



This update was published on www.baxter.com on 2024-10-31. 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.

"Recovery progress at our North Cove site continues to be very encouraging. In a matter of weeks, our team has advanced from the depths of Hurricane Helene's impact to restarting our highest-throughput manufacturing line. This is a pivotal milestone, but more hard work remains as we work to return the plant to full production. I want to recognize the dedication of our North Cove team as well as the countless Baxter employees globally who have committed themselves to helping contribute to supply continuity amid this unprecedented challenge. I also offer Baxter's gratitude for the steadfast support of ASPR, FDA, the State of North Carolina and HHS. And we are deeply appreciative of our customers' patience and partnership as progress continues."

-- José (Joe) E. Almeida, chair, president and chief executive officer

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:
 - **NEW: The Baxter International Foundation has donated ~\$4 million to support employees and communities impacted by Hurricane Helene**, including \$1.5 million in grants to three humanitarian partners and nearly \$2.5 million in funding to employees through Baxter's Employee Disaster Relief Fund.
 - 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.

Facilities and Infrastructure: As previously shared, and in coordination with FDA, our goal remains to begin resuming North Cove production in phases by the end of this year.

- **NEW:** We are pleased to announce that **Baxter has restarted the highest-throughput IV solutions manufacturing line**. At its peak operation (prior to Hurricane Helene), this line represented approximately 25% of the site's total production and approximately 50% of the site's production of one-liter IV solutions, the most commonly used size by hospitals and clinics.



- 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 start to ship is late November. This is ahead of our original expectations and 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 coordination of FDA, ASPR and HHS.
- Assessment and repair of equipment with phased testing continues to progress across all other production lines, which will, in coordination with FDA, support resumption of operations in phases.
- 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 885 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.
- **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.
- **U.S. Distribution for Products Authorized for Temporary Importation:** 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.
- **NEW: 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:**



- o 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.
- 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 be providing training and education materials in the first part of November so that patients and care teams can prepare to use 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.

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.