SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		76 Years	Male	Unk		AUG	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Prolia Indication: bone cancer metastatic/Dose/frequency: 120mg every 3 months [Off label use] underwent surgery in early August, but does not specify the type of surgery [Surgery]

Case Description: This non-serious spontaneous report (GTMSP2025108172) was reported to Amgen on 28/MAY/2025 by a consumer and involves a 76 years old male patient who received Prolia, Single Dose Prefilled Syringe. Off label use was reported.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Prolia (denosumab) Solution for injection {Lot # L14177A1}
#2) single dose prefilled syringe (single dose prefilled syringe) Device **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 120 milligram, q3mo	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) spinal cancer (Bone cancer metastatic)
#2) Spinal cancer (Bone cancer metastatic)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 20-MAY-2024 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Acetaminophen (Paracetamol) Unknown formulation ; Unknown
#2) Bicalutamide (Bicalutamide) Tablet ; 19-MAR-2024 / Unknown
#3) Tramacet (Paracetamol, Tramadol hydrochloride) Capsule ; 20-MAY-2024 / Unknown

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Prostate cancer metastatic (Prostate cancer metastatic)
Unknown to Ongoing	Current Condition	Prostate cancer metastatic (Prostate cancer metastatic)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Amgen Ltd
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS

24b. MFR CONTROL NO.
GTMSP2025108172

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
19-AUG-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
29-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's historical medical condition included flu-like symptoms, heart problems, pain in the lower limbs, headache, abnormal total prostate antigen. The patient's current medical condition included prostate cancer, spinal cancer, abdominal spasm, chills, intense heat, excess sweating. The patient's concomitant medications included Acetaminophen (paracetamol), Bicalutamide (bicalutamide), Tramacet (paracetamol, tramadol hydrochloride).The patient's co-suspect medication included Eligard (leuprorelin acetate), Xtandi (enzalutamide). On an unknown date in JAN/2024, the patient's laboratory test(s) included Prostatic specific antigen, revealing 900 ng/mL. On 17/MAY/2024, the patient's laboratory test(s) included Prostatic specific antigen, revealing 0 ng/mL.

The patient began Prolia, Single Dose Prefilled Syringe on 20/MAY/2024, 120 mg every 3 months for spinal cancer (off label use). No treatment information was received.

No follow-up attempts are possible. No further information is expected.

ADDITIONAL INFORMATION RECEIVED ON 19/AUG/2025:
The patient's current medical condition included burning in the pit of the stomach, spine pain. On an unknown date in AUG/2025, the patient indicated that, based on a medical decision and his own decision, he omitted treatment with Eligard and underwent surgery in early August, but does not specify the type of surgery [PT: surgery]. No Treatment information was received. The outcome of the event surgery was reported as recovering/resolving. Action taken with Prolia, Single Dose Prefilled Syringe was reported as unknown for the event surgery. The event surgery was not related to Prolia. The causal relationship between the event surgery and Prolia Single Dose Prefilled Syringe was not provided by the consumer.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	JAN-2024	Prostatic specific antigen Done	900 ng/mL	
2	17-MAY-2024	Prostatic specific antigen Done	0 ng/mL	

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#3) Eligard (Leuprorelin acetate) Inhalation powder; Regimen #1	22.5 milligram, q3mo; Subcutaneous use	Prostate cancer (Prostate cancer)	09-FEB-2024 / Unknown; Unknown
#3) Eligard (Leuprorelin acetate) Inhalation powder {Lot # L14177A1}; Regimen #2	45 milligram, q6mo; Subcutaneous use	Prostate cancer (Prostate cancer)	23-MAY-2024 / Ongoing; Unknown
#4) Xtandi (Enzalutamide) Capsule; Regimen #1	40 milligram (4 capsules together every 24 hours, 120 CAP x 30 END); Oral use	Spinal cancer (Bone cancer metastatic)	20-MAY-2024 / Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Flu-like symptoms (Influenza like illness);
Unknown	Historical Condition	Cardiac disorder (Cardiac disorder);
10-FEB-2024 to Unknown	Historical Condition	Pain in extremity (Pain in extremity);
10-FEB-2024 to Unknown	Historical Condition	Headache (Headache);
08-MAR-2024 to Ongoing	Current Condition	Abdominal spasm (Abdominal rigidity);
JAN-2024 to Unknown	Historical Condition	Prostatic specific antigen abnormal (Prostatic specific antigen

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
		abnormal);
Unknown to Ongoing	Current Condition	Chills (Chills);
FEB-2025 to Ongoing	Current Condition	Feeling hot (Feeling hot);
FEB-2025 to Ongoing	Current Condition	Excess sweating (Hyperhidrosis);
08-MAR-2024 to Ongoing	Current Condition	Dyspepsia (Dyspepsia);
Unknown to Ongoing	Current Condition	Spinal pain (Spinal pain);