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

Early Access

Despite increasing medical innovation, there are still situations where patients with severe, life-threatening, or life-altering diseases do not have sufficient treatment options available to them. Early Access Programs can provide a legitimate path for these patients to access treatments before they are widely available, when a patient's physician deems it appropriate. Accessing such treatments early may alleviate extreme suffering or potentially save lives of patients with severe diseases. Other terms commonly used to describe these programs are: Expanded Access Programs, Compassionate Use Programs, or Managed Access Programs. National health authorities around the world generally support Early Access if and when the potential benefits to patients outweigh the potential risks.

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 approach to Early Access allows access to medicines for patients in need, under strictly controlled circumstances prior to local regulatory approval and reimbursement.

UCB's Values

For patients who need our medicines, we aim to make them accessible 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

At UCB, we assess each request for Early Access on an individual basis, to find solutions for patients who have few other options. When a patient's physician assesses that a patient needs 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 a Managed Access Program. When we receive a request for early access, we consider factors such as whether a patient's physician believes the potential benefits outweigh the risk, if there is an acceptable level of evidence that the medicine will work for that patient, that the patient is not able to join a clinical trial, whether supply of the medicine will be stable enough to provide ongoing treatment, as well as what the regulatory framework in their country permits.

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.

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 Managed Access Programs.

Managed Access Programs provide access to patients outside of a clinical trial when requested by a physician on behalf of the patients that qualify. Through these programs, we aim to meet the needs of patients who do not have adequate alternative treatment options, when it is beneficial for the patient. While the primary purpose is to provide options to patients in need, these programs may also generate additional clinical knowledge on the use of our medicines or safety data to allow us to better understand the disease and treatment. At UCB, this happens most often for rare or ultra-rare diseases, where this important information is harder to gather.

Managed Access Programs are intended to support and not circumvent nor replace our primary goal of establishing broad access to our medicines. When deciding how and when to implement Early Access at UCB, we are guided by how to secure long-term access for patients after the program, how we can work with existing healthcare systems, and how we can continue to provide access to all patients that need our treatments.

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. We call these programs Post Trial Access.
2. **We are dedicated to finding solutions for patients with unmet medical 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. **We strive to provide access to innovative medicines to patients** irrespective of their location whenever practicable.