



This updated was published on www.baxter.com on 2024-10-24. 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.

- **NEW:** Baxter is pleased to report that all 2,500+ North Cove employees have now been accounted for following Hurricane Helene. Employees are returning to work at pre-hurricane staffing levels beginning this week, 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. Immediately following the storm, the Baxter team 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.
 - 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. These donations supplement other seasonal items supplied directly by Baxter.
 - 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.

- 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.
- 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 720 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.
- **NEW:** 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 within the next 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.

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: NEW:** To date, we have activated **nine plants** across our global network to help increase available inventory, which is contemplated in current allocation levels.
 - **NEW: FDA has authorized temporary importation for a variety of product codes from two additional Baxter manufacturing facilities, in Thailand and Singapore.** This brings the total number of facilities authorized for temporary importation to seven – including Canada, China (two sites), Ireland and the UK. Baxter sites in Mexico and Spain were previously FDA-approved and shipments from these sites began the week of Oct. 7th.
 - **NEW:** Additional shipments of product authorized for temporary importation arrived in the U.S. this week. **There is a range of time when providers may begin receiving this product.** Baxter will communicate distribution plans for this product with customers including direct communication to support any associated set-up and training needs.
 - **NEW:** Baxter is carefully managing the availability of both previously finished goods coming out of North Cove and the import of product to the U.S. Our goal is to distribute available product in the most equitable, efficient and responsible way possible – with an emphasis on reducing administrative burden for our customers.
 - We also continue to pursue 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.
 - 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.



- o 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. We want to reiterate our thanks to providers for supporting these temporary measures and working so closely with us during this time. 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.
- o **NEW: 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](#)
- [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.