REGENERON®

Managed Access Program Policy

Managed Access Programs (MAPs) are 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. MAP is a broad term that encompasses multiple types of access programs, including but not limited to "Named Patient", "Expanded Access", "Compassionate Use", and "Early Access."

To view a list of Regeneron's open clinical trials, visit www.clinicaltrials.gov.

To ensure the safety of patients, Regeneron has developed criteria to evaluate a physician's request on an individual patient basis. All such requests are required to be in accordance with local laws and regulations, as well as with Regeneron's 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 product by any individual patient.

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

When reviewing an individual patient MAP request, Regeneron considers key criteria, including but not limited to the following factors:

1. There are sufficient data to expect that the investigational 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 product, when required.
3. Providing the investigational product will not interfere with or compromise its clinical development. This means that adequate supply of the investigational product must be available to perform necessary clinical studies before access is provided through the MAP and that the patient is ineligible to participate in a study in the development program.
4. There is a legitimate medical need documented and submitted by the treating physician.
5. The physician initiating the individual patient MAP request and providing treatment must be qualified in terms of background, education, and experience to carry out the proposed treatment.
6. The initiating physician agrees to assume all responsibilities and obligations to comply with the relevant regulatory requirement