

JANSSEN'S APPROACH TO PRE-APPROVAL ACCESS

At the Janssen Pharmaceutical Companies of Johnson & Johnson, our **Credo** guides our decision-making. We are driven to find solutions to some of the most complex medical challenges. The following highlights Janssen's approach to evaluating requests for medicines not yet approved by health authorities.



WHAT IS PRE-APPROVAL ACCESS?



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.



WHY DOES JANSSEN SUPPORT PAA?



Janssen 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?

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



WHEN WILL A DECISION ABOUT A PAA REQUEST FROM JANSSEN BE AVAILABLE?

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



HOW DOES A PHYSICIAN SUBMIT A PAA REQUEST TO JANSSEN?

In the US:

1-800-JANSSEN

OR

janssenmedinfo@its.jnj.com



Outside the US:

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



WHERE CAN ADDITIONAL INFORMATION ON PAA BE FOUND?



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