

Novartis Update for Patients on Supply of Pluvicto™

Following recent delivery challenges for Pluvicto™, we understand you and your loved ones may have questions about the supply situation and the impact it may have on the treatment plans you made with your health care team. We recognize rescheduling doses may cause difficulties and uncertainties for you, and we are taking steps to enhance our supply reliability. While some of our efforts will make a difference over time, in the short term we are also taking key actions to address potential rescheduling of doses.

Background on Supply Challenges:

- Pluvicto is currently made in our manufacturing facility in Italy in small batches, with only a five-day window for each dose to reach its intended patient. Any interruption in the process – either caused by unplanned manufacturing events, weather-related shipping delays or the challenges associated with importing a nuclear medicine into the U.S. – can result in doses not arriving in time. When that happens, impacted doses must be rescheduled and remade, causing the need to also reschedule other patient doses behind them.
- We are operating our production site at full capacity to treat as many patients as possible, as quickly as possible. However, with a nuclear medicine like Pluvicto, there is no back-up supply that we can draw from when we experience a delay.
- We are working to increase production capacity and supply of Pluvicto over the next 12 months with two new manufacturing sites in the U.S. While this will make a difference over time, we will be adjusting our approach to supply in the short term.

Our Near-Term Approach to Supply:

- Our priority is to supply those patients who have received their first doses and are currently in the treatment process. This is important to allow patients who have already begun the treatment cycle to appropriately complete their course of therapy.
- As we endeavor to provide patients who have received one or more doses with their full treatment course, patients who are currently in our scheduling system and awaiting their first doses will need to be rescheduled. We will be reaching out to your health care provider with options for rescheduling. We are striving to serve as many patients as possible as quickly as possible as we work through the current situation.
- In the same spirit, we will not be able to take any new orders until we have clarity on the FDA's approval of one of our new sites (expected within the next four to six months).

We are working quickly to address these challenges as soon as possible. In the meantime, we are committed to continuing these updates as we work to meet the high demand for this medicine, so you and your health care providers can make the best treatment decision.

FAQS

How long do you anticipate these supply challenges will last?

We are making investments to increase our production capacity, and we aim to significantly increase Pluvicto supply over the next 12 months with two new manufacturing sites in the U.S.

I haven't received a first dose yet, when will I be able to start my treatment?

Patients who are currently in our scheduling system and awaiting their first doses will need to be rescheduled. We will be reaching out to your health care provider with options for rescheduling.

Why hasn't Novartis produced a mass amount of Pluvicto to store for situations like these?

As a nuclear medicine, Pluvicto is made in small batches with only a five-day window for each dose to reach its intended patient. Therefore, there is no back-up supply that we can draw from when we experience a delay.

Will Novartis cover travel expenses for rescheduled doses?

Please call 1-844-638-7222 with any questions related to travel impact due to dose rescheduling.

Who can I talk to at Novartis for more information?

Please call 1-888-NOW-NOVA (1-888-669-6682) to speak with a Novartis representative.