

A rheumatologist's decision to prescribe a biologic agent (biosimilar or innovator molecule) must be informed by the clinical need and must adhere to the principles of a sound therapeutic alliance. The Ontario Rheumatology Association (ORA) is aware that automatic (non-medical) switching from innovator to biosimilar molecule may achieve cost-savings to the health care system.

## **ORA Position on Non-Medical Switching:**

The ORA recognizes that non-medical switching\* from innovator to biosimilar biologic medications with approved indications for patients with rheumatic disease is safe and has the potential to save health care system resources. The ORA's support for non-medical switching is based on the following principles:

- 1. Switching results in no incremental cost borne by patients;
- 2. There are demonstrable cost savings to the health system

With respect to implementation of non-medical switching, the ORA makes the following recommendations:

- 1. To make the non-medical switch, a time period of no less than 6 months is permitted, recognizing that there are practical challenges involved in switching including counselling, additional clinic visits, and additional pharmacovigilance;
- 2. The payer should provide the option to switch back to the innovator biologic if criteria are met for disease flare within 6 months of switching.
- 3. A portion of the cost savings should be reinvested to support care for Rheumatology patients (examples include innovative technologies to improve and monitor quality of care for patients, team-based models of care, and access to specialists, medications, and currently non-funded laboratory tests such as ACPA, ANCA, or APAs).

<sup>\*</sup>Also called administrative switching or transitioning



# Frequently Asked Questions Will Be Posted On An Ongoing Basis Updated September 19, 2018

#### 1. Why have you published the position statement at this time?

Biologic therapies have had a significant positive impact on a proportion of our patients who have not responded to usual conventional therapies, however at a significant expense to the system. There is worldwide interest in the economic impact of biosimilar switching. It is possible that payers will choose to mandate this. In order to protect the interests of our members and their patients we wish to ensure that if non medical switching is mandated by a payer, that our position is clear.

## 2. Are you recommending switching?

No. We are responding to the current interest in the health economic impact of forced switching. We believe that outside this scenario the choice of biologic medication remains a discussion between clinician and patient, but we do believe that where equivalence has been demonstrated, that the potential for savings to the health care system should be considered by all stakeholders.

### 3. Is this your final position?

Our position statement will be an iterative process and may change as new information is available.

## 4. What is your position on interchangeability?

In the absence of data we have no current opinion on interchangeability and substitution. Our statement assumes a single one direction switch to a biosimilar medication.

#### 5. Have you consulted with all stakeholders?

We are always happy to receive feedback from stakeholders including patients, manufacturers (Pharma) and payers, both private and public. This position statement was primarily developed for members of our association.