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 or pre-approval product prior to regulatory approval, provided it is allowed by the applicable local laws. Within Novartis, we refer to such provision of investigational or pre-approval 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 Pre-Approval Access to Novartis Products through Novartis Managed Access Programs (PDF 0.2 MB)

How we reimagined MAPs in 2020 (PDF 0.4 MB)

Who is eligible for Novartis Managed Access programs?

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

- The patient to be treated has a serious or life-threatening disease or condition, and no comparable or satisfactory alternative therapy is available to monitor or treat the disease or condition;
- The patient is ineligible for enrolment into or unable to access ongoing clinical trials;
- The patient meets any other important medical criteria established by the medical experts working on the product development program;
- Sufficient data exists to believe the potential benefit of treatment outweighs the potential risk in the context of the disease or condition to be treated;
- Novartis has an adequate supply of the investigational product and providing the investigational product will not interfere with ongoing clinical trial(s) or with the 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

Guidance on using the portal is available here.

Novartis GEMS Portal External User Guide (PDF 0.1 MB)

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.

In addition, since 2017 Novartis has collaborated with an external Independent Bioethics Advisory Committee (IBAC), which provides analysis and recommendations on Novartis guidelines and policies for the ethical conduct of clinical research, and on selected ethical challenges which may arise in clinical trials, development programs, managed access programs and other areas across Novartis. The IBAC is comprised of bioethicists, clinicians, healthcare practitioners, patient advocates and other domain knowledge experts appropriate to the problem at hand.

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

Novartis Office locations
