Post Market Follow-up Form

FORM-100836 v6.0 Effective Date: 17-Dec-2018

AMGEN® CZECH REPUBLIC	Fax number: 800 900 625 Email Address: eu-cz-safety@amgen.com	AER No.

1. Reporter Information

☐ Physician
☐ Nurse
☐ Pharmacist
☐ Consumer
☐ _____

First name:	Last name:	
Address:		Zip/Post code:
City:	State:	Country:
Phone:	Fax or email:	

2. Prescribing Physician (if different than reporter)

First name:		Last name:
Phone:	Zip/Post code:	Country:

3. Patient

Initial or First Name:		Initial or Last Name:		Country:	

Date of Birth*: (dd-MMM-yyyy)	Age*: ☐ years ☐ months	Age group*: ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Elderly	Weight ☐ kg ☐ lbs	Height ☐ cm ☐ in	Race/Ethnicity	Gender ☐ Male ☐ Female

*Please provide at least one value (i.e. DOB or Age or Age group)

4. Suspect Products Information (include dosing details)

Suspect Product(s)	Product Form	Start Date	Stop Date	Action Taken	Dose/Units/ Frequency	Route	Indication	Lot/Batch/ Serial #:
Please list all the suspect product(s) below	01 – Sure Click 02 – Prefilled syringe 03 – Tablet 04 – On Body Injector/Infuser (OBI) 05 - Other	(dd-MON-yyyy)	(dd-MON-yyyy)	01 – Still being administered 02 – Permanently discontinued 03 - Withheld				(Provide Lot #/ Serial # in the cells below)
Product 1								☐ *Tick if unavailable or unknown*
Product 2								☐ *Tick if unavailable or unknown*

5. Adverse Event Information:

Event Term/Symptom	Onset Date (dd-MON-yyyy)	Resolved Date (dd-MON-yyyy) *(If patient died, list date of death)*	Seriousness criteria: 01=Death; 02=Immediately life threatening; 03=Required/prolonged hospitalization; 04=Persistent or significant disability/incapacity; 05=Congenital anomaly /birth defect; 06=Other medically important serious event; 07=None of the above/Non-serious	Seriousness Criteria code	If Hospitalization / Prolongation: Date Admitted (dd-MON-yyyy)	If Hospitalization / Prolongation: Date Discharged (dd-MON-yyyy)	Causality with product recorded in Section 4 (Y = Yes, N = No): Prod 1		Prod 2		Outcome: 01 – Resolved; 02 – Not resolved; 03 – Fatal*; 04 – Unknown. *Please provide cause of death, if known in section 9
							Y	N	Y	N	
							Y	N	Y	N	
							Y	N	Y	N	

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6. Relevant Concomitant Medications:

Drug Name (provide brand name if known)	Dosage		Indication	Start Date (dd-MON-yyyy)	Stop Date (dd-MON-yyyy)	Suspect	
	Units	Frequency				Yes	No
						☐	☐
						☐	☐
						☐	☐

7. Relevant Medical History and Allergies*:

*Please also include alcohol/drug/tobacco use/abuse if relevant

	Onset Date (dd-MON-yyyy)

Is the patient/patient's partner pregnant? ☐ Yes ☐ No ☐ Unk ☐ N/A | Is the patient/patient's partner breastfeeding? ☐ Yes ☐ No ☐ Unk ☐ N/A

8. Relevant Diagnostic Tests Performed?

☐ **Yes** ☐ **No**, If yes, please attach results or complete the table below:

Please indicate test unit where applicable (use additional pages if needed)

Date	Test Name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high

9. Event(s) Description: Chronological summary of reported events from section 5

(Please include information on the suspect drug(s) including method of administration and event(s) including the diagnosis, treatment, outcome and re-challenge info, if the event is persistent.)

Reporter Signature		Date (dd-MON-yyyy)	