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SUBJECT/TITLE **BIOSIMILARS INITIATIVE IMPLEMENTATION IN LTC**	ORIGINAL DATE **February 12, 2021** REVISION DATE **Feb 1, 2022**

Under the Alberta Biosimilar Initiative, adult patients, except pregnant women, currently taking a biologic product under Alberta government sponsored drug plans must switch to the respective biosimilar product as per the switch date published on the Alberta Biosimilar webpage for the drugs affected. Please refer to the program webpage and the Alberta Interactive Drug Benefit List for up-to-date listings.

Note that most biologic products (both originator and biosimilar) are considered non-formulary (NF) for Calgary Zone Long-Term Care (LTC) and require NF funding approval on a case-by-case basis.

Background: Biologic drugs are medications used to treat chronic health conditions. In Alberta, biologic drug expenditures were more than $238 million in the 2018 to 2019 fiscal year and increased at an average of 16.2% per year over the last five years. The originator biologic drugs Remicade, Humira and Enbrel are three of the top four drivers of drug spending in Alberta's government-sponsored drug plans. Biosimilars drugs (biosimilars) are similar but not identical to the originator biologics but are a cost-saving alternative and a clinically effective treatment option.

Costs per patient for originator biologics can exceed $25,000 per year, with biosimilar versions costing up to 50% less than the originator. Health Canada has indicated no differences are expected in efficacy and safety following a change between the originator biologic to its biosimilar for an authorized indication. Biologics have been used for over 10 years in Canada and in many other countries, including the United States, Australia, and the United Kingdom.

Policy for Calgary Zone LTC

The Alberta Biosimilars Initiative will expand the use of biosimilars by replacing the use of biologic drugs with their biosimilar versions whenever possible. In Calgary Zone LTC, if funding is requested and approved for a biologic drug that has a biosimilar version available for the medical condition being treated, funding approval would be limited to the biosimilar product.

Until the posted switch date, both the originator biologic drug may be covered to allow prescribers and residents time to discuss treatment options and develop a plan for switching. Any non-formulary approval in place for the originator biologic drug will be automatically applied to the biosimilar version. All subsequent submissions for new-use or renewals will be considered only for the biosimilar.

Residents who are to continue an established biologic therapy are expected to transition treatment to the biosimilar unless they have a medical reason that prevents switching from the originator. If there is a medical reason why they cannot switch to the biosimilar, the specialist or attending physician should provide the relevant information for the non-formulary request. Exceptions will be reviewed on a case-by-case basis.

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Procedure

1. The most responsible prescriber (specialist or attending - depending on resident's circumstance) should discuss switching to a biosimilar or other therapeutic options available with the resident/family.
    a. The clinical pharmacist should support with additional information as requested.
2. The attending physician orders the new prescription as per specialist recommendation or per independent assessment, clearly indicating the change to the biosimilar product.
3. If the resident is unable to switch to the biosimilar product for medical reasons, the pharmacist should submit a non-formulary request for exceptional coverage of the originator biologic with the relevant information.
4. The interdisciplinary care team should provide ongoing monitoring of effectiveness and therapeutic outcomes, adverse reactions or events, including those from administration or the medication management process.
5. Clinicians should document and report any adverse reactions or events associated with the use of a biosimilar product using the established Health Canada reporting process.

References:

Biosimilar drugs | Alberta.ca (accessed January 25, 2022)
Alberta Health - Drug Benefit List (bluecross.ca) (accessed January 25, 2022)