



XCURES POLICY FOR MANAGED ACCESS

The purpose of this Managed Access Policy is to describe the principles, criteria, and procedures that xCures will follow when considering a request for Managed Access. xCures' "Managed Access" terminology covers all locally defined pre-approval access mechanisms and programs such as "Compassionate Use", "Expanded Access", "Named Patient Supply", "Special Access Schemes/Programs", and others.

BACKGROUND

Managed Access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Investigational drugs have not yet been approved or cleared by FDA and FDA has not found these products to be safe and effective for their specific use.

POLICY FOR MANAGED ACCESS TO AN INVESTIGATIONAL PRODUCT

xCures is committed to helping patients who have no available therapeutic options and may benefit from access to the investigational drug that the company is developing. Access via xCures to investigational product may be appropriate when all of the following apply:

- The patient has a serious disease or condition, or their life is immediately threatened by their disease or condition, and no comparable or satisfactory alternative therapy is available to monitor, or treat the disease or condition.
- The requested investigational product is under active clinical development and there is sufficient data available to identify an appropriate dose and formulation for the investigational drug therapy.
- Patient enrollment in a clinical trial with the requested investigational product is not possible.
- Providing the investigational product will not interfere with ongoing clinical trial(s) or with the overall development program.
- Sufficient data exists to believe the potential benefit of treatment outweighs the potential risk in the context of the disease or condition to be treated.
- Such access provision is allowed as per local laws and regulations.



REQUESTING ACCESS TO AN INVESTIGATIONAL PRODUCT

To seek access to an investigational product via Managed Access, the following steps must be followed:

- Treating physicians interested in treating a patient with an investigational product must submit a written request to managedaccess@xcures.com.
- Making a request to xCures does not guarantee access to an investigational drug, and the company might ask the treating physician to evaluate the patient for ongoing clinical trials with the investigational drug.
- The time to ultimately decide to grant or deny the request will depend on the completeness of the initial request and the ability of the treating physician to provide additional information as requested.
- After review, the treating physician will be informed of the decision and will be provided with materials and instructions to move forward.

MANAGED ACCESS POLICY PRINCIPLES

xCures is committed to a fair and impartial evaluation of each request. Each request will be acknowledged and reviewed carefully and fairly by the appropriate medical experts with every effort made to provide a response promptly once we have all the necessary information. Our team conducts that evaluation based on the scientific and clinical evidence available at the time of the request. At this time, the Managed Access is only available for patients who are being treated in the United States.