Q&As on Temporary Facilitated Access (Rheumatology) Mechanism

General

Q1. How does the TFA Rheumatology mechanism work?

Effective January 1, 2018, the Ontario Public Drug Programs 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.

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). 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.**

Q2. How do I become an authorized prescriber who can use the TFA Rheumatology mechanism?

The TFA Rheumatology List of Authorized Prescribers is maintained by the Ontario Rheumatology Association (ORA), which is responsible for determining prescriber eligibility. For more information on TFA Rheumatology prescriber eligibility or to be added to the list, please contact the ORA at admin@ontariorheum.ca.

Duration of the TFA Rheumatology mechanism

Q3. When can I start using the TFA Rheumatology mechanism?

The TFA Rheumatology mechanism can be used by physicians on the TFA Rheumatology List of Authorized Prescribers starting January 1, 2018.

Q4. When will the TFA Rheumatology mechanism end?

The TFA Rheumatology mechanism will no longer be useable after December 31, 2018.

Q5. I am a physician registered on the TFA Rheumatology List of Authorized Prescribers. What should I do so my patient does not experience an interruption in coverage when the TFA Rheumatology mechanism ends on December 31, 2018?

Prior to December 31, 2018 you should submit a completed EAP request (on an ORA EAP form preferably) to the Ministry of Health and Long-Term Care. For patients who filled a prescription using the TFA Rheumatology mechanism in 2018, you would need to indicate on the form that the EAP request is for a "renewal" and that the TFA Rheumatology mechanism was previously used for funding (otherwise it will be

considered a "new" request to the Exceptional Access Program and both initial and renewal criteria would need to be met).

While a prescriber can submit an EAP request at any time, the approval start and end dates will be determined based on when the request is received. Therefore it is recommended that EAP requests for drug/indication combinations covered under the TFA Rheumatology mechanism be sent to the Ministry of Health and Long-Term Care in the fall of 2018.

Drugs and Indications

Q6. Which drug and indication combinations are eligible for the Temporary Facilitated Access mechanism?

The TFA mechanism will apply to the following rheumatology indications and drug combinations for children and youth:

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

*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.

Q7. Which DINs/PINs are eligible for funding under the TFA Rheumatology mechanism?

The DINs/PINs for eligible drugs under the TFA Rheumatology mechanism are listed below:

Drug and Indication	Dosage and DIN/PIN
Abatacept (Orencia) for: • Polyarticular juvenile idiopathic arthritis (pJIA)	250mg/15mL injection 02282097
Adalimumab (Humira) for: • 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: • Systemic juvenile idiopathic arthritis (sJIA)	150mg/mL 02245913
Etanercept (Enbrel) for: • 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: • 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: • 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

Q8. Is Rituxan part of the TFA Rheumatology mechanism?

While Rituxan is also considered for funding through the Exceptional Access Program for uveitis/OID and other indications not listed here, it is not part of the TFA Rheumatology mechanism. Only the drug and indication combinations listed below are covered through the TFA Rheumatology mechanism:

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

*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.**

Q9. When can I use the TFA Rheumatology mechanism for Enbrel?

Enbrel is only eligible for funding through the TFA Rheumatology mechanism 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. New patients who start Enbrel for pJIA in 2018 will not be approved for funding through the EAP.

Q10. Is Erelzi part of the TFA Rheumatology mechanism?

Erelzi (etanercept) is a new biosimilar that is listed on the ODB Formulary as a limited use (LU) product for several indications including pJIA. It is not part of the TFA Rheumatology mechanism. Please see the separate FAQs on Erelzi for more information (http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx).

For Physicians on the TFA Rheumatology List of Authorized Prescribers

Q11. I am a physician registered on the TFA Rheumatology List of Authorized Prescribers. For which of my patients can I use the TFA Rheumatology mechanism?

The TFA Rheumatology mechanism will only apply for Ontario Drug Benefit (ODB) eligible recipients aged 24 years and under. This includes all children and youth aged 24 years and under with OHIP coverage who are enrolled in the ODB program through OHIP+: Children and Youth Pharmacare and children and youth aged 24 years and under who are social assistant recipients (Ontario Works or Ontario Disability Support Program).

Q12. I am a physician registered on the TFA Rheumatology List of Authorized Prescribers. If the drug and indication combination I want to prescribe is not eligible for the TFA Rheumatology mechanism what should I do (e.g., my patient is 25 years old and I want to prescribe Remicade for uveitis, or my patient is 19 years old and I want to prescribe Humira for rheumatoid arthritis)?

The prescriber should complete an EAP request (preferably on an ORA EAP form available on the ORA website) and submit it to the Ministry of Health and Long-Term Care.

Q13. I am a physician registered on the TFA Rheumatology List of Authorized Prescribers. If my patient does not meet the clinical criteria posted on the Ministry of Health and Long-Term Care's website what should I do (e.g., my patient did not try the alternatives required prior to starting the biologic, or my patient is using a higher dosing regimen than what is posted online)?

If a patient does not meet the clinical criteria posted on the Ministry of Health and Long-Term Care's website at: http://www.health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf then the prescriber should complete an EAP request (on an ORA EAP form preferably) and submit it to the Ministry of Health and Long-Term Care.

Q14. I am a physician registered on the TFA Rheumatology List of Authorized Prescribers. What do I have to do when I am writing a prescription for a drug and indication eligible for funding through the TFA Rheumatology mechanism?

Physicians 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 an eligible 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

Q15. I am a physician who is listed on the TFA Rheumatology List of Authorized Prescribers. What should I do if my patient is currently covered by private insurance but didn't meet the initial EAP criteria when they started?

If a patient covered by private insurance didn't meet the initial EAP criteria when he/she started treatment, then the TFA Rheumatology mechanism should not be used. You should submit a completed EAP request (on an ORA EAP form preferably) to the Ministry of Health and Long-Term Care for assessment. If it is rejected, the response letter can then be forwarded to the private insurance for consideration of continued funding (if previously covered by the insurer).

<u>For Pharmacists</u>

Q16. As a pharmacist what do I have to do if a prescription has "TFA" or "Temporary Facilitated Access" written on it?

The TFA Rheumatology mechanism requires a pharmacist to validate that the drug and prescriber align with this special prescribing authority by verifying that the physician is on the TFA Rheumatology List of Authorized Prescribers and that the DIN/PIN is eligible for funding 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.