

Early Access

Despite increasing medical innovation, there are still situations where patients with severe or life-threatening diseases do not have sufficient treatment options available to them. Early Access Programs are programs which can provide a legitimate path for patients to access treatments before they have been authorized to be sold, which may be able to alleviate extreme suffering or save lives of patients with severe diseases. As finding suitable treatments can be particularly challenging for patients with rare diseases and specialty conditions, at UCB, we assess each request for entry into an Early Access Program on an individual basis, to find solutions for patients who have few other treatment options.

As a science led, patient-focused company, we strive to secure approval of our products as swiftly as possible to ensure access to our medicines for those patients that need them. Before we reach this stage, UCB's Early Access Programs allow access to medicines for patients in need, under strictly controlled circumstances prior to local regulatory approval and reimbursement.

UCB's Values

Our ambition is that by 2030, all patients who need our medicines, in countries where we operate, will have access to them, in a way which is viable and sustainable for patients, society, and UCB. We think that swift and safe approval of treatments is ultimately the best solution. We also think that patients who have no alternative treatment options should be able to access our solutions (outside of clinical trial or commercial access settings), if deemed appropriate and beneficial by their health-care provider, and in accordance with UCB's assessment of the benefit-risk for the treatment. We believe in doing the right thing for the patient, which means working in a timely manner to find sustainable solutions where we can.

UCB's Approach

UCB participates in national Early Access Programs in collaboration with governments where appropriate, which are tailored to specific circumstances and health systems. We also have several Early Access Programs, which can allow patients to access our investigational medicines when requested by their health-care provider. For example, when a patient shows a need to gain early access to a new medicine that is not yet commercially available in their country, and the patient is not eligible for a clinical trial, we will consider providing treatment through an Early Access Program. When we receive a request for early access, we consider factors such as whether a patient's doctor believes the potential benefits outweigh the risk, if there is an acceptable level of evidence that the medicine will work for that patient, whether supply for the medicine will be stable enough to provide ongoing treatment, and what the regulatory framework permits.

National Early Access Programs

UCB is committed to working in partnership with governments to provide access to our medicines via National Access Programs where it could be beneficial for patients. National Early Access Programs, available in some countries, are programs that have been developed by governments (in collaboration with the industry) to enable early access to specified treatments available under certain conditions. Under these national programs, such as the Early Access to Medicines Scheme (EAMS) in the UK or the L'Autorisation d'Accès Précoce (AAP) in France, UCB treatments can be made available for patients who meet the conditions. We work within these frameworks where they are available and appropriate, so that patients can benefit from access to innovative treatments via these official routes made available by their governments. In situations where programs are not available, UCB will work on a case-by-case basis to assess whether early access is a possibility to support patients with unmet need.

Putting Patients First: Access to UCB's Investigational Treatments

UCB is always working towards the development of long-term, sustainable solutions and widespread access to our treatments. In situations where this is not yet possible, we may consider entry into one of our Early Access Programs, when requested by a health-care professional(s) on behalf of their patients that qualify. These programs can provide a solution for patients who have no alternative treatment options. They are intended to support and not circumvent nor replace our primary goal of establishing broad access to our medicines.

In addition, UCB provides post-trial access, to ensure a patient's treatment does not stop following their involvement in a clinical trial if their physician believes the patient is deriving a continued benefit and that the patient would be negatively impacted by stopping the clinical trial treatment.

Our Commitments

1. **We will continue treatment for patients participating in our trials where possible and in the patient's interest** – When patients participate in one of our clinical studies, UCB will endeavor to provide continued treatment for those who respond after the end of the study. Which program a patient may qualify for will depend on their location and the stage of the study.
2. **We are dedicated to finding solutions for patients with unmet needs** – At UCB we are dedicated to continuing to innovate to find solutions for these patients. We work with governments and health-care systems to get our innovative treatments to the patients that need them as fast and as safely possible.
3. **Our goal is that by 2030, all patients who need our medicines in countries where we operate have access to them** – This includes improving access pathways for



Inspired by **patients.**
Driven by **science.**

patients who need our treatments quickly. We are dedicated to doing the right thing for the patient, guiding them to National Access Programs where appropriate or to UCB's Early Access Programs when it is the most suitable option.

