

Managed Access Programs

Patients with serious or life-threatening diseases or conditions sometimes seek medical products that are not yet approved or available in their country. Novartis “Managed Access” addresses this need by making certain investigational or unapproved treatments available to eligible patients. Below you’ll find additional details about these programs.

Product evaluation in clinical trials

Before a product can be placed on the market, it must undergo well-controlled clinical trials to prove that it is safe and effective, and its potential benefit to patients outweighs the possible risks. Clinical trial results and related product information are then submitted to the relevant health authorities for review. Clinical trials result in the generation of evidence that may lead to the approval of a product, which can make it more widely available to patients.

[Find out more about Novartis Clinical Trials](#)

What is Novartis Managed Access?

There are instances where a patient has a serious or life-threatening disease or condition, for which all currently available treatment options have been exhausted and enrollment into a clinical trial is not possible.

In these cases, the treating physician can request an investigational product prior to regulatory approval, provided it is allowed by the applicable local laws. Within Novartis, we refer to such provision of investigational products as “Managed Access.”

The Novartis “Managed Access” terminology covers all locally defined pre-approval access mechanisms and programs such as “Compassionate Use”, “Expanded Access”, “Named Patient Supply”, “Special Access Schemes/Programs”, “Autorisations temporaires d’utilisation (ATU)” and others.

[Novartis Position on Access to Unauthorized Novartis Products through Managed Access Programs \(MAPs\) \(PDF 0.2 MB\)](#)

[How we reimagined MAPs in 2025 \(50 KB\)](#)

Watch a message from Vas Narasimhan, Chief Executive Officer of Novartis, about Novartis' commitment to Managed Access

Who is eligible for Novartis Managed Access programs?

Novartis considers granting managed access to investigational products when all of the following criteria are met:

- Novartis received an independent request from a licensed physician on behalf of a patient
- The patient has a serious or life-threatening disease or condition and there is no comparable or satisfactory alternative therapy available for diagnosis, monitoring or treatment
- The patient is not eligible or able to enroll in a clinical trial or continue participation in a trial
- The patient meets any other medical criteria established by Novartis medical expert(s) responsible for the product or by the HA in the country of request (as applicable)
- There is a potential patient benefit that justifies the potential risk of treatment use, and these risks are not unreasonable in the context of the disease or condition to be treated
- Provision of the product will not interfere with the initiation, conduct, or completion of a Novartis clinical trial or overall development program
- Such access provision is allowed as per local laws and regulations

Information on ongoing Novartis Managed Access Programs are available at <https://clinicaltrials.gov/> and at <https://navigator.reaganudall.org>.

Outside these programs, individual patient requests can be submitted for other compounds provided the Managed Access criteria are fulfilled.

How do I submit a request for Managed Access?

A request must be submitted by the treating physician on behalf of the patient. Requests can be submitted via our portal by clicking here:

[Submit a Managed Access request](#)

[Managed Access patient privacy notice and consent templates](#)

Guidance on using the portal is available below.

[Novartis GEMS Portal External User Guide \(359 KB\)](#)

How are requests evaluated?

Each request will be acknowledged immediately, and reviewed carefully and fairly by the appropriate Novartis medical experts with every effort made to provide a response promptly once we have all the necessary information.

Please note that your request will be assessed in consideration of applicable local laws and regulations.

For Managed Access-related questions, please contact the medical team in your Novartis local country office.

[Novartis office locations](#)

Source URL: <https://www.novartis.com/healthcare-professionals/managed-access-programs>

List of links present in page

1. <https://www.novartis.com/healthcare-professionals/managed-access-programs>
2. <https://www.novartis.com/clinicaltrials>
3. https://www.novartis.com/sites/novartis_com/files/novartis-position-unauthorized-products-access.pdf
4. https://www.novartis.com/sites/novartis_com/files/how-we-reimagined-maps-2025.pdf
5. <https://clinicaltrials.gov/>
6. <https://navigator.reaganudall.org/>

7. <https://www.cybergrants.com/novartis/maps>
8. <https://www.novartis.com/healthcare-professionals/managed-access-programs/managed-access-patient-privacy-notice-and-consent-templates>
9. https://www.novartis.com/sites/novartis_com/files/novartis-gems-external-user-guide.pdf
10. <https://www.novartis.com/about/locations>