LYNOZYFIC™ *(linvoseltamab-gcpt)* injection, for IV use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>LYNOZYFIC™ is a bispecific B-cell maturation antigen (BCMA) directed CD3 T-cell engager.</td></tr>
<tr><td>Covered Uses
(FDA approved indication)</td><td>LYNOZYFIC is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody* (see Appendix).

*This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).</td></tr>
<tr><td>Dosing and Administration</td><td>
<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Multiple Myeloma</td><td>The recommended dosage of LYNOZYFIC is:
Step-up doses of 5 mg, 25 mg, and 200 mg, followed by 200 mg weekly for 10 doses, followed by 200 mg every two weeks.
In patients who have achieved and maintained VGPR or better at or after Week 24 and received at least 17 doses of 200 mg, decrease the dosing frequency to 200 mg every four weeks.
Patients must be hospitalized for 24 hours after administration of Day one and Day eight Step-Up doses.
Continue until disease progression or unacceptable toxicity.</td><td>1.8 x 10^{11} vector genomes</td></tr>
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<table>
<tr><th>Dosing Schedule</th><th>Day[a]</th><th>LYNOZYFIC Dose</th><th>Infusion Time</th></tr>
<tr><td rowspan="3">Step-Up Dosing</td><td>Day 1</td><td>5 mg</td><td rowspan="3">Four hours</td></tr>
<tr><td>Day 8</td><td>25 mg</td></tr>
<tr><td>Day 15</td><td>200 mg (1st treatment dose)</td></tr>
<tr><td>Weekly Dosing</td><td>Start one week from Day 15

Weekly from Weeks 4-13 for 10 treatment doses</td><td>200 mg</td><td>First weekly dose: one hour

Subsequent doses[b]: 30 min</td></tr>
<tr><td>Q2 weeks Dosing</td><td>Week 14 and q2 weeks thereafter</td><td>200 mg</td><td>30 min</td></tr>
<tr><td colspan="4">Patients who achieve and maintain VGPR or better at or after Week 24 AND receive at least 17 doses of 200 mg</td></tr>
<tr><td>Q4 weeks Dosing</td><td>Week 24 or after and q4 weeks thereafter</td><td>200 mg</td><td>30 min</td></tr>
</table>
[a] Weekly doses should be at least five days apart; q2 weeks dosing at least 10 days apart; q4 weeks dosing at least 24 days apart.
[b] For patients who experience CRS with a dose, duration of infusion should be maintained at the duration of the previously tolerated infusion.
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GOLD COAST HEALTH PLAN
TOTAL Care ADVANTAGE℠

Recommended Premedications Prior to EACH dose of LYNOZYFIC:

Medication	Dose	PO or IV	Timing Prior to LYNOZYFIC infusion
Acetaminophen (or equivalent)	650-1000 mg	PO	30-60 min prior
Diphenhydramine (or equivalent)	25 mg	PO/IV	30-60 min prior
Dexamethasone (or equivalent)	40 mg – Step-up Day 1, 8 and 15 IF no CRS and/or IRR with 40 mg after Day 15, decrease to 10 mg for all subsequent doses	IV	one-three hours prior

Pre-treatment medications *may be discontinued* once a treatment dose of 200 mg is tolerated without CRS and/or IRR following pre-treatment with 10 mg dexamethasone (or equivalent), acetaminophen (or equivalent), and diphenhydramine (or equivalent) as described.

Billing and Coding Information

	10-digit NDC	11-digit NDC
5 mg/2.5 ML SDV	61755-054-01	61755-0054-01
200 mg/10 mL SDV	61755-056-01	61755-0056-01

HCPCS Code	Description
C9307	Injection, linvoseltamab-gcpt, 1 mg

CPT Procedural Codes	Description
96413	Chemotherapy IV infusion, up to one hour
96415	Chemotherapy IV infusion, additional hour*

* Used as an add-on code for every hour of infusion that is more than 30 min past the initial one hour.

Product Availability

Single-dose vial: IV use only

- 5 mg/2.5 mL (2 mg/mL) SDV
- 200 mg/10 mL (20 mg/mL) SDV

Contraindications

None.

Recommended Medical Monitoring	**BLACK BOX WARNING: Cytokine Release Syndrome (CRS) and Neurological Toxicities, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)** – LYNOZYFIC is only available through **REMS** program. • Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 24 hours after administration of Day one and Day eight Step-Up doses. Further information about the **LYNOZYFIC REMS program** is available at www.lynozyficREMS.com or by telephone at 1-855-212-6391. In addition to black box warnings, LYNOZYFIC has been associated with: a. Infections, including serious or fatal b. Neutropenia c. Hepatotoxicity d. Embryo-Fetal Toxicity Patients should be monitored for any of these reactions. LYNOZYFIC dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions. LYNOZYFIC can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating LYNOZYFIC treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with Datroway and for **three months** after the last dose.
Approval Criteria	A. Physician administered IV infusion i. Cannot be self-administered B. Multiple Myeloma **(must meet all)**: i. Diagnosis of relapsed or refractory multiple myeloma ii. Prescribed by or in consultation with an oncologist iii. Patient age ≥ 18 years iv. Patient has ONE of the following: 1. Patient has measurable disease as evidenced by one of the following assessed within the last 28 days: a. Serum M-protein ≥ 0.5 g/dL b. Urine M-protein ≥ 200 mg/24 hr c. Serum free light chain (FLC) assay: involved FLC level ≥ 10 mg/dL 2. Patient has progressive disease as defined by International Myeloma Working Group (IMWG) response criteria (see Appendix), assessed within 60 days following last dose of last anti-myeloma drug regimen received. v. Member has documented intolerance to ≥ four prior lines of therapy (see Appendix for examples). Prior therapies must include **one of each** of the following: 1. *Proteasome Inhibitor* (e.g., bortezomib, Kyprolis, Ninlaro) 2. *Immunomodulatory Agent* (e.g., Revlimid, Pomalyst, Thalomid) 3. *Anti-CD38 monoclonal Antibody* (e.g., Darzalex, Sarclisa)

	vi. Member does not have known multiple myeloma brain lesions or meningeal involvement (these patients were excluded from the clinical trial) vii. Request meets **one** of the following: 1. Dose does not exceed recommended dose for current week of therapy (see Dosing Schedule); **OR** 2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)
Age Restriction	Adults ≥ 18 years old.
Coverage Duration	Initial: six months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Appendix	**Examples of Prior Alternative Therapies for Multiple Myeloma** • Bendamustine + Bortezomib + Dexamethasone • Bendamustine + Revlimid + Dexamethasone • Bortezomib + Cyclophosphamide + Dexamethasone • Bortezomib + Dexamethasone • Bortezomib + Doxorubicin (or liposomal doxorubicin) + dexamethasone • Bortezomib + Revlimid + Dexamethasone • Bortezomib + Thalomid + Dexamethasone • Cyclophosphamide + Revlimid + Dexamethasone • Darzalex (or Darzalex Faspro) • Darzalex (or Darzalex Faspro) + Bortezomib + Dexamethasone • Darzalex (or Darzalex Faspro) + Pomalidomide + Dexamethasone • Darzalex (or Darzalex Faspro) + Revlimid + Dexamethasone • Empliciti + Bortezomib + Dexamethasone • Empliciti + Pomalidomide + Dexamethasone • Empliciti + Revlimid + Dexamethasone • Kyprolis + Cyclophosphamide + Dexamethasone • Kyprolis + Dexamethasone • Kyprolis + Revlimid + Dexamethasone • Ninlaro + Pomalidomide + Dexamethasone • Ninlaro + Revlimid + Dexamethasone • Pomalidomide + Bortezomib + Dexamethasone • Pomalidomide + Cyclophosphamide + Dexamethasone • Pomalidomide + Dexamethasone • Pomalidomide + Kyprolis + Dexamethasone • Revlimid + Dexamethasone • Revlimid + low-dose Dexamethasone • Sarclisa + Pomalidomide + Dexamethasone • VTD-PACE (Dexamethasone + Thalomid + Cisplatin + Doxorubicin + Cyclophosphamide + Etoposide + Bortezomib)

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	9/19/2025	9/19/2025	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics (P&T) Committee	11/13/2025