Information on Early Access to AstraZeneca Investigational Medicinal Products

Foundational Principles
AstraZeneca’s primary focus is to develop new medicines that make a meaningful difference to patients’ lives.

As outlined in AstraZeneca’s Code of Conduct, we are committed to delivering success in the right way to bring benefit through both what we do and how we do it. Earning and maintaining the trust of our stakeholders starts with ensuring that we always act with integrity and consistency.

Our patient focused principles are based on the aspiration to be fair and impartial, to be transparent and to base our decisions on the best clinical and scientific evidence currently available for any given Investigational Medicinal Product.

Purpose & Scope
This document is intended to provide information regarding access to AstraZeneca Investigational Medicinal Products outside of a clinical trial (Early Access). The term “Investigational Medicinal Product” (IMP) is used to designate any product in active development that is not approved for marketing.

In pursuit of our goal to develop highly effective and safe therapies, the successful completion of a clinical trial programme and subsequent availability of data to support the safety and efficacy of an IMP is the most effective way of ensuring timely review and decision making by Health Authorities on a given product. This will ultimately result in access to new, safe, and effective approved medicines for the broadest patient population. For this reason, AstraZeneca prioritises access to an IMP through clinical trials and encourages appropriate patients interested in an IMP to enrol in such studies.

However, we recognise that there are circumstances wherein patients with serious or life-threatening diseases have exhausted all available therapeutic options and may not be eligible to enrol in one of our trials (geographic limitations alone would generally not be considered a barrier to participation in clinical trials). In such circumstances, subject to the criteria set forth below and country specific regulations, individual patients may be eligible for Early Access to an AstraZeneca IMPs.

Any use of an AstraZeneca IMP outside a clinical trial must be administered by a licensed and appropriately qualified physician, in accordance with local laws and regulations governing such programmes and AstraZeneca policies and procedures.

The Early Access programme does not apply to the use of a currently marketed medicinal product for an indication outside of the approved prescribing information. Access to marketed medicines outside of the approved indication is at the discretion of the competent healthcare provider and the patient and is neither facilitated nor endorsed by AstraZeneca.

Early Access programmes will terminate around the time of regulatory approval of the IMP.
Types of Access Programmes

AstraZeneca operates two distinct types of Early Access programmes: Named Patient Supply (NPS) and Multiple Patient Early Access Programmes (MPEAP). It is important to note that terminology used can vary from country to country and in some instances different countries use identical terminology to describe different approaches.

Named Patient Supply (NPS)

Named Patient Supply describes the process in which AstraZeneca makes an IMP available to a single patient in accordance with country-specific regulations. It includes treatment under an Investigational New Drug (IND) for individual patients in the US as defined by the US Food and Drug Administration (FDA). The treating physician contacts AstraZeneca for the IMP and is responsible for securing any required institutional and Health Authority authorisation, administering the treatment, coordinating the patient’s care and reporting any safety events. In some cases NPS may be managed by an external vendor appointed by AstraZeneca. The information provided here primarily describes NPS.

Multiple Patient Early Access Programmes (MPEAP)

Multiple Patient Early Access programmes (MPEAP) known as Expanded Access Programmes in the US or Compassionate Use in Europe, describes the process by which an IMP is made available to a cohort of patients under a specific treatment protocol. This is usually undertaken on AstraZeneca’s initiative and conducted following discussions with, and approval by, the relevant regulatory authorities. These programmes are always conducted within the anticipated product label and are only commenced after sufficient data are available to support regulatory submission and support Health Authority approval.


The procedures for conducting MPEAPs follow those for other AstraZeneca sponsored clinical studies and are separate from those further described in this document.

Eligibility Criteria

AstraZeneca evaluates the benefit-risk profile of its products throughout the lifecycle of clinical development. An Early Access programme for a specific product (via Named Patient Supply) may be opened if AstraZeneca determines that all the following criteria are met:

**Relevant to the IMP:**

1. The IMP is in active clinical development
2. There exists an adequate supply of the IMP to perform necessary clinical studies as well as to provide Early Access to patients who do not have alternative treatment options
3. Early Access does not impede or compromise the clinical development or regulatory approval of the medicine under investigation
4. There are sufficient clinical data available with respect to both the IMP and the disease condition for which the application is being sought to anticipate that any potential benefits from treatment are likely to outweigh any associated risks to the patient

Once an IMP is open for Early Access, individual NPS requests will be considered if:

**Relevant to the Patients:**

5. The patient is suffering from a serious or life threatening disease and has exhausted all available therapeutic options
6. Regulatory approval is planned to be sought in the country where the patient resides.
7. The patient’s medical status is deemed appropriate to receive the IMP.
8. The patient must be able to routinely travel to the clinical site for monitoring and follow up as required.

Relevant to the Treating Physician:
9. The treating physician(s) is appropriately qualified to administer the IMP and follow all relevant safety requirements and procedures.

To ensure a fair review of Early Access requests, only complete requests will be considered and decisions will be based on the above criteria. Requests will be considered on a first come first served basis for all patients dependent on drug availability.

Request Process
Requests for Early Access to an AstraZeneca IMP outside of a clinical study must be made by a patient’s treating physician.

Requests for and information about how to apply for Early Access can continue to be made through local country offices or:
- EarlyAccess@AstraZeneca.com.
- US Medical Information Call Center: 1800-236-9933 or local AstraZeneca country hotlines.

Treating Physician Criteria and Responsibilities
The physician(s) attending to the patient receiving an IMP through Early Access must be properly licensed and fully qualified to administer the product. In certain circumstances this may include relevant experience administering similar classes of medicines in highly controlled circumstances.

The physician will be responsible for collecting data throughout treatment and submitting it to AstraZeneca. In addition, the physician will be responsible for ensuring all local legal, regulatory and Health Authority requirements are met, including Investigational Review Board or Ethics Committee approval and reporting of Adverse Events.

The physician must agree in writing to comply with the following terms:

1. Any applicable country-specific legal and regulatory requirements related to providing an IMP under Early Access;
2. Any AstraZeneca requirements applicable to patient confidentiality and data privacy, medical criteria, safety reporting, drug supply handling and use, and protection of intellectual property; and
3. Obtaining informed consent from the patient approved by an Institutional Review Board. This must include a statement that the IMP will be provided free of charge by AstraZeneca until regulatory approval has been secured. However, any associated costs of treatment, including but not limited to drug administration costs, costs associated with laboratory or radiological monitoring, travel, physician and hospital fees will be the responsibility of the insurer, health care system, and/or patient.
AstraZeneca will send to the treating physician:

a. Letter of Acceptance (including a request for confirmation of the patient’s informed consent)
b. Drug Accountability/Investigator Brochure
c. Serious Adverse Event Report Form.

By signing a Letter of Acceptance the treating physician agrees to fulfill all the responsibilities outlined in the letter.

**Early Access Programme Closure**

Early Access may be discontinued at the discretion of the treating physician, the patient, or AstraZeneca when:

- The patient is no longer receiving any clinical benefit, typically documented by progression or deterioration of the underlying disease or adverse events that are deemed by the treating physician or patient to outweigh the potential benefit of the IMP
- An alternative effective medicine is available
- The patient becomes eligible to enroll in a clinical trial for the IMP
- The product receives regulatory approval
- The benefit/risk profile of the compound has been determined by AstraZeneca to no longer support further use of the compound.