SESSION I
GETTING SERIOUS ABOUT BIOSIMILARS
Interactive Case Presentation

Objectives

- Explore the role of biosimilars in the treatment of patients with IBD under two scenarios:
  1. The patient naïve to biologics
  2. The patient currently on biologics

CASE 1

Your 23-year-old female patient was diagnosed with ulcerative colitis (UC) in Ontario 6 months ago. The records are not complete, but sigmoidoscopy suggested left-sided colitis with normal mucosa above the sigmoid. No biopsy results are available.

She has been on oral mesalamine therapy since the diagnosis and recently moved to Alberta to attend university. She presents to you with a 3-month history of worsening diarrhea with bleeding despite mesalamine therapy. Relevant tests completed before she arrived for the consultation are:

- Hemoglobin (Hb): 93 g/L
- Iron: 5 µmol/L
- C-reactive protein (CRP): 47 mg/L
- Albumin: 29 g/L
- *Clostridium difficile* toxin and cultures: Negative
- Fecal calprotectin (FCP): 1675 µg/g

Her colonoscopy shows pancolitis, normal ileum (biopsy confirmed), and deep ulcers extending up from the rectum and transverse colon. Biopsies are compatible with severe active UC.

ARS Decision Node

1. Would you consider biologic therapy in this patient?
A. YES **B.** NO

During the office visit with your patient and her mother you explain the high-risk nature of her disease (i.e., the deep ulceration and pancolitis) and suggest therapy with a tapering course of a corticosteroid (prednisone 40 mg tapered) and a TNF-α inhibitor. The patient agrees to this course of therapy.

Your inflammatory bowel disease (IBD) nurse informs you that your patient's insurance plan will pay for either an originator or a biosimilar biologic.

ARS Decision Node

2. Would you begin her treatment with a biosimilar biologic?
A. YES **B.** NO

3. Are you as comfortable using a biosimilar as you are using the originator biologic?
A. YES **B.** NO

4. Are there differences between the biosimilar and the originator biologic that will affect safety?
A. YES **B.** NO **C.** NOT SURE

5. How important is it for you to know about the biologic support program and/or where the biosimilar or the originator biologic will be administered?
A. VERY IMPORTANT
B. SOMEWHAT IMPORTANT
C. NOT IMPORTANT

The mother asks if the originator and the biosimilar TNF-α inhibitor are equally effective.

ARS Decision Node

6. Do biosimilars and originator biologics have similar efficacy?
A. YES **B.** NO **C.** NOT SURE

CASE 2

Your patient, a 26-year old IT consultant, with well-documented jejunal and ileal Crohn's disease, is in endoscopic remission on his TNF-α inhibitor and azathioprine (150 mg/d). He has been on this treatment for 7 years and in endoscopic remission (double balloon and computed tomography enterography [CTE] confirmed) for at least the last 4 years.

His insurance plan now mandates you switch to a biosimilar biologic. He comes to your office and asks about the risks and benefits of switching his originator to a biosimilar TNF-α inhibitor.

ARS Decision Node

1. Based on your current knowledge, is it acceptable for your patient to switch from an originator to a biosimilar biologic?
A. YES **B.** NO **C.** NOT SURE YET

2. How much risk for therapeutic efficacy do you perceive if the switch occurs?
A. HIGH **B.** MEDIUM **C.** LOW **D.** MINIMAL **E.** NO RISK

3. Is more evidence needed before you will be comfortable allowing your patients to switch?
A. YES **B.** NO **C.** I WILL NEVER ALLOW SWITCHING
D. I AM COMFORTABLE WITH SWITCHING NOW