Access to Medicinal Products

Our Patient-Focused Mission

At Alfasigma, we are passionate about improving the health and quality of life for patients, through life-changing science and innovation.

If you are a patient or a caregiver interested in our medicinal products, please discuss it directly with your physician.

Clinical Trials

Clinical trials are essential to evaluate whether a new medicine is safe and effective. The data they generate support regulatory approval and reimbursement decisions, helping ensure that patients can access new treatments by prescription.

Clinical trial participation is the primary means for patients to receive medicinal products that are not yet approved and available by prescription. To learn about our ongoing clinical trials, visit ClinicalTrials.gov.

Under specific circumstances, Alfasigma may provide access to our medicinal products outside of clinical trials, before they are available by prescription, for patients without suitable treatment alternatives who are not able to participate in a clinical trial, meaning they have an unmet medical need.

Companies and regulators use various terms, such as compassionate use, named patient supply, early access, and special access, to refer to the use of medicinal products outside of clinical trials, to address unmet medical needs.

At Alfasigma we refer to this as **Expanded Access.**

In other cases, a patient who has participated in one of our clinical trials, may benefit from treatment with a medicinal product following their trial completion, before it is available by prescription; we refer to this as **Post Trial Access.**

Alfasigma will evaluate the possibility for post-trial access while designing our clinical trials in order to provide full transparency to patients, investigators, and other stakeholders in advance of their agreement to participate in those trials. This is in accordance with our commitment to the highest ethical standards, including the

Declaration of Helsinki[1] and the International Council for Harmonisation Good Clinical Practice[2].

Our Approach to Medicines Access

Alfasigma will consider unsolicited requests from physicians to access our medicinal products, outside of clinical trials, which are not yet available by prescription in accordance with all applicable laws and regulations. Our assessment is guided by a deep commitment to a fair, consistent, and ethical evaluation.

Access is never guaranteed and can cease at any time at the discretion of Alfasigma.

This policy outlines our principles for providing access to our medicinal products with the care and integrity that patients deserve.

Guiding Principles

All decisions are based on the following core considerations:

1. Patient Criteria

Our primary focus is on the individual patient for whom access is requested. All of the following criteria must be met:

- The patient has been diagnosed with a serious or life-threatening disease or condition.
- There are no comparable or satisfactory alternative treatments available, or they have been exhausted by the patient.
- There is a reasonable expectation that the potential benefits of treatment with the medicinal product will outweigh the potential risks for the patient.

[1] World Medical Association. (2024). WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 75th WMA General Assembly, Helsinki, Finland, October 2024.

2 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2016). ICH Harmonised Guideline: Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2).

- The patient is not eligible for or is otherwise unable to participate in an ongoing clinical trial for a comparable medicinal product for their disease or condition, as determined by the treating physician.
- The patient meets all other required medical criteria to be treated with the medicinal product, as established by Alfasigma.
- The patient specifically consents to being treated with the medicinal product.

2. The Medicinal Product

To safeguard patient well-being and advance our clinical development, the medicinal product must fulfill specific requirements:

- The medicinal product is in an active phase of clinical development.
- There is a clear scientific rationale for treating the targeted disease or condition with the medicinal product, supported by sufficient evidence to assess that the potential benefits of treatment justify the associated risks; the risks should be reasonable given the nature of the disease or condition.
- There are sufficient data available to specify a dosing regimen.
- Providing access is not expected to interfere with or compromise Alfasigma’s clinical development programs, including the conduct of ongoing or planned clinical trials, potential regulatory approvals or reimbursement decisions.
- Adequate supply of the medicinal product is available to support both access requests and the broader clinical development program, without interruption.
- An appropriate and sustainable supply chain is available to the required destination.

3. The Physician

The requesting physician is a crucial partner in this process. The physician must:

- Be properly licensed and fully qualified to administer the medicinal product and monitor the patient's specific condition.
- Formally agree to comply on an ongoing basis with all local legal and regulatory requirements, and adhere to Alfasigma's standards for medicinal product handling, safety reporting and patient monitoring, and protection of Alfasigma intellectual property.

Initiating a Request

To begin the process, a patient's treating physician must submit a request to Alfasigma.

The request will be acknowledged within 3 business days after receipt and will be evaluated to ensure all criteria are met. Alfasigma may request additional information to complete the assessment.

As soon as a decision is made by Alfasigma, the requesting physician will be notified.

If the request is approved, all documentation required to supply the medicine will be collected, in accordance with country-specific laws and regulations. Specific guidance about what is required will be provided to the physician by Alfasigma.

Following complete documentation, the medicinal product will be prepared for shipment to the designated location.

All resupply requests will be submitted and evaluated following the same process described above.

Link to Submit a Request

All access requests, including requests for resupply must be submitted electronically: Request access to Alfasigma products - myTomorrows

Information that may directly identify a patient must not be included in the request.

Other Resources

For Physicians: If you are a physician with access-related questions, please contact: medicalinfo@alfasigma.com

For Patients or Caregivers: While we are not able to accept requests directly from patients or caregivers, your doctor can request access on your behalf. Please speak with them about this option.

This policy is subject to change at any time. The posting of this policy does not guarantee access to any specific medicinal product.