**HERTFORDSHIRE AND WEST ESSEX AREA PRESCRIBING COMMITTEE (HWE APC)**

**Infliximab BIOSIMILAR for the management of diarrhoea or colitis**

**associated with Immune Checkpoint Inhibitor (ICPI) therapy**

**RED - RECOMMENDED FOR RESTRICTED PRESCRIBING BY SPECIALIST ONLY.**

**nOT RECOMMENDED FOR PRIMARY CARE PRESCRIBING.**

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| **Name: generic (trade)** | **What it is** | **Indication** | **Date decision last revised** | **Decision status** | **NICE / SMC Guidance** |
| Infliximab biosimilar**(**Flixabi® Inflectra®, Remicade®, Zessly®**)** | Tumour necrosis factor alpha (TNF) inhibitor | Licensed for the treatment of certain adult patients with moderately to severely active ulcerative colitis or Crohn’s disease. Use in the management of diarrhoea or colitis associated with ICPI therapy has been agreed locally. | March 2023 | Final  |  |
| **HWE APC recommendation:** Infliximab biosimilar is recommended as an option for treating diarrhoea or colitis associated with ICPI therapy in line with the recommendations in the East of England Priorities Advisory Committee (EoE PAC) guidance statement:* Treatment must be initiated and monitored under the guidance of a gastroenterologist and oncologist.
* All other causes, including cytomegalovirus (CMV) infection/reactivation and other viral, bacterial and parasitic aetiology, must be excluded along with any other clinical contraindications (e.g. gastrointestinal perforation or sepsis) before starting infliximab.
* A single dose of biosimilar infliximab 5mg/kg should be considered as a second line option for corticosteroid-refractory grade 3 or 4 diarrhoea or colitis related to the ICPI therapy, following treatment with systemic high-dose intravenous corticosteroids for three to five days.
* A second dose of infliximab at two weeks may be necessary for some patients. Very rarely a third dose may be required.
* For full details please refer to the guidance statement embedded below.

**RED STATUS:*** **NOT RECOMMENDED FOR PRIMARY CARE PRESCRIBING.**
* **RECOMMENDED FOR RESTRICTED PRESCRIBING BY SPECIALISTS**

**East of England Priorities Advisory Committee (EoE PAC) guidance statement:** |