Canadian Rheumatology Association (CRA) Position Statement on Biosimilars

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Highlights of Changes:

The position statement was updated to form a general statement applicable to all rheumatology populations and rheumatic diseases. Specific recommendations regarding pediatric populations and off label medication usage were removed.

It is acknowledged that evidence for the risk/benefit ratio of the use of biosimilars in the management of rheumatic diseases is rapidly accruing. The CRA encourages rheumatologists to provide the best care for individual patients and be fiscally responsible for the benefit of society as a whole. Rheumatologists should consider choosing the most cost-effective product when there is a choice available between an originator biologic and a biosimilar and must be mindful of cost savings. It is imperative that any substitution or transition/change to an approved biosimilar should result in no additional cost to the patient. The CRA recognizes the administrative challenges that patients may experience in accessing a biologic agent and therefore strongly encourages industry to provide and/or maintain patient support programs.

1. Biologic naïve patients:

   For a patient new to a specific biologic, cost effectiveness should be considered when there is an available choice between an originator biologic and one or more biosimilars.

2. Transitioning and changing for patients on biologics:

   There must be a respectful and informed conversation between the rheumatologist and patient prior to any transitioning/changing from an originator biologic to a biosimilar.
   Any change to or new start with a biosimilar must take into account agents which are the best tolerated and have the appropriate formulation.

3. Substitution by someone other than the prescriber:

   a. Notification of an intended substitution must be given to the prescribing rheumatologist and patient.
   b. There will be no substitution without an informed consultation by the patient with the prescribing rheumatologist prior to any treatment change. Thus, when a substitution is proposed, at least 6 months is required to allow sufficient time for a prescriber patient dialogue to occur.

c. In the event of substitution, the originator biologic must continue to be provided until access to the biosimilar is confirmed and available, without any interruption in patient care.
d. The CRA encourages payers to have a process in place via which the patient can revert to the original biologic agent in a timely fashion if there is a clinically relevant flare-up of the disease after an appropriate trial with up to two biosimilars; or if there is intolerance to the new formulation and alternate appropriate biosimilars are not available (e.g., citrate free or pediatric appropriate formulations).

4. The naming of biosimilars should be clear to enable tracking and post-marketing surveillance of new originator biologics and biosimilars, especially as new products enter the market.

Terminology clarification

Bridges et al. The science behind biosimilars, entering a new era of biologic therapy. *Arthritis Rheum* 2018, 3;334-44.

1. **Substitution:** is the FDA-preferred term that refers to a change in treatment by someone other than the prescriber and may be regulated by the law. Substitution is also termed non-medical or administrative substitution.
2. **Transitioning and changing:** an intentional therapeutic alteration to a biosimilar initiated by the health care provider in partnership with the patient.
3. **Switching:** this term is used, according to the US Biologics Price Competition and Innovation (BPCI) Act of 2009, when transitioning to or from a biosimilar which has been designated interchangeable
4. **Interchangeability:** refers to a status that may be granted to a biosimilar that is “expected to produce the same clinical result as the reference product in any given patient”. To date there is no product that has been designated interchangeable. This status can be achieved by results of post-marketing surveillance and at least one prospective controlled switching study requiring subjects to be switched over at least three times in the switching arm.