Biologics selectively target specific molecules or pathways in the inflammatory process, in order to control or eliminate the chronic inflammation of IBD and promote the healing of fistulas. They are used to induce and maintain remission in moderate-to-severe IBD.

Blood Work:
- Blood work should be completed every three (3) months when you are receiving biological therapy; if you are also prescribed an immunomodulator [azathioprine (Imuran®), 6-mercaptopurine (Purinethol®) or methotrexate], you should follow the monthly blood work schedule, unless instructed differently. You should be provided with a standing orders blood work requisition for the laboratory.

Getting Started:
- Your healthcare provider will have you complete a Mantoux (tuberculosis- TB) test to see if you have been previously exposed to TB prior to starting biological therapy, as this bacterial infection could be reactivated by the drug.
- You may need to update your vaccinations depending on your immune status, age, and childhood vaccination history. Your healthcare provider will instruct you on which vaccines are required and where to have these administered.

Symptoms to Report:
- If you are due to take your scheduled biologic and have signs and symptoms of an active infection, you should contact your gastroenterologist, nurse practitioner, or nurse immediately for instructions. Signs and symptoms of active infection may include: fever (greater than 100.5°F or 38.5°C), chills, feeling generally unwell, body aches, fatigue, flu-like symptoms, tooth pain/ache or tooth infection, very sore throat, persistent or worsening cough and/or nasal congestion, drainage from your nose or mucus in your chest that is yellow or green, sores that are draining pus or will not heal, very bad abdominal pain, pain with urinating (peeing), rectal pain or swelling, or any other signs of infection. Not all infections will prevent you from taking your scheduled dose of biologic therapy, but your healthcare provider needs to make this decision.
- Serious infections (including tuberculosis) and opportunistic infections have been reported in patients taking biological therapy; some of these infections have resulted in death. **It is always better to delay your dose of medication and wait to speak with your healthcare provider for instructions, than to take your biologic when you have an active infection.**

- If you are due to take your scheduled biologic and **have been prescribed an antibiotic, you should contact your healthcare provider immediately for instructions.**

- You should **contact your physician, nurse practitioner, or nurse immediately to report symptoms** of joint pain and/or swelling, muscle pain or aching, fever, chest pain or pressure, shortness of breath, vision changes, numbness or tingling, unusual tiredness or weakness, malaise, wheezing, itching, new skin rash or other skin reaction such as blistering or peeling, hives, open cuts or sores on your body, unusual bleeding or bruising, jaundice (yellowing of skin or eyes), significant headache, swelling to legs or hands, swelling to face, sudden weight gain, or difficulties swallowing, as this may indicate that you are hypersensitive, intolerant or potentially allergic to this medication. **If your symptoms are severe or worsening, you should go immediately to the nearest emergency department or activate your emergency response system.**

- Contact your healthcare provider if you develop a reaction at the injection site which may include redness, itching, pain, swelling and/or significant bleeding. Injection site reactions are a common side effect and may be controlled with pre-medication if appropriate.

**Prevention of Adverse Events and Management of Side Effects:**

- It is important to take your biologic therapy according to your dosing schedule and not miss any doses, unless instructed by your healthcare provider. Missing doses could result in a loss of response to the drug and a worsening of your disease.

- Before starting this medication, you should inform your gastroenterologist or nurse practitioner if you have a history of any problems or concerns with your heart (including congestive heart failure), liver (including hepatitis), lungs, nervous system, cancer, persistent blood work abnormalities, or chronic or recurrent infections.

- To prevent or reduce the chance of infusion reactions or the development of antibodies to your biologic, you may also be prescribed an immunosuppressant (azathioprine [Imuran®], 6-mercaptopurine [Purinethol®], or methotrexate).

- Your healthcare provider may prescribe pre-medications to take prior to receiving your infliximab (Remicade®) infusions, in order to prevent or minimize certain side effects.

(Continued on next page)
- Advise your gastroenterologist or nurse practitioner if you have a latex allergy, to ensure a latex-free product will be dispensed by the pharmacist.

- Prevention of infection is most important—remember to wash your hands regularly and avoid close contact with people who are sick with colds, the flu, or other infections.

Pregnancy:
- If you or your partner are thinking about pregnancy, please contact your physician, nurse practitioner or nurse to discuss the benefits and risks of continuing your IBD medications prior to or during a future pregnancy. Both partners are encouraged to attend this discussion and jointly participate in the decision-making process.

- The risk of infection may be increased in infants born to mothers who have received biological therapy during their pregnancies, for up to six months after delivery. **All live vaccines (example: Rotavirus) must be completely avoided for the first year of life** in infants born to mothers who have received biologics during the pregnancy. You should inform the individual administering any vaccine to your infant if you received biological therapy during pregnancy.

- Biologics are generally considered safe to use while breastfeeding in the post-partum period. You should speak with your physician or nurse practitioner if you plan to breastfeed after delivery or if you are starting a biologic and are currently breastfeeding.

Patient Support Programs and Medication Assistance:
- **Humira® (adalimumab):** PROGRESS Support Program  
  www.humira-progress.ca or 1-866-848-6472

- **Remicade® (infliximab):** BioAdvance® Program  
  www.bioadvance.ca or assigned BioAdvance® Coordinator

- **Simponi® (golimumab):** BioAdvance® Program  
  www.bioadvance.ca or assigned BioAdvance® Coordinator

- **Entyvio® (vedolizumab):** YOURVANTAGE® Program  
  www.yourvantage.ca or assigned YOURVANTAGE® Coordinator