

Compassionate Use Request

In the USA, this type of compassionate use program is also known as an Expanded Access Program (EAP) and is intended for patients with serious or life-threatening conditions who do not have any viable or available treatment options, and are unable to participate in ongoing clinical trials. To view a list of Regeneron's open clinical trials, visit clinicaltrials.gov.

To ensure the safety of patients, we have developed certain criteria to evaluate Compassionate Use requests. All such requests are required to be in accordance with local laws and regulations, as well as with Regeneron Policies. While Regeneron is committed to reviewing each request carefully, fairly and on a case-by-case basis, we cannot guarantee access to any specific investigational medical product by any individual patient.

Requests for compassionate use must be initiated by a treating physician, so if you are a patient or caregiver, please ask your doctor for support in this process. Physicians should send compassionate use requests to CompassionateUse_Requests@regeneron.com. Regeneron will acknowledge receipt of a physician's request within five business days.

The following criteria must be met for consideration of Compassionate Use request:

1. There is sufficient data to expect that the investigational medical product will have a favorable benefit-risk profile.
2. The regulatory agency in the country where the patient resides must also approve the proposed use of the investigational drug, when required.
3. Providing the investigational medical product will not interfere with or compromise its clinical development. This means that adequate supply of the investigational medical product must be available to perform necessary clinical studies before access is provided through the Compassionate Use program.
4. There is a legitimate medical need documented and submitted by the treating physician.
5. The physician initiating the Compassionate Use request and providing treatment must be qualified in terms of background, education, and experience to carry out the proposed protocol.
6. The initiating physician agrees to assume all responsibilities and obligations to comply with the relevant regulatory requirements.