

Streamlined Individual Patient Use (IPU) Request Infliximab

100mg Injection

Infliximab is available as a streamlined Individual Patient Use (IPU) request for acute severe checkpoint inhibitor mediated colitis refractory to steroids.

The following definitions/criteria apply to this form

Acute severe colitis is defined as ≥ 6 bloody bowel motions per day and one of:

- Tachycardia – Heart rate >90
- Fever – temp $> 37.8^{\circ}\text{C}$
- Haemoglobin <105 g/L
- C-reactive protein > 30 mg/L

Steroid refractory colitis is defined as failure to respond (≥ 8 stools per day or 3-8 Stools per day with C-reactive protein ≥ 45 mg/L) to intravenous methylprednisolone 1-2mg/Kg/day for three days.

Note: this form covers two doses of infliximab (if needed) of 5mg/kg at week 0 and week 2, or earlier if clinically indicated. Additional or higher doses are to be requested via IPU.

The following information is required to be provided by the **prescriber** prior to dispensing.

Patient details:

Patient UR number:

Patient location (site/hospital):

Patient eligibility for Infliximab:

1. Patient has acute severe checkpoint inhibitor mediated colitis refractory to steroids.

Prescriber eligibility:

1. Prescriber is a Consultant Medical Oncologist or Gastroenterologist
and
2. There is agreement by a Consultant Gastroenterologist and a

Consultant Medical Oncologist that infliximab is appropriate.

Outcome assessment:

1. Prescriber agrees to provide the following information at 6 months after treatment (or earlier if applicable):
 - Did the patient respond within 4 weeks of first dose of infliximab? (Yes/No)
 - Was the response complete (steroid ceased) or partial (steroid dependent)?
 - Did the patient require a colectomy? (Yes/No)
 - Has the patient been able to resume immunotherapy? (Yes/No)

I certify that the above information is correct _____	
Date:	
Prescriber Name:	
Position:	
Clinical unit:	
Telephone No:	Pager No:

This form must be completed and returned to Pharmacy prior to supply

Information for pharmacy

This form should be retained in the pharmacy department and a copy forwarded to:

- The Executive Officer
South Australian Medicines Evaluation Panel
Medicines and Technology Policy and Programs
Level 8, Citicentre
11 Hindmarsh Sq
Adelaide 5000
-  8226 7083
-  SAMEP@health.sa.gov.au

For more information:
<http://www.sahealth.sa.gov.au/samep>