Patient Request Form

Managed Access Program (MAP)

1. Request Information

Request ID (to be filled in by Grünenthal)

Date of Request

Condition to be treated

Country

Treating Institution

Requesting Physician Name

Specialty

Email

Phone Number

2. Patient Information

Use only coded or pseudonymized patient identifiers. Do not enter the patient name or other direct identifiers.

Patient Identifier

Year of Birth

Sex

Weight (optional)

Relevant Medical History

Diagnosis

Date of Diagnosis

Disease Stage/Severity

3. Eligibility Assessment - Clinical Need

- [ ] Patient suffers from a serious or life-threatening disease/condition
- [ ] No satisfactory authorized treatment options remain
- [ ] Available treatment options have been exhausted, failed, or are medically inappropriate
- [ ] Patient is not eligible for participation in an ongoing clinical trial
- [ ] Participation in a clinical trial has been considered

Patient Request Form

Managed Access Program (MAP)

Provide rationale

3. Requested Treatment

Product

Dosage

Route of Administration

Treatment Duration Requested

Requested Start Date

Expected Clinical Benefit

4. Clinical Justification

Previous Treatment 1 - treatment, dates and outcome

Previous Treatment 2 - treatment, dates and outcome

Previous Treatment 3 - treatment, dates and outcome

Scientific/Medical Rationale - explain why the requested treatment is medically justified

5. Risk-Benefit Assessment

- [ ] Potential benefits outweigh foreseeable risks for this individual patient
- [ ] Patient has been informed regarding the investigational/non-authorized nature of the treatment, if applicable
- [ ] Appropriate monitoring can be provided

Additional comments

6. Safety Monitoring and Reporting

Patient Request Form

Managed Access Program (MAP)

- [ ] Report all adverse events via following link: https://www.grunenthal.com/drug-safety-reporting
- [ ] Report serious adverse events immediately
- [ ] Provide follow-up information when requested
- [ ] Submit requested outcome information relating to continued benefit-risk evaluation

Primary safety reporting contact

8. Physician Declaration

I confirm that the information provided is accurate and complete; I am the treating physician responsible for the patient; the patient is not eligible for an appropriate clinical trial and has no satisfactory treatment alternatives; appropriate informed consent has been obtained; and I agree to comply with all safety reporting obligations.

- [ ] I confirm the declaration above

Name

Date

Signature (type name or apply a digital signature in your PDF application)

The complete Data Privacy Note follows on the next page.

Data Privacy Note

Managed Access Program (MAP)

Information provided in this request may include personal data required for evaluating eligibility, monitoring safety, assessing continued benefit, fulfilling pharmacovigilance obligations, and complying with applicable regulatory requirements. Only the minimum amount of information necessary for these purposes should be submitted. Please make sure to anonymize any patient information that is contained in your request.
Grünenthal GmbH (Zieglerstraße 6, 52078 Aachen, Germany) processes the personal data contained in this request, , for the purposes of reviewing and assessing eligibility for the Managed Access Program, administering the requested treatment, complying with applicable medical, regulatory, pharmacovigilance and safety reporting obligations, and protecting patient safety.

Personal data will be accessed only by authorized personnel and trusted service providers acting on Grünenthal's behalf where necessary for these purposes.
The processing of personal data is necessary to comply with Grünenthal's legal and regulatory obligations and for reasons of public interest in the area of public health, including ensuring the quality and safety of medicinal products.[CK1.1] Below kindly find a table that covers our legal basis for personal data processing:

Purpose of Processing	Data Privacy Lawful Basis	Cross-Border/National Healthcare Framework
Verifying Medical Credentials & Licensing	• UK GDPR Art. 6(1)(f) • EU GDPR Art. 6(1)(f) • State-level US Privacy Exemptions	• UK Medical Act 1983 / GMC Registry • EU National Medical Registers • US State Medical Licensing Board verification requirements
Administering Product Supply for Managed Access	• UK GDPR Art. 6(1)(f) • EU GDPR Art. 6(1)(f)	• Regulation 167 of the UK Human Medicines Regulations 2012 • Article 83 of EU Regulation (EC) No 726/2004 • US FDA 21 CFR Part 312 (Subpart I)
Pharmacovigilance & Safety Reporting	• UK GDPR Art. 6(1)(c), Art. 9 (2) (i) • EU GDPR Art. 6(1)(c), Art. 9 (2) (i)	• Part 11 of the UK Human Medicines Regulations 2012 • EU Directive 2001/83/EC (EMA GVP Module VI) • US FDA 21 CFR 312.32 / 314.80

Personal data will be retained only for as long as necessary to fulfil the above purposes and to comply with applicable legal, regulatory and record-retention requirements. If your enquiry includes information about an adverse event, the data will be stored in our systems at least 10 years after the respective product has been withdrawn from the market.

For further information regarding the processing of personal data or to exercise applicable rights, please check our privacy statement https://www.grunenthal.com/other-privacy-statements or contact us: Dataprivacy.de@grunenthal.com.