



Q&A: Answering your questions about PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) supply

We know that the current PLUVICTO shortage is difficult for patients, families, health care providers, and treatment sites. Our goal in this Q&A is to let you know what is happening and what we are doing to address these issues.

- ↓ **Why are patients' PLUVICTO appointments being rescheduled or canceled?**
- ↓ **What is causing the PLUVICTO supply shortage?**
- ↓ **When will patients who have started PLUVICTO treatment get their next doses?**
- ↓ **What about patients who are eligible for PLUVICTO but have not started treatment?**
- ↓ **What is Novartis doing to make more PLUVICTO?**
- ↓ **Now that the Millburn facility has been FDA approved, can we expect the PLUVICTO supply challenges to end? When will you start scheduling new patients?**
- ↓ **Now that there is more supply from the Millburn facility, will PLUVICTO doses still need to be rescheduled? When will PLUVICTO supply challenges end?**
- ↓ **What if I have had to incur nonrefundable travel expenses due to my PLUVICTO doses being canceled or rescheduled?**
- ↓ **Where can I learn more?**

Q&A: Answering your questions about PLUVICTO[®] (lutetium Lu 177 vipivotide tetraxetan) supply (continued)

Why are patients' PLUVICTO appointments being rescheduled or canceled?

We have faced challenges with making enough PLUVICTO. We know patients, families, and health care providers are waiting for this treatment, and that rescheduled or canceled appointments are extremely distressing. Getting this treatment to the patients who need it is very important to us. We are working night and day to address this and increase our capacity.

What is causing the PLUVICTO supply shortage?

Until the recent FDA approval of our manufacturing facility in Millburn, New Jersey, Novartis was manufacturing PLUVICTO for commercial use in the United States only at its facility in Ivrea, Italy. Making and shipping PLUVICTO has its own unique challenges:

1. A patient in the United States needs to get PLUVICTO within 5 days after it is made.
2. When problems in manufacturing, weather, or transportation happen, they affect the supply chain, causing delays in getting PLUVICTO to patients.
3. As a result, planned patient doses must be rescheduled.

When will patients who have started PLUVICTO treatment get their next doses?

Our priority is to make sure that patients who have started treatment can complete their full course. We are working with each treatment site to help schedule treatments as quickly as possible. If you or a loved one needs to schedule subsequent doses, contact your health care provider.

What about patients who are eligible for PLUVICTO but have not started treatment?

Patients who are already in our scheduling system and waiting for their first dose may need to be rescheduled. Unfortunately, patients who are not yet in our scheduling system cannot start this treatment until we are able to make more PLUVICTO.

We understand the urgent needs of patients with advanced disease and are in frequent contact with health care providers and treatment sites about product supply and scheduling. We hope to have greater supply available as we expand our manufacturing capacity in the coming months.



Q&A: Answering your questions about PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) supply (continued)

What is Novartis doing to make more PLUVICTO?

The recent FDA approval of our manufacturing facility in Millburn, New Jersey, will allow us to gradually increase supply. Additionally, we are seeking FDA approval for a new manufacturing facility in Indianapolis, Indiana, which could be ready by the end of this year (2023). This would further expand our supply and allow us to get PLUVICTO to more patients faster.

We recognize the worry and frustration that patients, families, and health care providers are having during this shortage. Our entire organization is committed to addressing the supply issues and getting this treatment to every patient who needs it.

Now that the Millburn facility has been FDA approved, can we expect the PLUVICTO supply challenges to end? When will you start scheduling new patients?

We continue to expand our capacity to deliver more PLUVICTO to patients faster and provide stable, reliable PLUVICTO supply in the long term. FDA approval of the Millburn facility is a first step in that direction. With this approval, our priority is still to make sure that patients who have started treatment can complete their full course. In the coming months, we expect to be able to schedule new patients for PLUVICTO treatment as supply increases gradually.

We are working with each site to help schedule treatments as quickly as possible. If you or a loved one needs to schedule PLUVICTO doses, contact your health care provider.

Now that there is more supply from the Millburn facility, will PLUVICTO doses still need to be rescheduled? When will PLUVICTO supply challenges end?

There may be a need to reschedule some doses at times, as manufacturing and delivery of PLUVICTO remains complex. However, as we expand our capacity, we expect PLUVICTO supply to become more stable and reliable.



Q&A: Answering your questions about PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) supply (continued)

What if I have had to incur nonrefundable travel expenses due to my PLUVICTO doses being canceled or rescheduled?

If you or a loved one had to cancel travel reservations due to rescheduled or canceled PLUVICTO treatments, Novartis may be able to reimburse you for certain out-of-pocket costs on a case-by-case basis. To learn more, please call 1-844-638-7222.

Where can I learn more?

Patients or care partners

Patients or care partners should reach out to their health care providers for details or may call Novartis at 1-888-NOW-NOVA (1-888-669-6682).

US health care professionals

Medical information

☎ 1-844-662-4636

✉ mic.inquiry@novartis.com

Access and reimbursement support

☎ 1-844-638-7222

Product ordering support

☎ 1-844-367-3222

✉ customerserv-us.aaa@novartis.com

Visit the PLUVICTO Website
(For US Health Care Professionals)

Visit the PLUVICTO Consumer Website
(For US Residents)

