Johnson & Johnson Innovative Medicine's approach to pre-approval access

At Johnson & Johnson (J&J) Innovative Medicine, our <u>Credo</u> guides our decision-making. We are driven to find solutions to some of the most complex medical challenges. The following highlights our approach to evaluating requests for medicines not yet approved by health authorities.



What

is pre-approval



Whv

does J&J Innovative Medicine Support PAA?



Pre-approval access (PAA), also known as expanded access or compassionate use, is a way for eligible patients to access investigational medicines that have not yet been approved by health authorities.



J&J Innovative Medicine provides pathways for patients with serious health conditions to gain access to investigational treatments, advancing patient care and public health, which is our first priority.



Who

is eligible for PAA?



will a decision about a PAA request from J&J Innovative Medicine be available?

Patients may be eligible for PAA if they:

Have a serious or life-threatening disease or condition Are **not eligible** for a clinical trial

Have an unmet need or alternative therapies are not available

We commit to providing a decision as quickly as possible, ideally, within 5 to 10 business days of receiving all required medical information.





does a physician submit a PAA request to J&J Innovative Medicine?



can additional information on PAA be found?

In the US: 1-800-JANSSEN OR

janssenmedinfo@ its.jnj.com



Outside the US:

http://www.janssen.com/contact-us



http://www.janssen.com/compassionate-use-pre-approval-access