

Elranatamab Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
As monotherapy for the treatment of adult patients with relapsed and refractory (R/R) multiple myeloma (MM), who have received at least three prior therapies including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI) and an anti-cluster of differentiation 38 (anti-CD38) antibody and have demonstrated disease progression on the last therapy.	C90	00917a	ODMS 01/04/2026

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Elranatamab is administered at a dose of 76mg by subcutaneous (SC) injection once weekly.

In Cycle 1, to reduce the incidence and severity of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), there are two step-up doses of 12mg and 32mg on Day 1 and Day 4, followed by a full treatment dose of 76mg from Day 8 and onwards.

For patients who have received at least 24 weeks of treatment and have achieved a response, the dosing interval should transition to an every two-week schedule. For patients who have received at least 24 weeks of treatment at the every two-week schedule and have maintained the response, the dose interval should transition to an every four-week schedule.

Treatment should be continued until disease progression or unacceptable toxicity occurs. Each cycle is 28 days.

Elranatamab should be administered by a healthcare professional with adequately trained medical personnel and appropriate medical equipment to manage severe reactions, including CRS and neurologic toxicity, including ICANS.

Due to the risk of CRS and ICANS, patients should be **monitored for signs and symptoms for 48 hours** after administration of each of the 2 step-up doses and instructed to remain within proximity of a healthcare facility.

Facilities to treat anaphylaxis **MUST** be present when systemic anti-cancer therapy (SACT) is administered.

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Cycle 1

Drug	Day	Dose	Route	Cycle
Elranatamab ^{a, b}	1	12mg ^c	SC	Cycle 1 only
	4	32mg ^{c, d}	SC	
	8, 15, 22	76mg ^{c, e, f}	SC	

^a See Table 1 for recommendations on restarting elranatamab after dose delays; If a dose is missed, the dose should be administered as soon as possible, and the dosing schedule should be adjusted to maintain the dosing interval as needed (see Table 1).

^b The required dose should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, it may be injected into the subcutaneous tissue of the thigh. Elranatamab should not be injected into areas where the skin is red, bruised, tender, hard, or areas where there are scars.

^c Pre-treatment medicinal products should be administered prior to the first three doses of elranatamab.

^d A minimum of 2 days should be maintained between step-up dose 1 (12 mg) and step-up dose 2 (32 mg).

^e A minimum of 3 days should be maintained between step-up dose 2 (32 mg) and the first full treatment (76 mg) dose.

^f A minimum of 6 days should be maintained between doses.

Cycle 2-6

Drug	Day	Dose	Route	Cycle
Elranatamab ^{a, b}	1, 8, 15, 22	76mg ^c	SC	Every 28 days for 5 cycles

^a See Table 1 for recommendations on restarting elranatamab after dose delays; If a dose is missed, the dose should be administered as soon as possible, and the dosing schedule should be adjusted to maintain the dosing interval as needed (see Table 1).

^b The required dose should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, it may be injected into the subcutaneous tissue of the thigh. Elranatamab should not be injected into areas where the skin is red, bruised, tender, hard, or areas where there are scars.

^c A minimum of 6 days should be maintained between doses.

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Cycle 7-12

Drug	Day	Dose	Route	Cycle
Elranatamab ^{a, b}	1, 15	76mg ^{c, d}	SC	Every 28 days for 6 cycles
^a See Table 1 for recommendations on restarting elranatamab after dose delays; If a dose is missed, the dose should be administered as soon as possible, and the dosing schedule should be adjusted to maintain the dosing interval as needed (see Table 1).				
^b The required dose should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, it may be injected into the subcutaneous tissue of the thigh. Elranatamab should not be injected into areas where the skin is red, bruised, tender, hard, or areas where there are scars.				
^c A minimum of 6 days should be maintained between doses.				
^d For patients who have received at least 24 weeks of treatment at the once weekly schedule and who have achieved a response.				

Cycle 13 onwards

Drug	Day	Dose	Route	Cycle
Elranatamab ^{a, b}	1	76mg ^{c, d}	SC	Every 28 days from cycle 13 onwards
^a See Table 1 for recommendations on restarting elranatamab after dose delays; If a dose is missed, the dose should be administered as soon as possible, and the dosing schedule should be adjusted to maintain the dosing interval as needed (see Table 1).				
^b The required dose should be injected into the subcutaneous tissue of the abdomen (preferred injection site). Alternatively, it may be injected into the subcutaneous tissue of the thigh. Elranatamab should not be injected into areas where the skin is red, bruised, tender, hard, or areas where there are scars.				
^c A minimum of 6 days should be maintained between doses.				
^d For patients who have received at least 24 weeks of treatment at the every two week schedule and have maintained the response.				

ELIGIBILITY:

- Indication as above
- ECOG 0-2
- Adequate hepatic, renal and haematologic function

CAUTIONS:

- Vaccination with live virus vaccines is not recommended within the four weeks prior to the first dose of elranatamab, during treatment, and at least 4 weeks after treatment.
- Active serious infection. Withhold treatment until infection resolves.

EXCLUSIONS:

- Hypersensitivity to elranatamab or to any of the excipients
- Pregnancy
- Breastfeeding

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PREScriptive AUTHORITY:

The treatment plan must be initiated by a Consultant Haematologist working in the area of haematological malignancies.

TESTS:

Baseline tests:

- FBC, renal, liver and bone profile
- Serum protein electrophoresis (SPEP) to assess disease response in terms of paraprotein and also quantitative immunoglobulins i.e. total IgG as clinically indicated
- Pregnancy test for pre-menopausal women
- Virology screen - Hepatitis B (HBsAg, HBcoreAb) & C, HIV

Regular tests:

- FBC periodically during treatment as clinically indicated.
- Renal, liver and bone profile
- SPEP to assess disease response in terms of paraprotein and also quantitative immunoglobulins i.e. total IgG as clinically indicated
- Patients should continue to be monitored for signs and symptoms of CRS and ICANS (refer to Tables 4 and 5 for management of CRS and ICANS) *

*See Regimen Specific Complications

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Dose reductions of elranatamab are not recommended. Dose delays may be required to manage toxicities. Refer to Table 1 for recommendations on restarting elranatamab after a dose delay.
- See Table 2 for recommended dose modifications for haematological toxicities.
- See Table 3 for recommended dose modification in renal and hepatic toxicity.
- See Tables 4 and 5 for recommended actions for the management of CRS and ICANS.
- See Table 6 for recommended dose modifications for other non-haematologic adverse reactions.
- Any dose modification should be discussed with a Consultant.

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Table 1: Recommendations for restarting therapy with elranatamab after dose delay

Last dose administered	Duration of delay from the last administered dose	Action
Step-up dose 1 (12 mg)	2 weeks or less (≤ 14 days)	Restart at step-up dose 2 (32mg). ^a If tolerated, increase to 76mg 4 days later.
	Greater than 2 weeks (> 14 days)	Restart step-up dosing schedule at step-up dose 1 (12mg). ^a
Step-up dose 2 (32 mg)	2 weeks or less (≤ 14 days)	Restart at 76mg. ^a
	Greater than 2 weeks to less than or equal to 4 weeks (15 days and ≤ 28 days)	Restart at step-up dose 2 (32mg). ^a If tolerated, increase to 76mg 1 week later.
	Greater than 4 weeks (> 28 days)	Restart step-up dosing schedule at step-up dose 1 (12mg). ^a
Any full treatment dose (76 mg)	12 weeks or less (≤ 84 days)	Restart at 76mg.
	Greater than 12 weeks (> 84 days)	Restart step-up dosing schedule at step-up dose 1 (12mg). ^a If tolerated, increase to 76mg 1 week later.

^a Administer pre-treatment medicinal products prior to the elranatamab dose.

Haematological:

Table 2: Dose modification of elranatamab in haematological toxicity

Haematologic toxicity	Recommended action
ANC $< 0.5 \times 10^9/L$	Withhold elranatamab until ANC $\geq 0.5 \times 10^9/L$. ^a
Febrile neutropenia	Withhold elranatamab until ANC $\geq 1 \times 10^9/L$ or and fever resolves. ^a
Platelet count $< 25 \times 10^9/L$	Withhold elranatamab until platelet count is $\geq 25 \times 10^9/L$ and no evidence of bleeding. ^a
Platelet count 25 – 50 $\times 10^9/L$ with bleeding	
Haemoglobin < 8 g/dL	Withhold elranatamab until haemoglobin ≥ 8 g/dL. ^a

^a See Table 1 for recommendations on restarting elranatamab after dose delays

Renal and Hepatic Impairment:

Table 3: Dose modification of elranatamab in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No dose adjustment is recommended in patients with mild to moderate renal impairment. Limited data are available from patients with severe renal impairment.	No dose adjustments are required for mild hepatic impairment.
Renal and hepatic: Recommendations as per SmPC for elranatamab	

Management of adverse events:

Cytokine release syndrome (CRS):

- CRS should be identified based on clinical presentation. Patients should be evaluated and treated for other causes of fever, hypoxia, and hypotension. Supportive therapy for CRS (including but not limited to anti-pyretic agents, intravenous fluid support, vasopressors, interleukin-6 (IL-6) or IL-6 receptor inhibitors, supplemental oxygen, etc.) should be administered as appropriate. Laboratory testing to monitor for disseminated intravascular coagulation (DIC), haematology parameters, as well as pulmonary, cardiac, renal, and hepatic function should be considered.

Table 4: Recommendations for management of CRS

Grade ^a	Presenting symptoms	Recommended action
Grade 1	Temperature $\geq 38^{\circ}\text{C}^{\text{b}}$	- Withhold treatment until CRS resolves.^c - Provide supportive therapy.
Grade 2	Temperature $\geq 38^{\circ}\text{C}$ with either: - Hypotension responsive to fluid and not requiring vasopressors, and/or - Oxygen requirement of low-flow nasal cannula^d or blow-by	- Withhold treatment until CRS resolves.^c - Provide supportive therapy. - Monitor patients daily for 48 hours following the next dose of elranatamab. Instruct patients to remain within proximity of a healthcare facility.
Grade 3 (first occurrence)	Temperature $\geq 38^{\circ}\text{C}$ with either: - Hypotension requiring one vasopressor with or without vasopressin, and/or - Oxygen requirement of high-flow nasal cannula^d, facemask, non-rebreather mask, or Venturi mask	- Withhold treatment until CRS resolves.^c - Provide supportive therapy, which may include intensive care. - Administer pre-treatment medicinal products prior to the next dose of elranatamab. - Monitor patients daily for 48 hours following the next dose of elranatamab. Instruct patients to remain within proximity of a healthcare facility.
Grade 3 (recurrent)	Temperature $\geq 38^{\circ}\text{C}$ with either: - Hypotension requiring one vasopressor with or without vasopressin, and/or - Oxygen requirement of high-flow nasal cannula^d, facemask, non-rebreather mask, or Venturi mask	- Permanently discontinue therapy. - Provide supportive therapy, which may include intensive care.

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Grade ^a	Presenting symptoms	Recommended action
Grade 4	Temperature $\geq 38^{\circ}\text{C}$ with either: - Hypotension requiring multiple vasopressors (excluding vasopressin), and/or - Oxygen requirement of positive pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation)	- Permanently discontinue therapy. - Provide supportive therapy, which may include intensive care.

^a Based on American society for transplantation and cellular therapy (ASTCT) 2019 grading for CRS.

^b Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anticytokine therapy.

^c See Table 1 for recommendations on restarting elranatamab after dose delays.

^d Low-flow nasal cannula is ≤ 6 L/min, and high-flow nasal cannula is >6 L/min.

Neurologic toxicity, including ICANS:

- Other causes of neurologic symptoms should be ruled out. Patients should be immediately evaluated and treated based on severity. Supportive therapy, which may include intensive care, for severe or life-threatening neurologic toxicities, should be provided. Patients who experience Grade 2 or higher ICANS with the previous dose of elranatamab should be instructed to remain within proximity of a healthcare facility and be monitored for signs and symptoms daily for 48 hours following the next dose.

Table 5: Guidelines for management of immune effector cell-associated neurotoxicity syndrome (ICANS)

Grade ^a	Presenting symptoms ^b	Actions
Grade 1	ICE score 7-9 ^c or, depressed level of consciousness ^d : awakens spontaneously.	- Withhold treatment until ICANS resolves.^e - Monitor neurologic symptoms and consider consultation with a neurologist for further evaluation and management. - Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis.
Grade 2	ICE score 3-6 ^c or, depressed level of consciousness ^d : awakens to voice.	- Withhold treatment until ICANS resolves.^e - Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. - Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. - Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. - Monitor patients daily for 48 hours following the next dose of elranatamab. Instruct patients to remain within proximity of a healthcare facility.

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Grade 3 (First occurrence)	ICE score 0-2^c or depressed level of consciousness^d: awakens only to tactile stimulus, or seizures^d, either: - any clinical seizure, focal or generalised, that resolves rapidly, or - non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local oedema on neuroimaging^d.	- Withhold treatment until ICANS resolves.^e - Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. - Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. - Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. - Provide supportive therapy, which may include intensive care. - Monitor patients daily for 48 hours following the next dose of elranatamab. Instruct patients to remain within proximity of a healthcare facility.
Grade 3 (Recurrent)	ICE score 0-2^c or depressed level of consciousness^d: awakens only to tactile stimulus, or seizures^d, either: - any clinical seizure, focal or generalised, that resolves rapidly, or - non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local oedema on neuroimaging^d.	- Permanently discontinue treatment. - Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. - Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. - Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. - Provide supportive therapy, which may include intensive care.

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Grade 4	ICE score 0^c Or, depressed level of consciousness^d either: - patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or - stupor or coma, or seizures^d, either: - life-threatening prolonged seizure (>5 minutes), or - repetitive clinical or electrical seizures without return to baseline in between, or motor findings^d: - deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure/cerebral oedema^d, with signs/symptoms such as: - diffuse cerebral oedema on neuroimaging, or - decerebrate or decorticate posturing, or - cranial nerve VI palsy, or - papilloedema, or - Cushing's triad	- Permanently discontinue treatment. - Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. - Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously for 3 days. - Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. - Consider non-sedating, anti-seizure medicinal products (e.g., levetiracetam) for seizure prophylaxis. - Provide supportive therapy, which may include intensive care.
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^a Based on American society for transplantation and cellular therapy (ASTCT) 2019 grading for ICANS.

^b Management is determined by the most severe event, not attributable to any other cause.

^c If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, e.g., point to clock, pen, button = 3 points); **Following Commands** (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point; and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.

^d Not attributable to any other cause.

^e See Table 5 for recommendations on restarting elranatamab after dose delays.

^f All references to dexamethasone administration are dexamethasone or equivalent medicinal products.

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Table 6: Recommendations for management of other non-haematologic adverse reactions

Adverse reactions	Severity	Actions
Other* non-haematologic adverse reactions ^a	Grade 3 or 4	- Withhold treatment until recovery to Grade 1 or less or baseline.^b - Permanently discontinue if recovery does not occur.

^a Based on National cancer institute common terminology criteria for adverse events (NCI-CTCAE), Version 5.0.

^b See Table 1 for recommendations on restarting elranatamab after dose delays.

* Other than CRS and ICANS

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - [Available on the NCCP website](#)

Elranatamab: Low (Refer to local policy)

For information:

Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - [Available on the NCCP website](#)
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - [Available on the NCCP website](#)

PREMEDICATIONS:

- Table 7 below provides details of recommended premedications.

Table 7: Recommended premedications prior to elranatamab doses

Cycle	Patient requiring pre-medication	Pre-medication*	Administration
1 (step-up dose 1, step-up dose 2, and first full treatment dose)	All patients	dexAMETHasone 20mg IV	60 minutes prior to dose
		Chlorphenamine 10mg IV	60 minutes prior to dose
		Paracetamol 500mg PO	60 minutes prior to dose

OTHER SUPPORTIVE CARE:

- Antiviral prophylaxis (**Refer to local policy**)
- Tumour lysis prophylaxis (**Refer to local policy**)
- Anti-bacterial prophylaxis (**Refer to local policy**)
- Anti-fungal prophylaxis (**Refer to local policy**)
- Consider PJP prophylaxis (**Refer to local policy**)
- Immunoglobulin replacement** is recommended for all patients receiving elranatamab as they will quickly become hypogammaglobulinaemic when on treatment with an anti-BCMA bispecific antibody
- G-CSF support (**Refer to local policy**)

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- Women of child-bearing potential should use effective contraception during treatment with elranatamab and for six months after the last dose.

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics for details.
- **Elranatamab is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.**

REGIMEN SPECIFIC COMPLICATIONS

- **Hepatitis B Reactivation:** Patients should be tested for both HBsAg and HBcoreAb as per local policy. If either test is positive, such patients should be treated with anti-viral therapy (**Refer to local infectious disease policy**). These patients should be considered for assessment by hepatology.
- **Cytokine release syndrome (CRS):** CRS, including life-threatening or fatal reactions, may occur in patients receiving elranatamab. Clinical signs and symptoms of CRS may include, but are not limited to, fever, hypoxia, chills, hypotension, tachycardia, headache and elevated liver enzymes. Therapy should be initiated according to the step-up dosing schedule to reduce risk of CRS and patients should be monitored following administration of elranatamab accordingly. Pre-treatment medicinal products should be administered prior to the first three doses to reduce risk of CRS. Patients should be counselled to seek urgent medical attention should signs or symptoms of CRS occur. At the first sign of CRS, elranatamab should be withheld and patients should be immediately evaluated for hospitalisation. CRS should be managed according to the recommendations in Table 4, and further management should be considered per local institutional guidelines. Supportive therapy for CRS (including but not limited to anti-pyretic agents, intravenous fluid support, vasopressors, IL-6 or IL-6 receptor inhibitors, supplemental oxygen, etc.) should be administered as appropriate. Laboratory testing to monitor for disseminated intravascular coagulation (DIC), haematology parameters, as well as pulmonary, cardiac, renal, and hepatic function should be considered.
- **Neurologic toxicity, including ICANS:** Serious or life-threatening neurologic toxicities, including ICANS, may occur following treatment with elranatamab. Patients should be monitored for signs and symptoms (e.g., decrease level of consciousness, seizures and/or motor weakness) of neurologic toxicities during treatment. Patients should be counselled to seek urgent medical attention should signs or symptoms of neurologic toxicity occur. At the first sign of neurologic toxicity, including ICANS, elranatamab should be withheld and neurology evaluation should be considered. General management for neurologic toxicity (e.g., ICANS) is summarised in Table 5. Due to the potential for ICANS, patients should be advised not to drive or operate heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completing each of the two step-up doses and in the event of new onset of any neurological symptoms.
- **Influence on driving ability/use of machinery:** Elranatamab has major influence on the ability to drive and use machines. Due to the potential for ICANS, patients receiving elranatamab are at risk of depressed level of consciousness. Patients should be instructed to refrain from driving or operating heavy or potential dangerous machinery during and for 48 hours after completing each of the 2 step-up doses and in the event of new onset of neurologic toxicity until resolution of any neurological symptoms.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

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COMPANY SUPPORT RESOURCES/Useful Links:

Please note that this is for information only and does not constitute endorsement by the NCCP.

Patient Alert Card:

<https://assets.hpra.ie/products/Human/40117/34a8a318-dea3-44c6-acbb-74874c3b65d1.pdf>

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Version	Date	Amendment	Approved By
1	19/01/2026		NCCP Plasma Cell Disorders SACT CAG
1a	01/04/2026	Update to the reimbursement status box. Update to other supportive care section.	NCCP

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

NCCP Regimen: Elranatamab Monotherapy	Published: 19/01/2026 Review: 19/01/2027	Version number: 1a
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