Hurricane Helene Updates

- **Beginning the week of Dec. 2, Baxter will provide bi-weekly updates regarding its progress to restore operations at its North Cove, N.C., site following Hurricane Helene.**

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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 colleagues, who have fueled our ongoing recovery while navigating Hurricane Helene's personal toll.

employees have returned to work across the facility.

- Baxter has responded to the hurricane's devastating local impact through a range of initiatives:
  - The Baxter International Foundation has donated more than $4 million to support employees and communities affected by the hurricane, 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.
  - A temporary employee support center helped 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 is, in coordination with FDA, supporting resumption of operations in phases.

- **NEW: We are making continued strong progress at our North Cove site, including the initial resumption this week of the following:**
  - **All 3L irrigation manufacturing lines**

- **Note that while production on these lines has restarted, it will take some time for the lines to ramp up and produce at pre-hurricane levels.**

- Two IV solutions manufacturing lines that restarted in November produce ~85% of the site's pre-hurricane capacity of 1-liter IV solutions, the most commonly used size by hospitals and clinics.

- Baxter released the first product – 1-liter IV solutions -- that was manufactured post-hurricane the week of Nov. 18.
    - 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.

- All of the above milestones have been 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.

- While we currently expect that all available lines will be restarted by the end of the year, we do not yet have a specific date 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.



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:**

  - **Baxter communicated details on allocation increases for several IV product groups to U.S. customers and distributors effective Nov. 26.** Customers are advised that there is a typical 1 to 2-week lag time for product to flow through the full distribution network after allocation changes are implemented.

planned, phased increases in allocations again in mid-December and at year-end, which includes reaching 100% allocation across several IV product codes by the end of 2024.

- Baxter's ability to adjust allocation levels 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 of 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 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

- 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 initial resumption of production in North Cove. With a better understanding of each of these factors, we intend to provide an update in December to the current PD solutions allocation quantities.

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 communications channels with Baxter, please contact HurricaneHeleneSupport@baxter.com.

Previous Updates

- November 26, 2024 Update

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- November 14, 2024 Update
- November 11, 2024 Update
- November 7, 2024 Update
- October 31, 2024 Update
- October 28, 2024 Update
- October 24, 2024 Update
- October 21, 2024 Update
- October 17, 2024 Update
- October 14, 2024 Update
- October 9, 2024 Update
- October 7, 2024 Update
- October 3, 2024 Update
- September 29, 2024 Press Release

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Policies & Positions

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