Medical Affairs Department
Novartis Pharmaceuticals Australia Pty Ltd

Novartis Unique ID #:

Compassionate Use Request Form

Please complete and fax or scan and email to Compassionate Use Coordinator:

***Fax**: 02 8874 2322* ***Email**:compassionate.use-aunz@novartis.com*

Section A: REQUESTING PHYSICIANS DETAILS	
Treating Physician Name:	
Provider Number:	
Institution / Hospital Name:	
Address **(Street, City, State)**	
Telephone Number:	
Email Address:	

Section B: PATIENT DETAILS *provide only patient details as per below and remove all other identifiers on any relevant attachments*			
Patient Initials		**Date of Birth (DOB):**	
Gender:	☐ Male ☐ Female	**Does the patient have a valid Medicare card?**	☐ Yes ☐ No

Section C: PRODUCT REQUEST DETAILS	
Product Requested:	
Date of Request:	
Dose, Dosing Frequency and Duration:	
Indication for which Compassionate Use is requested:	

Is this request for Compassionate supply for a <u>new</u> patient or for <u>continued</u> treatment of a patient?

☐ New Patient

OR

☐ Continued treatment *(Only complete if patient was previously supplied this product for this indication, via the Novartis Compassionate Use Program)*

Only applicable for continued treatment:

☐ I confirm that this patient continues to derive benefit from this treatment

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Clinical justification for treating patient with the requested product: *(Section required for new patients only)*
(Please include appraisal of seriousness of patient's condition, detail of previous treatments and expected benefits from use of the product, reference to meaningful clinical data (eg literature, case studies) to support that the potential benefits outweigh the risks to the patient).

The patient for whom Compassionate Supply is sought : (please check all criteria)

☐ Is suffering from a serious or life-threatening disease or condition

☐ Does not have access to a comparable or satisfactory alternative treatment

☐ Is not currently in an ongoing clinical trial for this product

As Treating Physician, I understand that prior to this request being approved and product supplied:
(please check all criteria)

☐ I will be required to make the relevant arrangements for supply and treatment of my patient with an unapproved therapeutic good in accordance to the Special Access Scheme of the TGA

☐ Novartis will seek formal written confirmation that I have obtained written informed consent from the patient, as per the guidelines of the TGA Special Access program

☐ I will comply with the Novartis Safety Reporting Requirements for Compassionate Supply which will be provided by Novartis upon approval

As a healthcare professional participating in this activity sponsored by Novartis, I have read and understood the enclosed privacy statement and I agree with it. I understand that information relating to an adverse event with a Novartis product that is identified during this activity will be forwarded to Novartis drug safety department, and possibly to health authorities when required.

I understand that my participation in this activity indicates my consent for Novartis' drug safety department to contact me for further information regarding any adverse event identified as part of this activity. If the activity also involves patients, I acknowledge that I must check with my patient before providing the requested follow-up information.

Physician Signature:	**Date:**

AE Definition

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable or unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal product.

In addition, pregnancy cases and drug use during lactation (via the mother or father); transmission of infectious disease via medication; withdrawal reaction/syndrome and rebound effects, with or without clinical symptoms; lack of efficacy, with or without clinical symptoms; overdose, with or without clinical symptoms; intentional drug misuse/abuse with or without clinical symptoms; drug dependence/addiction with or without clinical symptoms; medication errors, including maladministration, occupational/ accidental exposures and dispensing/prescribing errors with or without clinical symptoms; drug-drug, drug-food interactions, with or without clinical symptoms; disease progression and aggravation, with or without clinical symptoms; off-label use including pediatric exposure, with or without clinical symptoms; treatment non-compliance with clinical symptoms and unexpected beneficial effect.

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Product Complaints (PC)

This may include any fault of the quality and/or effectiveness, any fault of the containers and outer packages, any fault of labeling and package insert, any falsification of the medicinal product, any verbal written or electronic expression of dissatisfaction with Novartis product's identity, quality, stability, reliability, safety, effectiveness, performance or usage. The report could be made by a patient, pharmacist, health professional or another firm/site performing further operations to the product.
e.g. complaints about the product itself (label, tablet package), unusual appearance, odor or characteristics of the drug.
The elements particularly relevant for clinical trial drug supplies are:
Any fault of quality
Any fault of the container and outer packages
Any fault of labelling
Any suspected falsifications of the medicinal product
Any verbal written or electronic expression of dissatisfaction with the product e.g identity, quality

Product Complaints must be reported to Novartis within 24 hours.

Privacy Statement

By providing your personal information to Novartis Pharmaceuticals Australia Pty Ltd or its related bodies corporate (Novartis), you consent to Novartis collecting, storing and using your personal information in accordance with the Novartis Privacy Policy. In particular, you consent to Novartis using your personal information to communicate with you about Novartis products and/or to support your use of those products. You also consent to Novartis using your personal information to (where applicable) invite you to, or arrange your participation in, activities managed by (or on behalf of) Novartis.

Novartis is committed to patient safety. In accordance with regulatory obligations, Novartis has a systematic process in place to collect, store and process reports of adverse events experienced by patients taking a Novartis product, when identified by a Novartis representative (or by a third party acting on behalf of Novartis).

All information forwarded to the Novartis drug safety department is treated in accordance with local privacy laws and may be captured and processed in countries outside of the national territory, and shared with health authorities or other Pharmaceutical companies with whom Novartis has a license agreement, for the purpose of meeting the regulatory requirements for reporting safety information on Novartis products. Novartis drug safety department may contact the patient's healthcare professional in order to collect further information on the adverse event.

You are not obliged to provide personal information. However, if you do not provide information you may not for example, be able to participate fully in activities managed by us.

You have the right to access, update or correct your personal information and/or decline to receive communications from Novartis. To find out how, please refer to our Privacy Policy: https://www.novartis.com.au/privacy-policy or contact our Privacy Officer at Novartis Australia,
54 Waterloo Road, Macquarie Park NSW 2113. Ph: +61 2 9805 3555 or Email: privacy.au@novartis.com