Managed Access at Gilead

Gilead's vision is to create a healthier world for all people by achieving its mission of discovering, developing, and delivering innovative therapeutics for people with life-threatening diseases. To this end, Gilead is committed to providing Managed Access to Medicines for eligible patients with serious unmet medical needs.

This Statement outlines Gilead's position on providing managed access to medicines manufactured or owned by Gilead or its affiliates or subsidiaries ("Medicines").

Managed Access is a term used to describe various access pathways that are initiated by a health care provider (HCP) for a patient with a serious or immediately life-threatening disease or condition to access a Medicine for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Managed Access at Gilead is a term used to encompass compassionate use, expanded access, early access, named patient access and individual patient use. Gilead refers to these programs collectively as "Managed Access Programs" (MAP), which can include individual requests for access to a Medicine as well as cohorts or groups with defined eligibility criteria.

Managed Access Criteria

Wherever possible, use of a Medicine by a patient as part of a clinical trial is preferable to Managed Access because clinical trials generate data regarding efficacy and safety. Additionally, various regulatory pathways exist in different countries to provide Managed Access to Medicines, and as a result, local variations in Managed Access will occur. However, when requested, Gilead will consider providing Managed Access under the following circumstances:

- The patient:
    - Has a serious or life-threatening disease or condition.
    - Is not eligible or able to participate in a clinical trial.
    - Has no comparable or satisfactory alternative treatment options currently available.
    - In special circumstances, patients at risk for life-threatening diseases may be considered if there are no alternative prevention options currently available.
- Gilead considers whether there is sufficient scientific evidence or clinical efficacy data available, whether the potential benefits of Managed Access to the Medicine outweigh known or potential risks and whether there is adequate supply of the Medicine.
- The Medicine will be administered in accordance with applicable laws and regulatory requirements of the country where the patient is treated, including importation requirements.

Additional Managed Access Considerations

To participate in a MAP, a patient must be under the care of an HCP who can evaluate the benefits and risks of participating in a MAP and who can directly request Managed Access from Gilead. Gilead will not provide Medicine when the development of the Medicine has been discontinued for safety reasons.

Gilead may close a MAP in one or more countries because of, but not limited to, any of the following reasons:

- The Medicine has received regulatory authorization and patients may transition to commercially available Medicine in that country.
- There is not adequate supply of the Medicine.
- The Medicine is no longer under development by Gilead through clinical research programs or Gilead is no longer pursuing marketing authorization and/or commercialization efforts.
- Clinical data suggest that the potential benefits of the Medicine do not outweigh any known or potential risks, or the Medicine is discontinued for safety reasons or marketing authorization of the Medicine is withdrawn.
- The Medicine does not receive marketing authorization or reimbursement approval in a given country or region.
- There are alternative treatments available that can meet the needs of patients.
- By request of a health authority or for any other lawful, ethical or compliance reason.

Post Trial Access via Managed Access

Gilead seeks to conduct its clinical trials ethically and endeavors to maintain access to medicines without interruption, where feasible and appropriate. Determination of post-trial access provision and mechanisms for post-trial access are dependent on factors determined during the Medicine's development lifecycle including study design as well as local laws and regulations. To receive access to Medicine post-trial, patients must, in the investigator's judgement, be deriving clinical benefit from treatment. Gilead will not provide continued access to its Medicines through a MAP for a clinical trial that has terminated for safety concerns.

Transparency

Gilead aims to be transparent in external communication of its Managed Access Position. In conjunction with the 21st Century Cures Act, Gilead supports ethical and industry standards around transparency related to managed access. This Statement is subject to revision based on changes in laws, regulations, and guidance governing managed access to Medicines.

Contact

For questions on this Statement, or to discuss possible exceptions, please contact the Managed Access Program Team at ManagedAccessProgram@gilead.com or KiteCompassionateAccess@gilead.com.

The posting of this Statement does not serve as a guarantee of access to any Medicine by any HCP or patient.