

Managed Access Programs

For products that have not yet been approved, our focus is on the generation of clinical trial data to enable regulatory authorities to assess whether these new medicines satisfy the requirements for quality, safety and efficacy for registration and market authorisation purposes. Approval by regulatory authorities is the only accepted route for allowing medicines to be made more broadly available to patients.

However, patients with serious and/or life-threatening diseases or conditions may not be eligible for participation in a clinical trial, nor may there be other treatment options available. Under specific circumstances and in compliance with the requirements of applicable local laws and regulations, Grünenthal may make unapproved medicines, or medicines approved for a different indication, available to these patients at the request of a treating physician, Authorities and/or Institutional Review Boards/Independent Ethics Committees, by conducting a Managed Access Program.

Managed Access covers all locally defined pre-approval programs and mechanisms such as, but not limited to, Compassionate use, Named Patient Supply, Expanded Access, Special Access Programs, L'Autorisation d'Accès Précoce (AAP).

The request must be unsolicited and the following criteria must be fulfilled:

- The patient has a serious or life-threatening disease
- No similar or satisfactory authorized therapy is available
- Patient enrollment in a clinical trial is not possible
- The medicine must be part of an active program or development with Grünenthal or marketed for another indication
- The risk/benefit profile of the product is evaluated as favorable for the relevant patient(s) as per Grünenthal internal procedures, meaning that the potential benefit of the treatment outweighs the potential risk of the treatment
- An appropriate access pathway exists based on local regulatory requirements
- The medicine is available, can be supplied without negative impact to ongoing programs and in a timeframe that will allow for meaningful intervention
- Additional criteria as per local law and regulations

An existing managed access program does not guarantee availability in all countries. Various regulatory mechanisms exist in different countries for managed access to new medicines and, as a result, country-specific variations for managed access occur. Any managed access to medicines must always comply with the applicable country-specific laws and regulations, including medicine importation requirements.

The requests for participation of a patient in a Managed Access Program can only be made by the treating physician of a patient.



Managed Access Policy

The request should be made via email to map@grunenthal.com.

Grünenthal will assess the request as per their internal procedures and in accordance with applicable local law and regulations. Grünenthal medical teams will work closely with the patient's doctor and this will be the primary communication channel. Pre-approval access may be limited in scope due to limited resources such as insufficient medicinal supply available.

For any question related to Managed Access Programs, please contact us through map@grunenthal.com.

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