



This updated was published on www.baxter.com on 2024-10-21. 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 is fueling our recovery while continuing to navigate the storm's personal toll.

- Baxter's more than 2,500 North Cove employees are returning to work at normal pre-hurricane staffing levels beginning this week. The team is working alongside more than 1,000 remediation contractors that have been engaged for site recovery.
- Our local colleagues are simultaneously continuing to navigate the storm's devastating personal impact, including significant property damage; injury and loss of life across the broader community; and disruption of essential services. The Baxter team mobilized immediately following the storm as we worked to ensure that all colleagues were safe and accounted for; and activated a range of initiatives to offer critical employee assistance.
 - An employee support center established near the North Cove site is providing 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.
 - **NEW:** 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 via the support center. These donations supplement other seasonal items supplied directly by Baxter.
 - **NEW:** 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 site cleanup and remediation.

- Utilities, including electric capability, water and wastewater treatment, have been fully restored. Boilers and backup systems are operational; IT infrastructure is also fully operational.
- Outside engineers confirmed that the site is structurally sound.
- **NEW:** Deep cleaning has been completed for production rooms within the facility. Assessment and repair of equipment with phased testing is progressing across all production lines, which will, in coordination with FDA, support resumption of operations in phases.
- **NEW:** Our first temporary bridge has already transported more than 600 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.
- **Our goal is to begin restarting North Cove production as soon as possible and in phases by the end of this year.** We do not yet have a timeline for when we expect production to be fully restored to pre-hurricane levels.

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.

- **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.
- **Global Manufacturing Network:** To date, we have activated seven plants across our global network to help increase available inventory, which is contemplated in current allocation levels.
 - Currently, FDA has authorized temporary importation for a variety of product codes from five Baxter manufacturing facilities in Canada, China (two sites), Ireland and the UK. Baxter sites in Mexico and Spain were previously FDA-approved. We continue to work closely with FDA to authorize temporary importation for additional Baxter manufacturing sites and products.
 - **NEW:** The first shipments of product authorized for temporary importation arrived in the U.S. over the weekend. There is a range of time over the coming weeks when providers may begin receiving this product. Additional details will be available to customers in the coming days and as appropriate.
 - We are also pursuing other avenues to support product availability, such as expiration date extension requests. We will provide updates as available.
- **IV Solutions Allocations:**
 - In the U.S., allocation levels for both direct customers and distributors remain as previously communicated by Baxter on Oct. 9th.
 - **NEW:** We recognize that not all customers are yet experiencing the increase in allocation. This may be due to a variety of factors, including the typical 1 to 2-week lag time for product to flow through the full distribution network. We are doing everything we can to help balance the network and get product out as quickly as possible.
 - **NEW:** To help maintain supply continuity for the most vulnerable patient populations, on Oct. 9th, Baxter increased IV allocations for standalone, designated U.S. children's hospitals to 100%. We've now implemented a process to evaluate requests for neonatal and pediatric needs for other Baxter customers. Please email our Hurricane Helene inbox with subject line "Pediatric Allocation Request" for more information.
 - Based on 1) the current status of our 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. Quality, safety and education are at the core of our plan to temporarily use these imported PD solutions. 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. We want to reiterate our thanks to providers for supporting these temporary measures and working so closely with us during this time.

- o **NEW: Plan for New PD Patient Starts:** 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. Thanks to the collective conservation efforts of our partners and providers, and the anticipated product authorized for temporary importation from sites around the world, we expect to be in a position to accept new patients on a limited basis beginning in the next few weeks. Our goal is to restore the number of new patient starts to pre-Hurricane Helene levels by the end of the year. Over the next couple of weeks, we plan to communicate with providers and patients to ensure they are well equipped to adapt and implement adjustments to their prescriptions for new patients as appropriate.

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](#)
- [October 1 Medical Information Letter for Home Dialysis Customers](#)
- [September 30 Medical Information Letter for Healthcare Facilities](#)
- 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.