Elranatamab-bcmm: Dosing & Administration

INDICATIONS & USAGE

Elranatamab-bcmm is a bispecific BCMA-directed CD3 T-cell engager indicated for:

Adults with RRMM who have received:

≥4 prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb

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 of clinical benefit in a confirmatory trial(s). Please see FULL PRESCRIBING INFORMATION, including boxed warning

Elranatamab-bcmm should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS

IMPORTANT DOSING INFORMATION

Due to the risk of CRS, patients should be hospitalized after the 1st and 2nd elranatamab-bcmm step-up doses for

- 48 hr *after Dose 1*
- 24 hr *after Dose 2*

Administer pre-treatment medications 1 hr prior to each dose in the step-up dosing schedule

- Acetaminophen or equivalent, 650 mg PO
- Dexamethasone or equivalent, 20 mg PO or IV
- Diphenhydramine or equivalent, 25 mg PO

RECOMMENDED DOSAGE

Dosing Schedule	Day	Dose	
Step-up dosing	Day 1	Step-up dose 1	**12 mg SC**
	Day 4*	Step-up dose 2	**32 mg SC**
	Day 8†	First treatment dose	**76 mg SC**
Weekly dosing	One week after first treatment dose and weekly thereafter‡, through Week 24	Subsequent treatment doses	**76 mg SC**
Biweekly (Q2W) dosing Responders‡, only Week 25 onward	Week 25 and Q2W thereafter§	Subsequent treatment doses	**76 mg SC**

Following… **≥24 weeks** Elranatamab-bcmm treatment *And…* **≥2 months** PR or better *Switch to Q2W dosing* and continue until **disease progression** or **unacceptable toxicity**

*A minimum of 2 days should be maintained between step-up dose 1 (12 mg) and step-up dose 2 (32 mg). †A minimum of 3 days should be maintained between step-up dose 2 (32 mg) and the first treatment (76 mg) dose. ‡Patients who have received at least 24 weeks of treatment with elranatamab-bcmm and have achieved a response (PR or better) and maintained this response for at least 2 months; §A minimum of 6 days should be maintained between treatment doses.

PREPARATION & ADMINISTRATION

Elranatamab-bcmm is supplied as a **ready-to-use solution** (single-dose vials of 76 mg /1.9 mL [40 mg/mL] and 44 mg /1.1 mL [40 mg/mL])

2–8°C; 36–46°F Remove the **vial** from storage and **equilibrate to ambient temperature** **15–30°C; 59–86°F**

Do not warm in any other way. Use **aseptic technique** for preparation and administration

Withdraw **required injection volume** from vial and discard unused portion (see Table)

Total Dose	Dose Volume, mL
12 mg	0.3
32 mg	0.8
76 mg	1.9

Inspect elranatamab-bcmm prior to administration: it should be **clear to slightly opalescent, colorless to pale brown liquid solution**; and free from **particulate matter** and **discoloration**

Elranatamab-bcmm vials are for **one-time use** in a single patient, and do not contain any preservatives

Withdraw the required injection volume of elranatamab-bcmm from the vial into an **appropriately sized syringe** with **stainless steel injection needles** (**30 G or wider**) and polypropylene or polycarbonate syringe material. **Discard unused portion.**

Inject elranatamab-bcmm into the **subcutaneous tissue** of the **abdomen** (preferred site) or subcutaneous tissues at other sites (e.g., thigh)

Do not inject into tattoos or scars or areas where the skin is red, bruised, tender, hard or not intact

If prepared syringe is not used immediately, store at **2–30°C (36–86°F)** for a maximum of **4 hours**

REMS

- Elranatamab-bcmm is available only through a **restricted program called ELREXFIO REMS** because of the risks of CRS and neurologic toxicity, including ICANS
- Further information about the ELREXFIO REMS program is available at www.ELREXFIOREMS.com or by telephone at 1-844-923-7845

REFERENCE: ELREXFIO® (elranatamab-bcmm) Prescribing Information. New York, NY: Pfizer Inc.; August 2023.

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RECOMMENDED DOSE MODIFICATIONS FOR ARs FOLLOWING ELRANATAMAB-BCMM ADMINISTRATION

- Dosage reductions of elranatamab-bcmm are not recommended
- Dosage delays may be required to manage toxicities related to elranatamab-bcmm
- **This table provides an overview of dose modifications in the USPI. Please refer to the USPI for additional detail**

CRS

- **Grade 1–3 (first occurrence):** Withhold elranatamab-bcmm until CRS resolves
- **Grade 3 (recurrent) and Grade 4:** Permanently discontinue elranatamab-bcmm

HEMATOLOGIC ARs

- **ANC <0.5 x 10^9/L:** Withhold elranatamab-bcmm until ≥0.5 x 10^9/L
- **Febrile neutropenia:** Withhold elranatamab-bcmm until ANC is ≥1 x 10^9/L and fever resolves
- **Hemoglobin <8 g/dL:** Withhold elranatamab-bcmm until ≥8 g/dL
- **Platelet count <25,000/mcL or 25,000–50,000/mcL with bleeding:** Withhold elranatamab-bcmm until ≥25,000/mcL and no evidence of bleeding

NEUROLOGIC TOXICITY AND ICANS

- **Grade 1:** Withhold elranatamab-bcmm until ICANS/neurologic toxicity resolves or neurologic toxicity stabilizes
- **Grade 2 and 3 (first occurrence):** Withhold elranatamab-bcmm until neurologic toxicity symptoms improve to ≤Grade 1, or ICANS resolves
- **Grade 3 (recurrent) and Grade 4:** Permanently discontinue elranatamab-bcmm

INFECTIONS AND OTHER NON-HEMATOLOGIC ARs

- **Grade 3:** Withhold elranatamab-bcmm until adverse reaction improves to Grade ≤1 or baseline
- **Grade 4:** Consider permanent discontinuation of elranatamab-bcmm. If elranatamab-bcmm is not permanently discontinued, withhold subsequent treatment doses of elranatamab-bcmm (e.g., doses administered after elranatamab-bcmm step-up dosing schedule) until adverse reaction improves to ≤Grade 1

RESTARTING ELRANATAMAB-BCMM THERAPY AFTER DOSAGE DELAY

- If dose of elranatamab-bcmm is delayed, restart therapy based on the recommendations below and resume the dose schedule accordingly

Last Dose Administered	Time Since the Last Administered Dose	Action for Next Dose of Elranatamab-bcmm
Step-up dose 1 (12 mg)	≤14 days	• Restart at step-up dose 2 (32 mg)* • If tolerated, increase to 76 mg 4 days later
	>14 days	• Restart at step-up dose 1 (12 mg)*
Step-up dose 2 (32 mg)	≤14 days	• Restart at 76 mg*
	15 days to ≤28 days	• Restart at step-up dose 2 (32 mg)* • If tolerated, increase to 76 mg 1 week later
	>28 days	• Restart at step-up dose 1 (12 mg)*
Any treatment dose (76 mg)	≤42 days	• Restart at 76 mg
	43 days to ≤84 days†	• Restart at step-up dose 2 (32 mg)* • If tolerated, increase to 76 mg 1 week later
	>84 days†	• Restart at step-up dose 1 (12 mg)*

*Administer pre-treatment medications prior to elranatamab-bcmm dose; †Consider benefit-risk of restarting elranatamab-bcmm in patients who require dose delay of >42 days due to an AR.

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ABBREVIATIONS

ANC = absolute neutrophil count; AR = adverse reaction; BCMA = B cell maturation antigen; CD = cluster of differentiation; CRS = cytokine release syndrome; HCP = healthcare provider; ICANS = immune effector cell-associated neurotoxicity syndrome; IMiD = immunomodulatory agent; IV = intravenously; mAb = monoclonal antibody; PI = proteasome inhibitor; PO = orally; PR = partial response; Q2W = once every 2 weeks; RRMM = relapsed/refractory multiple myeloma; SC = subcutaneously

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