology mechanism ends until the expiry date of the EAP approval, at which point a renewal EAP request will be required.

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