Linvoseltamab-gcpt inj (LYNOZYFIC)
Criteria for Use
July 2026

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.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for linvoseltamab.

- ☐ Known hypersensitivity to linvoseltamab or its excipients (e.g. polysorbate 80)
- ☐ Baseline Absolute Neutrophil Count (ANC) < 1000/mm^3 unless Duffy Null phenotype
- ☐ Baseline platelet count < 50,000/mm^3
- ☐ CrCl $\leq$ 30 ml/min
- ☐ Moderate or severe hepatic impairment (Child-Pugh class B/C or NCI Organ Dysfunction Working Group Classification)
- ☐ Known active central nervous system or meningeal involvement
- ☐ Active or uncontrolled infection
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ Relapsed or refractory multiple myeloma in a patient who has received at least four prior lines of therapy including a proteasome inhibitor, immunomodulatory agent and an anti-CD38 monoclonal antibody
- ☐ Myeloma care provided by VA or VA Community Care oncology provider certified with the LYNOZYFIC REMS program
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group Performance Status 0-1

Additional Inclusion Criteria – Select If Applicable

- ☐ For females who can become pregnant: Pregnancy should be excluded prior to receiving linvoseltamab.
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 3 months after stopping treatment

Other Justification

- ☐ _____

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