SESSION 3

Biosimilars: Where are we now?

INTERACTIVE CASE PRESENTATION

Bruce is a 45-year-old, part-time factory worker and artist. Six months ago, he presented with bloody diarrhea and was diagnosed with moderately active ulcerative pancolitis. For the last four months, he has been steroid-dependent and unable to taper below 15 mg of oral prednisone PO daily without relapse. You recommend a change in therapy.

ARS Decision Node

1. What would you recommend?

- **a.** Add 5-ASA 4.0-4.8 g PO daily
- **b.** Add azathioprine 2.5 mg/kg PO daily
- **c.** Add adalimumab 160 mg SC then 80 mg SC in 2 weeks
- **d.** Add golimumab 200 mg SC then 100 mg SC in 4 weeks
- **e.** Add infliximab 5 mg/kg IV at weeks 0, 2, and 6
- **f.** Add vedolizumab 300 mg IV at weeks 0, 2 and 6

You discuss all options. Bruce recalls that his cousin takes infliximab for arthritis and had a good experience. He wishes to do the same. His public drug plan rejects your application for the innovator product and will only fund a biosimilar.

ARS Decision Node

2. What would you do?

- **a.** Agree to start the biosimilar
- **b.** Appeal to the insurer for access to the originator
- **c.** Prescribe a subcutaneously administered anti-TNF agent
- **d.** Prescribe vedolizumab

The patient's common-law wife is a postal worker with private drug coverage. After some negotiation, the support service for the innovator company manages to secure reimbursement for Bruce's therapy. He starts on infliximab as monotherapy and does well.

Six months later and after five infusions of infliximab, his partner's insurer announces that it has changed its policy and will no longer reimburse the innovator biologic. The patient will need to switch to the biosimilar.

ARS Decision Node

3. How would you respond?

- **a.** Agree to switch Bruce to the biosimilar
- **b.** Appeal to the insurer for continued access to the originator
- **c.** Switch Bruce to a subcutaneous anti-TNF agent
- **d.** Switch Bruce to vedolizumab

You appeal to the insurer, but they are unwilling to compromise. Bruce agrees to switch to biosimilar infliximab. The support service offers routine therapeutic drug monitoring (TDM), and you find out that Bruce has a trough level of 1.2 mcg/mL. Thankfully, he continues to do well and remains in clinical and biochemical remission.

At his six-month follow-up appointment, he tells you he is now working full time for an automobile parts manufacturer and will have a new drug plan in three months. One of his co-workers was just started on innovator infliximab, and Bruce finds out it is listed on his new insurer's formulary. He asks if he should switch back.

ARS Decision Node

4. What would you advise Bruce to do?

- **a.** Continue on the biosimilar infliximab, but increase the dose
- **b.** Continue on the biosimilar infliximab at the same dose
- **c.** Switch back to the innovator infliximab and increase the dose
- **d.** Switch back to the innovator infliximab at the same dose
- **e.** Switch back to the innovator infliximab and repeat TDM