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		Unk	Female	Unk	11	JUL	2025

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

Bone pain [Bone pain]

Case Description: This non-serious spontaneous report (GTMSP2025142518) was reported to Amgen on 16/JUL/2025 by a physician and involves a female patient who had bone pain [PT: bone pain] while receiving Prolia, Single Dose Prefilled Syringe.

No historical medical condition was reported. The patient's current medical condition included osteoporosis. No concomitant medications were provided. No co-suspect medications were 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
#2) single dose prefilled syringe (single dose prefilled syringe) Device

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 60 milligram per millilitre, q6mo	#1) Subcutaneous use
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Osteoporosis (Osteoporosis)
#2) Osteoporosis (Osteoporosis)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 11-JUL-2025 / 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)

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	Osteoporosis (Osteoporosis)

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.
GTMSP2025142518

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

24c. DATE RECEIVED BY MANUFACTURER
16-JUL-2025

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

DATE OF THIS REPORT
21-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient began Prolia, Single Dose Prefilled Syringe on 11/JUL/2025. On same day, the patient had bone pain. The physician mentions that this was the first patient to report this adverse event with Prolia and recommended that the patient take a painkiller and that the pain was temporary. The physician considered that the sign or symptom experienced was related to the product administered. The outcome of the event bone pain was reported as unknown. Action taken with Prolia, Single Dose Prefilled Syringe was reported as unknown for the event bone pain.

The physician reported that the event bone pain was possibly related to Prolia. The causal relationship between the event bone pain and Prolia Single Dose Prefilled Syringe was not provided by the physician. No follow-up attempts are possible. No further information is expected.