NON-MEDICAL SWITCH PATIENT DECISION MATRIX

Crohn's and Colitis Canada
Crohn et Colite Canada

This decision matrix, developed by patients and physicians, identifies numerous patient disease situations and categorizes each disease situation on probability of the patient experiencing a flare if switched to a biosimilar and the severity of the impact if the patient experiences a flare.

Using the decision matrix, Crohn's and Colitis Canada has identified three groups of patients:

1. Proceed with switch;
2. Delay switch until an event is triggered; and
3. Exempt patient from switch.

PROBABILITY OF FLARE OR WORSENING SYMPTOMS	SEVERITY OF IMPACT ON PEOPLE AND THE HEALTHCARE SYSTEM				
	Very Low	Low	Medium	High	Very High
Very High	Moderate	Severe	Severe	Critical	Critical
High	Sustainable	Moderate	Severe	Critical	Critical
Medium	Sustainable	Moderate	Moderate	Severe	Critical
Low	Sustainable	Sustainable	Moderate	Severe	Critical
Very low	Sustainable	Sustainable	Sustainable	Moderate	Severe

FINAL DETERMINATIONS

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Proceed with Switch

- Women actively undergoing IVF/fertility treatments
- Patients stable[A] on biologic[B] for >12 months

[A] Normal scope/MRI, CT, and calprotectin levels

[B] Biologics include originators and biosimilars

Delay Switch

CATEGORY	TRIGGER TO PROCEED WITH SWITCH
Pregnant women and women within 12 months of delivery	12 months after delivery
Within 12 months of starting or changing biologics	Patient is stable for at least 12 months
History of intestinal resective surgery within past 12 months	Patient is stable for at least 12 months
Uncontrolled (by therapy or medication) mental health issues being treated by a professional (with letter from psychiatrist, family physician, psychologist, or licensed therapist to support diagnosis)	Mental health issue controlled (letter from from psychiatrist, family physician, psychologist, or licensed therapist)
Children (<18 years)	Patient reaches 18 years of age
Malnutrition (BMI less than 18.5)	Malnutrition controlled and patient stable

Exempt

- Patients who have failed on two classes[C] of biologics
- Fistulizing Crohn's disease (active and in remission)
- Patients with history of developing antibodies to two or more biologics
- Comorbidities (current cancer, short gut, diabetes with poor or inadequate glycemic control, advanced liver disease[D])
- Immune-mediated extraintestinal manifestations (EIM)[E] that rely on the biologic to control both IBD and the extra-intestinal manifestation

[C] Classes of biologics: (a) Anti-tumor necrosis factor alpha antibodies (anti-TNFs), anti-interleukin antibodies, anti-integrin antibodies, janus kinase (JAK) inhibitors.

[D] Presence of ascites, hepatic encephalopathy, jaundice, INR>1.4.

[E] Inflammatory arthritides (juvenile rheumatoid arthritis, psoriatic arthritis, type 1 IBD-associated arthritis / concordant arthritis), dermatological conditions (psoriasis, Hidradenitis suppurativa, Pyoderma gangrenosum, erythema nodosum), ocular conditions (uveitis, episcleritis)

Decision Matrix Footnotes

The Decision Matrix is based on the Risk Matrix originally developed by the US Department of Defense - [1] Biologics includes originators and biosimilars; [2] "Stable" defined as normal scope/MRI, CT, normal calprotectin levels; [3] Classes of biologics: anti-Tumor necrosis factors (TNFs), Interleukins (IL), integrins, Janus kinase (JAK); [4] Mental health issues: stress, anxiety, PTSDF and/or depression; [5] Immune-mediated extraintestinal manifestations : inflammatory arthritides (juvenile rheumatoid arthritis, psoriatic arthritis, type 1 IBD-associated arthritis / concordant arthritis), dermatological conditions (psoriasis, Hidradenitis suppurativa, Pyoderma gangrenosum, erythema nodosum), ocular conditions (uveitis, episcleritis); [6] Advanced liver disease defined as presence of ascites, hepatic encephalopathy, jaundice, INR>1.4.