



Expanded Access Policy Updated July 18, 2022

Insmmed is dedicated to improving the lives of patients battling serious and rare diseases. These patients sometimes need medical products that are still being investigated and not approved for the treatment of a condition or have been approved but may not be commercially available in their country. Insmmed's Expanded Access Programs ("EAPs") can help to address these needs by making certain investigational medical products (e.g., drug or medical device) or unapproved products (unlicensed medicines) available to eligible patients, in accordance with applicable local laws. Programs to access that may be available include: compassionate use program, named patient program, early access, special access, managed access, temporary authorization for use, pre-approval access.

To be considered for EAP,

- The patient must have a serious or life-threatening condition for which there are no alternative available treatments for the condition, or all available treatments have been tried or are contraindicated.
- The requesting physician is qualified and experienced and agrees to comply with local laws and regulations.
- The patient does not meet criteria for a clinical trial or is unable to participate.
- The requesting physician and Insmmed Medical team agree the potential benefit outweighs the potential risk to the patient.
- Fulfillment of the request for the investigational product will not interfere with completion of the ongoing registrational clinical trials and/or the overall development program.
- Medical criteria specific to the disease defined by the Insmmed Medical team must be met.
- Country laws and regulations permit patient use of the investigational or unapproved product.

Upon receipt of all necessary information, all requests for Expanded Access are reviewed and evaluated promptly by Insmmed. Insmmed is committed to a fair and impartial evaluation of each request for access to investigational or unapproved products. All decisions are based on evaluation of the criteria listed above.

To submit a request for Expanded Access, physicians should email compassionateuse@insmed.com.

Receipt of a request will be acknowledged within 5 business days.