Infliximab-dyyb (ZYMFENTRA) for SC Injection in Crohn's Disease and Ulcerative Colitis Criteria for Use May 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Inclusion Criteria

ALL the following must be selected to meet criteria:

- ☐ Prescribed and monitored by a VA / VA Community Care gastroenterologist / hepatologist or locally designated expert in inflammatory bowel disease.
- ☐ Moderate to severe active Crohn's disease (CD) or moderate to severe active ulcerative colitis (UC) confirmed by endoscopy or imaging at baseline.

Additional Inclusion Criteria

ONE of the following must be selected to meet criteria:

- ☐ Achieved clinical response after Week 10 following three intravenous (IV) induction doses of infliximab / biosimilar at Weeks 0, 2 and 6 ^1, ^2
- ☐ Clinically stable and receiving IV infliximab / biosimilar to maintain clinical remission
- ☐ Unable to accommodate or comply with maintenance therapy intravenous infusion schedule (e.g., because of difficult intravenous access, travel limitations, work requirements, lack of sick leave, etc.)

Other Justification

- ☐ _____

Footnotes

1. In the UC clinical trial, clinical response was defined as a decrease from baseline of ≥ 2 points and at least 30% on the modified Mayo score (range 0–9) which includes subscores of 0–3 each for stool frequency, rectal bleeding and endoscopic findings.
2. In the CD clinical trial, clinical response was defined as a decrease from baseline in the Crohn's Disease Activity Index (CDAI) of ≥ 100 points.

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