Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

One Wales Medicines Assessment Group Recommendation
Infliximab powder for concentrate for solution for infusion (OW31)

Date of advice: September 2025
AWTTC reference number: OW31

Using the agreed starting and stopping criteria infliximab can be made available within NHS Wales for the treatment of grade 3–4 steroid-refractory myocarditis induced by immune checkpoint inhibitor (ICI) therapy.

The risks and benefits of the off-label use of infliximab for this indication should be clearly stated and discussed with the patient to allow informed consent.

Providers should consult the relevant guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed.

The choice of infliximab product prescribed should be based on the acquisition cost and in accordance with the One Wales advice on use of biosimilars.

This recommendation has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

This recommendation will be reviewed after 12 months or earlier if new evidence becomes available.

Clinician responsibility
Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Medicines Assessment Group decision.

Health board responsibility
Health boards will take responsibility for implementing One Wales Medicines Assessment Group decisions and ensuring that a process is in place for monitoring clinical outcomes.

One Wales advice assists consistency of access across NHS Wales and will be disseminated to the service following ratification by Welsh Government.

AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Starting and stopping criteria for infliximab: for the treatment of immune checkpoint inhibitor (ICI) induced grade 3-4 myocarditis, where symptoms have not responded to first-line immunosuppression with corticosteroids

Developed in collaboration with clinicians in Wales and based on the South East Wales Immunotherapy Toxicity Guidelines (v3)[1].

Starting criteria

Infliximab is an option for patients with severe or life threatening (grade 3–4) myocarditis indicated by severe symptoms at rest or with minimal exertion, with elevated cardiac enzyme markers and/or with an abnormal ECG/ECHO/cardiac MRI

And no improvement in symptoms and/or cardiac markers is noted within 48–72 hours of starting high-dose methylprednisolone (2–4 mg/kg/day or 500 mg – 1 g).

Screening

Prior to commencing infliximab, pre-screening should be undertaken to exclude:

- Active or latent tuberculosis or screen and found to be low risk
- Hepatitis virus or HIV
- Current acute infections (viral, bacterial, fungal or parasitic)
- Moderate to severe heart failure (NYHA class III/IV)
- Gastrointestinal perforation.

This list is not exhaustive; refer to local guidelines and Summary of Product Characteristics[2]. In cases of life-threatening toxicity, consider risk/benefit if screening could result in significant delay to treatment.

Infliximab is contra-indicated in patients with moderate to severe heart failure (NYHA class III/IV)[2].

Dose

The recommended treatment dose regimen for infliximab is 5 mg/kg by intravenous infusion on Weeks 0, 2 and 6. Some cases may require a shorter interval than two weeks between doses; specialist advice should be sought from the immunotherapy multidisciplinary team (MDT) or cardiology team. Not all cases will require three doses, treatment can be stopped before completing the course if there is sufficient response after the first or second dose; however, standard treatment is three doses.

Only one course (three doses) may be issued in accordance with this advice. Requests for repeat courses or continuing treatment beyond three doses should be explored through funding mechanisms such as the individual patient funding request process.

The infliximab product available at the lowest acquisition cost should be prescribed.

Once infliximab has been given switch to oral prednisolone and wean as per local steroid taper guidelines.

Outcome data

The following should be collected to inform future policy changes:

- Patient numbers
- Number of doses received by the patient
- Grade of disease at start of treatment
- Prior myocarditis treatments before starting infliximab
- Myocarditis response to treatment with infliximab
- Time from decision to treatment administration with infliximab.

Monitoring

- Infusion-related reactions including anaphylactic shock
- Injection site for signs of phlebitis
- Cardiac enzymes (CK, Troponin, NT-pro-BNP)
- Daily bloods e.g., FBC, U&E, LFTs, CRP
- Blood cultures if pyrexial
- National Early Warning Score (NEWS) assessment
- Cardiac monitoring as appropriate

Prescribers should consult the relevant Summary of Product Characteristics for any additional monitoring requirements and potential adverse effects[2].

Stopping criteria

- Treatment failure, progression of symptoms or minimal response
- Toxicity to treatment (that cannot or does not respond to temporary treatment interruption)
- Patient request

For patients who develop hepatotoxicity during treatment (alanine aminotransferase [ALT] increases or aspartate aminotransferase [AST] increases at or above 5 times the upper limit of normal), treatment should be discontinued.

References

1. Velindre Cancer Centre. South East Wales Immunotherapy Toxicity Guidelines (v3). Oct 2022. Available at: https://velindre.nhs.wales/velindrecs/health-care-professionals-information/immunotherapy-guidelines/io-docs/immunotherapy-guidelines-v3/. Accessed Sept 2025.
2. Merck Sharp Dohme. Infliximab (Remicade) 100 mg powder for concentrate for solution for infusion. Available at: https://www.medicines.org.uk/emc/product/3831/smpc. Accessed Sept 2025