



This update was published on [www.baxter.com](http://www.baxter.com) on 2024-11-21 For more up-to-date information, please go to [Hurricane Helene Updates | Baxter](#).

Beginning the week of Nov. 4, Baxter will provide weekly updates regarding its progress to restore operations at its North Cove, N.C., site following Hurricane Helene.

Baxter's North Cove manufacturing site was significantly impacted by the rain and storm surge from Hurricane Helene, which was unprecedented in Western North Carolina and resulted in water flooding the facility.

**Supporting our employees in the impacted communities, bringing the North Cove facility back online and helping to ensure ongoing supply to patients are our top priorities.**

We are appreciative of the ongoing support and patience of our customers and partners as we continue to work diligently and with urgency to fulfill our Mission to Save and Sustain Lives for our employees, patients and communities.

Below are the latest updates in each area:

**Employees and Community:** We salute our North Cove team, who are fueling our ongoing recovery while continuing to navigate the storm's personal toll.

- All 2,500+ North Cove employees have been accounted for following Hurricane Helene. Employees have returned to work across the facility. Remediation contractors also remain engaged on a temporary basis to support site recovery.
- Our local colleagues are simultaneously continuing to navigate the storm's devastating personal and community impact. Baxter has responded by offering critical employee assistance through a range of initiatives:
  - The Baxter International Foundation has donated more than \$4 million to support employees and communities impacted by Hurricane Helene, including \$1.5 million in grants to three humanitarian partners and more than \$2.5 million in funding to employees through Baxter's Employee Disaster Relief Fund.
  - An employee support center has been established on a temporary basis to help provide for immediate needs in the wake of the storm, including basic supplies, such as food, water, and toiletries, as well as access to portable generators, showers, laundry machines, credit union services, and laptop workstations with internet access.
  - Colleagues at multiple Baxter sites across the U.S. initiated clothing drives to collect cold weather gear and other items for delivery to the North Cove team.

**Facilities and Infrastructure:** Led by Baxter's commitment to product quality and patient safety, equipment repair and phased testing continues to progress across all production lines, which will, in coordination with FDA, support resumption of operations in phases.

- **NEW: This week, Baxter released the first product – 1-liter IV solutions – that was manufactured post-hurricane.** This is ahead of our original expectations and made possible by the dedication and resilience of the North Cove and broader Baxter teams, working in coordination with FDA.
- We are making continued strong progress at our North Cove site, including the recent resumption of two manufacturing lines that represent ~50% of the site's total pre-hurricane production and ~85% of the site's production of 1-liter IV solutions, the most commonly used size by hospitals and clinics.
  - Initial batches were manufactured concurrently with ongoing quality activities and are only being released in accordance with applicable regulatory requirements to ensure the quality and safety of the products.
- Barring any unanticipated developments, we currently expect that **peritoneal dialysis (PD) solutions and irrigation** will be the **next two manufacturing lines to restart in early December**.
- While we currently expect that all lines will be restarted by the end of the year, we do not yet have a timeline for when we expect North Cove production to be fully restored to pre-hurricane levels.
- Thanks to the support of ASPR, North Carolina Department of Transportation and our local team, **the second temporary bridge has been installed at the site and is officially in operation as of the week of Nov. 4.** This bridge enables additional truck and equipment traffic to enter and leave the site. Our first



temporary bridge has already **transported more than 1,200 truckloads of finished product (manufactured pre-hurricane) off site and to customers.**

**Supply Continuity:** We are grateful for the ongoing partnership and efforts of our customers as we navigate this complex and challenging situation to prioritize patient care.

- **Global Manufacturing Network:** To date, we have activated nine plants across our global network to help increase available inventory, which is contemplated in current allocation levels.
- **U.S. Distribution for Products Authorized for Temporary Importation:** Baxter continues to carefully manage the availability of both previously finished and newly manufactured goods coming out of North Cove and the import of product to the U.S., providing specific resources and training to those customers receiving product imported to the U.S.
- **U.S. Expiry Extensions for IV and Irrigation Products:** Baxter has received FDA authorization to extend the use dates of 50+ IV and irrigation codes to provide up to an additional 12 months of expiry. Products now have a 24-month expiry period from the date of manufacture. This extension only applies to products manufactured prior to the end of September 2024. Details have been communicated directly to customers.
- **Conservation:** Conservation efforts for IV and PD solutions across the healthcare system remain essential to supplement allocation levels and help preserve supply, and we are grateful for our customers' efforts in this area. Our Medical Affairs team is offering support and resources for product management and conservation strategies. Visit our [clinical webpage](#) for more information.
- **U.S. IV Solutions Allocations:**
  - **NEW: Baxter expects to communicate details on the next planned allocation increases to U.S. customers on Nov. 25.** Until then, allocation levels for both direct customers and distributors remain as previously communicated by Baxter on Oct. 9.
  - On Nov. 11, Baxter communicated with customers that, barring any unanticipated developments, we expect to reach 100% allocation across several IV product categories by the end of the year with additional details on planned, phased increases in allocations in late November, mid-December and end of year. This update is to help support customers' ability to plan for patient care, and is based on 1) the current and projected status of our North Cove remediation efforts, 2) our expectations regarding our ability to reallocate capacity from other Baxter facilities, and 3) temporary importation on certain products.
  - To date, we have evaluated and approved hundreds of allocation exception requests to help support neonatal and pediatric patient needs.
- **U.S. PD Patient Starts:** We have begun to expand our support for new peritoneal dialysis (PD) patients on a limited basis, beyond the highly restricted medical exceptions to date, to help providers address urgent medical needs. The volume of new patients should continue to increase in the coming weeks, with the goal of returning to pre-Hurricane Helene levels for new patient starts by the end of the year.
- **PD Solutions Allocations and Ongoing Patient Support:**
  - We are closely partnering with the kidney community, including physicians, nurses and care teams, to enhance our support for patients. This includes working to improve the ordering and delivery process to help reduce wait times and increase the accuracy of our target delivery dates and times. We are grateful to have excellent provider partners, who have been agile and proactive in helping us meet patient needs while conserving supply. Because PD patients have individualized prescriptions, this has allowed for some additional flexibility in our ongoing ability to support them within the allocation protocols already put in place.
  - We have begun providing training and education materials so that patients and care teams can prepare to use imported PD solutions. All these PD solutions have been granted temporary import status by FDA to be used in the U.S. Our global footprint and quality standards have allowed us to rapidly respond and shift supply accordingly, to help address the needs of existing and new patients in the U.S. We are evaluating the effects on supply of ongoing conservation, the arrival of imported product, and the expected resumption of production in North Cove. With a better understanding of each of these factors, we now intend to provide an update in early December to the current PD solutions allocation quantities.



## Resources for Healthcare Professionals and Customers

- [Conservation and Medical Information Resources](#)
- Please reach out to your Baxter representative or distributor for questions regarding supply. For customers who need additional assistance beyond their existing communications channels with Baxter, please contact [HurricaneHeleneSupport@baxter.com](mailto:HurricaneHeleneSupport@baxter.com).