ADVOCARE
CONSUMER ADVOCARE NETWORK

CORD Canadian Organization for Rare Disorders

How NOT to Treat Patients with Biosimilars … and What Drug Plans Should Do

Question: Drug plans are forcing patients to switch from their current biologic medicine to a similar but not identical biologic to save money. *Should patients be allowed to stay on their original drugs if they priced the same?*

Biosimilars are *similar but not identical* versions of an original biologic medicine that becomes available after the original patent has expired. They are not the same as a generic drug which is identical to the original chemical drug. Even as Canadian patients have become more aware and better informed about biosimilars, their views about use have remained much the same. The Consumer Advocare Network and the Canadian Organization for Rare Disorders have been assessing Canadian patient knowledge and attitudes about biosimilars annually over the past four years. Patients have consistently and overwhelmingly continued to reject *substitution, interchangeability, and forced switching.*

- Patients want to stay on their original biologic medicines.
- Patients do not want to switch clinics to get their biologics infused.
- Patients understand biosimilars are not identical to the original and worry about differences in effectiveness and adverse effects.
- Patients often struggle to adapt to a biologic medicine and do NOT believe they should be switched once they have become stabilized.
- Patients believe drug plans should seek lower prices on the original biologics rather than switch patients to a biosimilar.
- Patients believe there should be more than one biologic available in case of shortages or supply disruption.

Over the past four years of our annual survey, Canadian awareness, knowledge and even confidence about biosimilars have increased but resistance to substitution, interchangeability, and forced switching have remained overwhelmingly negative.

Why? *"It takes a long time for your body to adapt to a biologic medicine, and the effectiveness and side effects can change over time. The last thing you want is to worry about whether a change in response is due to a change in your condition or the medicine."*

Familiarity with Biosimilars: In 2016, when ADVOCARE/CORD sent out the first survey through the joint patient network, only about half of respondents reported they had some familiarity with biosimilars. Moreover, most were getting their information from the Internet. By the fourth survey in 2019, biosimilar familiarity had increased by about 50% (three-fourths of respondents) and the majority looked to the government, patient organizations and their physicians for reliable information.

The number of biosimilars approved in Canada has steadily increased, especially with a streamlined approval pathway and a direct path to price negotiations and listing agreements. As of June 2019, there have been nine biosimilars approved in Canada and also as of June 2019, approved biosimilars were no longer assessed by the Canadian Agency for Drugs and Technologies in Health for cost-effectiveness but proceed directly to the panCanadian Pharmaceutical Alliance for price negotiation and provincial listing agreements.

Attitudes about Switching: Rejection of substitution or forced switching among those already on biologics has remained very high, with 80% to 94% rejecting the practice. Patients express fear about potential disruption to their treatment program, especially when their day-to-day condition varies. Overall, patients who voice greater resistance to change are those who have experienced challenges managing their treatment regimen, had more problems with severe adverse effects (or potential SAEs), normally experience more variances in their disease expression, such as unpredictable flares or episodes or peaks and valleys (highs and lows) in symptoms, blood levels, biomarkers, emotions, and other indicators of disease impact.

How NOT to Treat Patients with Biologics: Over the past four years, Canadian patients have increased their knowledge about biosimilars but it is clear they are not at all comfortable about switching from an original to a biosimilar. They recognize biosimilars are not identical to the original biologics. They are somewhat accepting of biosimilars for "new starts" (naïve patient) but strongly reject forced switching from the original biologic, substitution without physician prescription, or interchangeability between biologics (between original and biosimilar or between different biosimilars). Patients do NOT support having ONLY the biosimilar available through their drug plan. Patients do they NOT endorse competitive bidding that could require them to continuously switch to the "lowest cost" alternative.

What Should Drug Plans Do? Patients endorse lower prices for biologics that are no longer protected by patent. Patients endorse having **both** original and similar biologics available on drug plans. Patients unanimously believe they should receive all of the information necessary to make an informed choice about the best biologic for their individual needs. To achieve lower prices AND informed choice, patients call for drug plans to negotiate lower prices for original biologics and NOT switch all patients to biosimilars. Patients believe drug plans should offer more than one biologic to assure back-up supply and to assure patients have the option to "stay or switch" rather than being forced to a single biologic.

Survey of Patient Knowledge and Attitudes About Biosimilar Use

Source of information

2016	60+% Internet; 25% HCPs
2017	Trusted source of information: 71% Government; 70% Patient group; 70% HCPs; 17% Pharma website; 10% public media; 7% social media

Knowledge about biosimilars

2016	54% somewhat or very familiar with biosimilars
2017	51% somewhat or very well informed about biosimilars

Confidence in biosimilars

2016	72%-75% believe difference in effectiveness and adverse effects
2017	77% believe difference in effectiveness and adverse effects

New patient starts with biosimilars

2016	57% agree/16% disagree
2017	33% agree/46% disagree

Willingness to use biosimilars based on cost

2016	42% agree if much cheaper
2017	20% agree/52% disagree if much cheaper
2018	29% agree/55% disagree if much cheaper

Attitudes toward switching to biosimilars

2016	96% right to informed choice; 88% interchangeability; 78% no recommendation to (forced) switch; 57% unwilling to switch (24% willing to switch)
2017	95% no substitution or switch; 92% right to informed choice
2018	71% no automatic substitution; 69% no forced switching; 92% right to informed choice
2019	94% no forced switching; 82% no automatic substitution

Factors influencing use of biosimilars

Cost factors

Patients prefer not to switch based on cost (alone)

- More than half would not switch if biosimilar cheaper (55%)
- Almost half would not switch if savings were redirected to other drugs or services (47%)
- Patients not use biosimilar even if pay for original
- Less than one-fourth would switch to biosimilar (23%)
- Almost 2/3 would not switch to biosimilar (61%)

Patients strongly reject automatic substitution (not by physician) on basis of cost (alone)

Almost 3/4 would not accept biosimilar substitution (71%)

- Less than one-fifth would accept biosimilar substitution (19%)

Management factors

87% agree National formulary should include biosimilars

98% agree National formulary should include original biologics (if similarly priced)

87% agree no competitive bidding, no single source biologic, and no regular switching

Clinical factors

56% agree/23% disagree if monitoring and follow-up

49% agree/31% disagree with biosimilar use if physician discusses switching

21% agree/61% disagree with biosimilar use if switch clinics

20% agree/57% disagree with biosimilar use if no clinical trials for condition (extrapolation)

Sample

2016	320/200 respondents
2017	588 respondents (multiple disease types)
2018	428 respondents
2019	223 respondents