# inFLIXimab Infusions: Treatment of Acute Severe Colitis

# **Site Applicability**

**SPH Inpatient Units** 

# **Practice Level**

Basic: Registered Nurses

# Requirements

Resuscitative equipment and treatment for anaphylactic reactions must be available.

Providers should order the Hypersensitivity / Anaphylaxis Treatment module in Cerner prior to the infusion.

The ordering provider must indicate if the patient is at higher risk of infusion reaction in the order comments and communicate to the unit Clinical Nurse Leader and/or Patient Care Manager that the patient will require a higher level of monitoring.

If the provider determines that the patient has a higher risk of infusion reaction, the patient will require a dedicated nurse during the infusion.

If higher monitoring is required, nursing teams will require 24 hours notice to ensure staffing is available.

The provider should communicate intent to order inFLIXimab with the clinical pharmacist.

## **Need to Know**

Acute severe colitis is a medical emergency. The outcome in up to 30% of patients is a colectomy. If IV steroid therapy fails, inFLIXimab should be administered on day 3, or earlier, if recommended by the treating GI physician.

inFLIXimab is a biological agent indicated for the treatment of acute severe ulcerative colitis, moderate to severe Crohn's disease and immune check-point inhibitor (e.g. ipilimumab) induced enterocolitis in the setting of steroid failure, or where biological therapy is required to maintain disease remission.[1-4]

The risk of an infusion reaction for a first infusion is less than or equal to 5%.[5-8]

Patients who have a higher risk of infusion reaction are those who have had a previous infusion reaction, and those who have had a period of more than 16 weeks since a previous inFLIXimab infusion.

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Effective date: 21/FEB/2024 Page 1 of 6

Signs and symptoms of an infusion reaction include: headache, vasodilation, flushing, pruritus, rash, hives, respiratory distress, swelling of the lips or larynx, hypotension, abdominal pain, hypoxemia, and flu-like symptoms.

Premedication with acetaminophen, antihistamines and/or corticosteroids may help prevent or lessen infusion reactions for high-risk patients. In clinical practice, these patients are likely to be receiving IV corticosteroids already to treat their underlying disease.

# **Equipment and Supplies**

- Alaris®PC CareFusion Edition Infusion Pump with Guardrails
- Infusion set with low sorbing, low protein-binding in-line filter, 1.2 microns or less
- inFLIXimab dose prepared by pharmacy

# **Protocol**

# For patients at standard risk of infusion reaction

Rates of inFLIXimab up-titration may differ from those in the PDTM.

#### Infusion protocol:

- 10 mL/hour for 30 to 60 minutes, then
- 20 mL/hour for 30 to 60 minutes, then
- 40 mL/hour for 30 to 60 minutes, then
- 80 mL/hour for 30 to 60 minutes, then
- 150 mL/hour for 30 to 60 minutes, then
- increase to 250 mL/hour until completed

# Monitoring requirements:

Blood Pressure (BP), pulse, oxygen saturation, respiratory rate and temperature prior to infusion, Q 1 hour during the infusion, at the end of the infusion, and PRN.

Monitor for signs and symptoms of an infusion reaction throughout the infusion.

# For patients at higher risk of infusion reaction

Patients who have been identified as having a higher risk of infusion reaction require dedicated nursing resources.

#### Infusion protocol:

- 10 mL/hour for 15 minutes, then
- 20 mL/hour for 15 minutes, then
- 40 mL/hour for 15 minutes, then

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Effective date: 21/FEB/2024 Page 2 of 6

- 80 mL/hour for 15 minutes, then
- 150 mL/hour for 30 minutes, then
- increase to 250 mL/hour until completed

# Monitoring requirements:

Blood Pressure (BP), pulse, oxygen saturation, respiratory rate and temperature prior to infusion, every 15 minutes for one hour, then every 30 minutes during the infusion and continue for one hour after infusion, and PRN.

Monitor for signs and symptoms of an infusion reaction throughout the infusion.

#### Interventions

Administer pre-medications including hydrocortisone and antihistamines as ordered prior to the infusion.

#### Infusion Reaction

If the patient demonstrates signs or symptoms of an infusion reaction:

Mild reactions: (no respiratory or vascular instability)

- slow infusion to 10 mL/hour or stop infusion; may give acetaminophen, diphenhydrAMINE, dimenhyDRINATE, or hydrocortisone PRN as ordered
- monitor vital signs Q15 MIN; if symptoms clear, restart infusion at half previous rate and slowly increase

Severe reactions: (anaphylaxis, vascular instability, SBP change of 40 mmHg or more, rigors)

- stop infusion and call a Code Blue
- administer diphenhydrAMINE, hydrocortisone, epinephrine (if anaphylaxis) or salbutamol nebulized PRN as ordered
- monitor vital signs every 2 to 5 minutes until within normal limits; continue monitoring patient for a minimum of 2 to 4 hours or longer as necessary

## **Documentation**

Within the Cerner electronic health record, document vital signs and assessments in iView. Document medication administration on the MAR, and document fluid intake in In and Outs.

Document in a Nursing Narrative Note as appropriate.

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Effective date: 21/FEB/2024 Page 3 of 6

# **Patient and Family Education**

Explain the procedure to the patient and family. Explain the signs and symptoms of an infusion reaction and ask the patient to report any symptoms or concerns immediately.

# **Related Documents**

<u>BD-00-12-40091</u> – Anaphylaxis: Initial Emergency Management (Adult and Pediatric)

# References

- 1. Hanauer, S.B., et al., *Maintenance infliximab for Crohn's disease: the ACCENT I randomised trial.* Lancet, 2002. **359**(9317): p. 1541-9.
- 2. Järnerot, G., et al., *Infliximab as rescue therapy in severe to moderately severe ulcerative colitis: a randomized, placebo-controlled study.* Gastroenterology, 2005. **128**(7): p. 1805-11.
- 3. Rutgeerts, P., et al., *Infliximab for induction and maintenance therapy for ulcerative colitis.* N Engl J Med, 2005. **353**(23): p. 2462-76.
- 4. Williams, J.G., et al., Infliximab versus ciclosporin for steroid-resistant acute severe ulcerative colitis (CONSTRUCT): a mixed methods, open-label, pragmatic randomised trial. Lancet Gastroenterol Hepatol, 2016. **1**(1): p. 15-24.
- 5. Colombel, J.F., et al., *The safety profile of infliximab in patients with Crohn's disease: the Mayo clinic experience in 500 patients.* Gastroenterology, 2004. **126**(1): p. 19-31.
- 6. Lees, C.W., et al., *The safety profile of anti-tumour necrosis factor therapy in inflammatory bowel disease in clinical practice: analysis of 620 patient-years follow-up.* Aliment Pharmacol Ther, 2009. **29**(3): p. 286-97.
- 7. O'Donnell, S., et al., *Safety of infliximab in 10 years of clinical practice.* Eur J Gastroenterol Hepatol, 2011. **23**(7): p. 603-6.
- 8. Targan, S.R., et al., A short-term study of chimeric monoclonal antibody cA2 to tumor necrosis factor alpha for Crohn's disease. Crohn's Disease cA2 Study Group. N Engl J Med, 1997. **337**(15): p. 1029-35.
- 9. Hamzaoglu, H., et al., *Safety of infliximab in Crohn's disease: a large single-center experience.* Inflamm Bowel Dis, 2010. **16**(12): p. 2109-16.
- 10. Hanauer, S.B., et al., *Maintenance infliximab for Crohn's disease: the ACCENT I randomised trial.* Lancet, 2002. **359**(9317): p. 1541-9.
- 11. Keshavarzian, A., et al., A multicenter retrospective experience of infliximab in Crohn's disease patients: infusion reaction rates and treatment persistency. Gastroenterol Hepatol (N Y), 2007. **3**(5): p. 381-90.
- 12. Present, D.H., et al., *Infliximab for the treatment of fistulas in patients with Crohn's disease.* N Engl J Med, 1999. **340**(18): p. 1398-405.
- 13. Zabana, Y., et al., *Infliximab safety profile and long-term applicability in inflammatory bowel disease: 9-year experience in clinical practice.* Aliment Pharmacol Ther, 2010. **31**(5): p. 553-60.

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Effective date: 21/FEB/2024 Page 4 of 6



- 14. Alex, A., et al., Early management of acute severe UC in the biologics era: development and international validation of a prognostic clinical index to predict steroid response. Gut, 2023. 72(3): p. 433.
- 15. Lichtenstein, L., et al., *Infliximab-Related Infusion Reactions: Systematic Review.* J Crohns Colitis, 2015. **9**(9): p. 806-15.

Effective date: 21/FEB/2024 Page 5 of 6



# **Groups/Persons Consulted:**

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SPH Surgical Program Patient Care Manager

**Professional Practice** 

Medication Use Evaluation Pharmacist

Regional VCH-PHC Pharmacy and Therapeutics Committee

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Effective date: 21/FEB/2024 Page 6 of 6