Temporary Facilitated Access Mechanism (Rheumatology) for OHIP+: Children and Youth Pharmacare

Objective

In order to ensure that children and youth requiring certain biologic medications for approved rheumatology indications under the Exceptional Access Program are able to seamlessly transition to OHIP+, the Ministry of Health and Long-Term Care ("ministry") will be implementing a Temporary Facilitated Access (TFA) mechanism in consultation with the Ontario Rheumatology Association (ORA).

Approach

- The TFA mechanism will only apply for OHIP+ eligible patients (i.e., patients aged 24 and under who are OHIP-insured). There are two scenarios for which the TFA mechanism would apply:
    1. Patients who are stable and/or responding to a designated biologic prior to January 1st, 2018 (for at least 3-6 months or to be determined by the ORA); or
    2. New patients (that are aged 24 and under) that start a biologic after January 1st, 2018 who meet the drug and indication criteria.
- The TFA mechanism would apply to the following rheumatology indication/drug combinations for children/youth:

Indication	***Drugs Covered Under TFA***
Polyarticular juvenile idiopathic arthritis (pJIA)	Actemra, Enbrel, Humira*, Orencia, Remicade (*for Humira – patients under 10 years of age are to be funded by the manufacturer)
Systemic juvenile idiopathic arthritis (sJIA)	Actemra, Kineret (disease onset must be before age of 16 even if patient 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 currently over 16 years of age)
Uveitis/non-infectious ocular inflammatory disease (OID)	Remicade, Humira

- The TFA mechanism can only be used if the posted online Exceptional Access Program (EAP) criteria are met for the indication specified. A patient must meet the initial criteria prior to starting the biologic and, in the case of renewals, any renewal criteria. The drug and indication combinations noted above are currently funded under EAP according to specific criteria. All criteria are posted online (http://www.health.gov.on.ca/en/pro/programs/drugs/docs/frequently_requested_drugs.pdf). Note that Rituxan is also funded for uveitis/OID but these indications will not be part of the TFA mechanism.
- If the EAP criteria are met, then the physician's prescribing of the therapy shall be deemed to satisfy the requirements in section 16 of the *Ontario Drug Benefit Act* for an EAP approval.

- If the EAP criteria are not met, a full EAP request should be submitted for review along with the rationale for the patient continuing on the biologic, in accordance with section 16 of the ODBA.
- The approval start date would be the date when the first claim is submitted to the Health Network System (HNS) at a pharmacy.
- The approval end date would be December 31st, 2018.
    - The TFA mechanism would be 'turned off' at that time. An EAP 'renewal' request would need to be made before the end date to prevent any gaps in therapy.
    - Requests for renewal for patients previously funded through the TFA mechanism after the end date would only require that renewal criteria for the drug/indication combination are met. In some cases, in order to assess the request for renewal, details of clinical history, alternatives tried, the dosing regimen, etc. may be required (e.g., baseline swollen joint count may be required in order to assess response to therapy).
        - Requests for renewal MUST also state that the TFA mechanism was previously used for funding (otherwise, it will be treated as a new request to EAP and initial and renewal criteria will need to be met as per current guidelines).
    - Continuation of funding after the end date is not guaranteed even if the TFA mechanism was previously utilized.
- If an EAP request is denied sometime during the year when the TFA mechanism is used, the patient will continue to have access to the biologic through the TFA mechanism for the remainder of the year, after which time, funding will not be provided.
- For patients under the age of 25 with a current EAP approval on file for one of the above indications, it is recommended that the regular EAP/ORA renewal form be completed for the specific indication and that the TFA mechanism not be used as some indications allow for more than one year approval duration on renewal.

Requirements for Implementation of TFA

- The ORA will provide the ministry with the following information:
    - A list of rheumatology specialists identified by the ORA (possibly in conjunction with the OMA);
    - The physicians' corresponding CPSO numbers; and
    - The physicians' city of practice.
- The identified rheumatology specialists must make a self-declaration to the ORA that he/she provides medical care for the OHIP+ population (i.e., children and youth aged 24 and under).
- The information provided by the ORA to the ministry may be shared with pharmacies/pharmacists in order to process prescriptions under the TFA mechanism. The physician must provide their consent to sharing this information with pharmacies/pharmacists.
- The ministry will tag the physicians' CPSO numbers in HNS to a specific set of identified EAP drugs that they can prescribe under the TFA mechanism to streamline access for OHIP+ eligible patients.

Prescribing Requirements

- The prescriber must be a rheumatology specialist identified by the ORA (possibly in conjunction with the OMA).
- The physician should indicate “TFA” or “FA” on the prescription for a designated biologic if it is for an indication funded under the TFA mechanism (if the prescription is already at the pharmacy, a new prescription with “TFA” or “FA” does not need to be written).
- 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); higher doses should not be funded through the TFA mechanism , in which case a full EAP request should be submitted.
- Requests for other biologics or for other indications not specified above will require a regular EAP request to be submitted.
    - For example, a request for rheumatoid arthritis for a patient > 18 years of age regardless of the biologic would require a complete EAP request.
    - Note that if a patient is between 18 and 24 years of age but was previously diagnosed with one of the above indications, the TFA mechanism could still be used.