Rheumatoid Arthritis Biologic Criteria for All Canadians

By Jane Purvis, MD, FRCPC

The treatment of rheumatic diseases has changed dramatically in the last 15 years with the advent of new, effective therapies and the reassessment of older medications, leading now to the concept of treating patients to target and working to avoid disability and deformity. Along with this revolution in treatment has come a significant increase in the direct costs of therapy, especially as related to the expense of biologic medication. This reality has resulted in payers and prescribers attempting to rationalize or strategize the use of these therapies; such strategies have included requiring various older medications to be used first, or selecting only patients with certain levels of disease activity to be given access to the biologics. This had led to situations where patients with similar diseases, but different insurance companies, were not able to access the same medication. The provincial criteria for biologic access in the rheumatic diseases are also very different, so that current portability of coverage across insurers and provinces is uneven and not particularly equitable.

To proactively address this situation, the Third Party Payer Committee of the Ontario Rheumatology Association (ORA), with the blessing of the CRA, entered into discussions with the Canadian Life and Health Insurance Association (CLHIA), who were also interested in bringing more standardization to the system. For the first effort, it was decided to address biologic access for adults with rheumatoid arthritis (RA), as there are published treatment criteria from the CRA that have been well-accepted, and the disease is well characterized and relatively common. Given that the number of rheumatologists across the country is fairly small, it was felt that this was a reasonable first target for attempting to create pan-Canadian criteria for biologic access for private insurers.

Early on, it was decided that the specific biologic drug name was not as important as gaining access to biologics as a class. This was an important decision to allow the insurers to proceed further with the discussions. As a result, all the biologics approved for RA as of January 2014 were considered as a group, excluding rituximab, which is approved as a second-line drug after a first biologic in most cases. The criteria were derived from the evidence-based guidelines available, especially the CRA guidelines for RA.[1,2] The CLHIA helped facilitate the discussion with its member insurance companies through meetings with industry, as well as a teleconference with the ORA/CRA committee members. The ORA/CRA team included Dr. Jane Purvis (Committee lead), Dr. Arthur Karasik, Dr. Philip Baer, Dr. Carter Thorne (ORA Past-President, CRA Past-President, CRA Therapeutics Committee lead), Mr. Denis Morrice, Ms. Dawn Richards (Canadian Arthritis Patient Alliance [CAPA] representative), with consultations with Dr. Cathy Flanagan and Dr. Jason Kur (British Columbia), Dr. Cory Baillie (CRA President, Manitoba), Dr. Jamie Henderson and Dr. Peter Docherty (New Brunswick), Dr. Frédéric Morin, Dr. Boulos Haraoui, and Dr. Denis Choquette (Quebec), and Dr. Janet Pope, Dr. Vandana Ahluwalia, Dr. Henry Averns, Dr. Nikhil Chopra, and Dr. Felix Leung (Ontario). Supportive and dissenting opinions were all carefully considered by the committee.

The final accepted criterion is as follows:

- A minimum 12-week trial of methotrexate plus one other disease modifying anti-rheumatic drug (DMARD).
  - Where combinations of non-biologic DMARDs are impossible (a rare situation), three consecutive non-biologic DMARDs would be acceptable.

The agreement with the insurers is that, going forward, unless a plan sponsor instructs otherwise, private insurance plans will adhere to this standard criteria across the country. This initial step—reached with much discussion and consideration—is only our starting point on this journey, with plans to review the functionality of the criteria after their use for a few months. Input from prescribers, insurers and patient groups will be welcomed. The CLHIA along with the ORA/CRA team will meet to assess any

modifications that may be required. It is hoped that this simple criterion, applied across all insurers across the country, could lead to similar standardized outcomes with provincial formularies for RA patients. We will be speaking with each province over the coming months to see if there is a willingness to move in this direction.

References
1. Bykerk VP, Akhavan P, Hazlewood GS, et al. Canadian Rheumatology Association Recommendations for Pharmacological Management of Rheumatoid Arthritis with Traditional and Biologic Disease-modifying Antirheumatic Drugs. J Rheumatol 2012; 39(8):1559-82.
2. Bombardier C, Hazlewood GS, Akhavan P, et al. Canadian Rheumatology Association Recommendations for Pharmacological Management of Rheumatoid Arthritis with Traditional and Biologic Disease-modifying Antirheumatic Drugs: Part II Safety. J Rheumatol 2012; 39(8):1583-602.

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Therapeutic Updates: Where We Stand

By Carter Thorne, MD, FRCPC, FACP

The CRA is undergoing a transformation in order to better serve its members and fulfill its mission. As part of the reorganization, we have made changes to the Secretariat—we now have a CEO position—and have reviewed committees, both regarding their accountability and mandates. We now have "Board" committees and "Operational" committees, the former overseeing the mission of the CRA, and the latter tasked with implementation.

The "old" Therapeutics Committee has now been spilt into the Guidelines Committee whose mandate is review, development and implementation of guidelines; chaired by Dr. Shahin Jamal, their activities are more often than not reflective and proactive. The "new" Therapeutics Committee is tasked with the review of issues that may present themselves, including requests from members, agencies, and payers, which are often reactive.

Recent examples include the success the CRA had in securing access to naproxen suspension; see "An Advocacy Success Story", in the Winter 2014 *CRAJ* for more details. In that case, the CRA was able to facilitate a process that was expected to take two years and complete it within only 10 months.

More recently, our pediatric colleagues identified another care gap, notably the absence of triamcinolone hexacetonide (TH) from the retail market; this agent is particularly favoured for young patients. Though the Drug Identification Number (DIN) was still held by a Canadian company, we were unable to generate any interest from that source. Contacts developed by members of the committee were identified and a strategy meeting was held in Newmarket in July 2015, which included Dr. Deborah Levy, Christine Charnock, Denis Morrice, Ken D'Entremont of Medexus, and myself. Ken was able to identify an European Medicines Agency (EMA)-approved manufacturing source in Europe, secured a commitment for supply, and made application to Health Canada through the appropriate regulatory pathway. At the same time, the CRA contacted individuals at Health Canada to provide background and garner their commitment to this project. Within one month, we had received Health Canada approval for a Special Access Program (SAP) for TH, and product "landed" in Canada for distribution in August 2015 – a remarkable timeline of less than six weeks!

Projects under development include a response to pharmacists regarding drug interactions with methotrexate, and addressing ophthalmology concerns about hydroxychloroquine.

Any members interested in participating in the action-oriented Therapeutics Committee: please contact myself or Christine Charnock.

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