



Novartis Gene Therapies GEMS portal for Managed Access Program (MAP) Requests

An introduction for external users

Version 1.0
Release Date February 14, 2022



Welcome to the Novartis Gene Therapies GEMS portal for Managed Access Program (MAP) requests

The GEMS initial request submission portal is part of a new, global, end-to-end MAP request management system that has been designed to make the application process faster and easier for physicians and other HCPs.

The system offers an easy-to-complete submission form, a reduction in processing time and the ability to submit or access an existing request through any desktop or mobile device.

The form and ongoing management process is largely intuitive. However, should you require any technical assistance, just click on the link at the bottom of any page in GEMS to raise a query with our support team who will either answer your query directly or redirect it to the correct team for a response. If you require any other form of assistance related to your request, please email us at ngtx.maps@novartis.com.

Below is some guidance for using the portal.

1. Registration


- Begin by clicking on the link below which takes you to the welcome page. Here, you will be asked to complete a brief registration form.
[Novartis welcome page](#)

2. Completing the request submission form

- Once registered, log in to the Managed Access portal where you can submit your request. Go to **Submit New Request** at the bottom of the page to initiate a new application. You will be asked to complete further details, including information about your organization, your request and shipping requirements.
- Depending on the compound, product or indication, you may be asked to complete additional questions and / or product-specific forms.
- Complete the Terms and Conditions section, Privacy notice, and submit your request. Please note that once your request is submitted the form is locked and you will not be able to make any changes to the content.
- When the request has been assigned to a member of the Novartis Gene Therapies Medical team, the status of your application will change to **Pending** to show that it has started the review and approval process.
- If further information to support your request is required during the review and approval process, you will be contacted by a member of the Novartis Gene Therapies Medical team.

3. Notification of decision

- If your Request is *denied*, you will receive an email informing you about the decision and reason why we cannot support your request.

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- If your Request is *approved* and product supply has been confirmed as available, the status will change to **Approved**, and you will be prompted at various points to submit further information such as treatment milestones.

4. Adverse Event Reporting

- Please report Adverse Events (AEs) relevant to Novartis products as per the AE training documentation provided. When the online tool should be used click [here](#).

You can access the GEMS online portal by clicking [here](#).