Managed Access Programs [1]

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 [2]

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 Novartis 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 Pre-Approval Access to Novartis Products through Novartis Managed Access Programs (PDF 0.2 MB) [3]

Who is eligible for Novartis Managed Access programs?

The following criteria* must be met by a patient to participate in a Novartis Managed Access program:

- The patient seeking treatment has a serious or life-threatening disease or condition, and

no comparable or satisfactory alternative therapy to monitor or treat the disease or condition is available;
- The patient is not eligible to enroll in a clinical trial;
- The potential benefit of treatment use outweighs the potential risk in the context of the disease or condition to be treated as confirmed by the treating physician at the time of request;
- Provision of the investigational product will not interfere with ongoing clinical trial(s) or overall development program; and
- The patient must meet any other important medical criteria established by the medical experts working on the product development program.

* All above criteria are subject to local laws and regulations

How do I submit a request for Managed Access?

A request must be submitted by the treating physician on behalf of the patient. Request forms can be accessed here:

Submit a Managed Access request [4]

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 [5]

Links
[1] https://www.novartis.com/our-focus/healthcare-professionals/managed-access-programs
[2] https://www.novartis.com/our-science/clinical-trials
[3] https://www.novartis.com/sites/www.novartis.com/files/novartis-position-pre-approval-access-june-2017.pdf
[4] https://www.novartis.com/our-focus/healthcare-professionals/managed-access-programs/managed-access-request-form
[5] https://www.novartis.com/about-us/contact/office-locations