REGENERON
SCIENCE TO MEDICINE®

Compassionate Use Policy

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 compassionateuserequests@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.

Special Information regarding COVID-19:

In November 2020, the antibody cocktail of casirivimab and imdevimab was granted Emergency Use Authorization (EUA) for the treatment of mild-to-moderate COVID-19 in adult and pediatric (at least 12 years of age and weighing at least 40 kg) patients who are at high risk for progressing to severe COVID19 and/or hospitalization. The EUA and ongoing Phase 2/3 clinical trial are intended to be the main mechanisms of access for these patient populations in the United States.

Compassionate Use requests will be considered for the following individuals who test positive for SARS-CoV-2:

- Patient-facing healthcare workers, including individuals who may not be at high risk for poor outcomes or otherwise do not meet the current EUA criteria
- Individuals at high risk for poor outcomes who do not meet the conditions for treatment under the EUA

The process and evaluation criteria on Page 1 apply to all other patient populations.

As a result of Regeneron's collaboration with Roche, ex-US development and distribution of casirivimab and imdevimab will be handled by Roche. Currently, Roche is not offering a compassionate use program for casirivimab and imdevimab. Regeneron and Roche are working to achieve regulatory approvals broadly outside of the US as soon as possible. If you have additional questions about ex-US product availability, please contact your Roche country affiliate at https://medinfo.roche.com.