CRA Position Statement on Canadian Access to Citrate-free Adalimumab

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Highlights of Changes:

- Title of position statement
- Addition of biosimilar adalimumab drugs
- Advocating for both 20 mg and 40 mg citrate free formulations

Adalimumab is proven to be effective in a number of rheumatic diseases. Unfortunately, adherence to injections of adalimumab can be limited by the associated pain reported by patients[1], a particularly important issue for young children. Painful injections impact negatively on the quality of life of children and their families. Studies have shown that 40% of children resist medications that involve injections, and parental fear of pain predicts a decrease in treatment adherence[2].

Citrate-free Humira (the originator adalimumab drug) at both the 20 and 40 mg doses is available to patients in the United States, Europe and many other countries world-wide. Studies have shown that the citrate-free formulation causes significantly less pain[3,4], thereby improving adherence and quality of life. Citrate-free Humira has Health Canada approval; however, it is only commercially available in the concentrated 20mg/0.2mL pre-filled syringe formulation in Canada. Recently, multiple biosimilar adalimumab drugs have been approved by Health Canada for multiple adult and pediatric indications; some (but not all) of these biosimilars are available in citrate-free formulations (40 mg/0.8 mL and/or 20 mg/0.4 mL).

The Canadian Rheumatology Association strongly recommends that access to citrate-free adalimumab continues to be available for Canadian children requiring adalimumab treatment at both the 20 mg and 40 mg doses. We strongly recommend that private and public payers ensure access to at least one citrate-free adalimumab originator and biosimilar on their formularies.

References:

1. Gely C, Marín L, Gordillo J, Mañosa M, Bertoletti F, Cañete F, González-Muñoza C, Calafat M, Domènech E, Garcia-Planella E. Impact of pain associated with the subcutaneous administration of adalimumab. Gastroenterol Hepatol. 2020 Jan;43(1):9-13.
2. Yvonne N Brandelli, Christine T Chambers, Perri R Tutelman, Jennifer N Stinson, Adam M Huber, Jennifer P Wilson, Parent Pain Cognitions and Treatment Adherence in Juvenile Idiopathic Arthritis, Journal of Pediatric Psychology, Volume 44, Issue 9, October 2019, Pages 1111–1119, https://doi.org/10.1093/jpepsy/jsz067
3. Nash P, Vanhoof J, Hall S, Arulmani U, Tarzynski-Potempa R, Payne AN, Cividino A. Randomized Crossover Comparison of Injection Site Pain with 40 mg/0.4 or 0.8 mL Formulations of Adalimumab in Patients with Rheumatoid Arthritis. Rheumatol Ther. 2016 Dec; 3(2): 257–270.
4. Tomohiko Yoshida, Yasuhiro Otaki, Naooki Katsuyama, Michiko Seki & Junko Kubota (2019) New adalimumab formulation associated with less injection site pain and improved motivation for treatment, Modern Rheumatology, DOI: 10.1080/14397595.2018.1520426