



This updated was published on [www.baxter.com](http://www.baxter.com) on 2024-10-28. For more up-to-date information, please go to [Hurricane Helene Updates | Baxter](#).

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.**

Below are the latest updates in each area:

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

- All 2,500+ North Cove employees have been accounted for following Hurricane Helene. Employees are returning to work at pre-hurricane staffing levels, working alongside remediation contractors that have been engaged on a temporary basis for site recovery.
- Our local colleagues are simultaneously continuing to navigate the storm's devastating personal and community impact. Baxter continues to offer critical employee assistance through a range of initiatives:
  - An employee support center provides 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. have initiated clothing drives to collect cold weather gear and other items for delivery to the North Cove team.
  - The Baxter International Foundation has donated nearly \$3.7 million to support employees and communities impacted by Hurricane Helene, including \$1.5 million in grants to three humanitarian partners and more than \$2 million in funding to employees through Baxter's Employee Disaster Relief Fund.

**Facilities and Infrastructure:** Our progress in restoring the physical facilities has exceeded our expectations in many respects, with meaningful advances in our recovery efforts.

- As previously shared, and in coordination with FDA, our goal remains to begin resuming North Cove production as soon as possible and in phases by the end of this year. **We are encouraged to report that, barring any unanticipated developments, Baxter anticipates restarting the highest-throughput IV solutions manufacturing line this week.** Initial batches will be manufactured concurrently with ongoing quality activities and would only be released in accordance with applicable regulatory requirements to ensure the quality and safety of the products. It is important to note that the earliest that new North Cove product could begin entering the distribution channel is mid- to late-November. This is, however, ahead of our original expectations and is a testament to the urgency, diligence and resiliency of the North Cove and broader Baxter teams as we've worked to accelerate recovery, with the support of FDA, ASPR and HHS.
- We do not yet have a timeline for when we expect North Cove production to be fully restored to pre-hurricane levels.
- **NEW:** Our first temporary bridge has already transported **more than 825 truckloads** of finished product off site and to customers.
  - We continue to make progress on the second temporary bridge being installed at the site, thanks to the support of ASPR, North Carolina Department of Transportation and our local



team. This bridge, currently estimated to be completed in early November, will enable additional truck and equipment traffic to enter and leave the site.

**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.
  - **NEW:** 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.
  - **NEW:** Baxter has communicated to customers its distribution plans for products authorized for temporary importation. We are carefully managing the availability of both previously finished 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.
  - **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.
- **IV Solutions Allocations:**
  - In the U.S., allocation levels for both direct customers and distributors remain as previously communicated by Baxter on Oct. 9th.
  - Based on 1) the current 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, our goal remains to return to 90% to 100% allocation of certain IV solution product codes for U.S. customers by the end of 2024.
- **PD Solutions Allocations and Patient Support:**
  - We are closely partnering with the kidney community, including physicians 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 peritoneal dialysis (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.
  - While the allocations for PD solutions in the U.S. currently remain as communicated with patients and clinicians, thanks to FDA's recent temporary importation authorizations, we are temporarily importing additional product into the U.S. to help support supply. We will work to ensure patients and care teams have the training materials and information they need to feel comfortable using these imported PD solutions. 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.
  - **Plan for New PD Patient Starts:** With the ongoing conservation efforts and regulatory authorization from FDA to temporarily import product from our global supply chain, our goal is to return to pre-Hurricane Helene levels for new patient starts by the end of the year. To date, we have been partnering with healthcare professionals to limit new PD patient starts in the U.S. to pediatric patients (those under 18 years old) and communicated that other medically necessary patient exceptions may be considered.



We expect to be in a position to accept new patients on a limited basis beginning in the next few weeks. We will be providing training and education materials in the first part of November so that providers can continue preparing new patients to start PD with the imported products. The volume of new patients should continue to increase as we move closer to the end of the year.

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.

#### **Resources for U.S. 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 Baxter communications channels, please contact [HurricaneHeleneSupport@baxter.com](mailto:HurricaneHeleneSupport@baxter.com).