

Saline Supply Shortage

AABB is monitoring the current Saline Supply shortage. Check back frequently for updates.

Links and Resources to Consider:

1. AABB Resources:

- [Saline Supply Shortage – AABB’s Clinical Transfusion Medicine Committee Considerations for Mitigation](#) – 10/08/24

The CTMC developed considerations for inventory management during the current saline shortage and strategies to manage shortages in the future.

- 2. [Baxter – Hurricane Helen Updates](#) – Baxter’s North Cove Manufacturing Site - updated 11/26/24

NEW 11/26/24:

Below is an update on U.S. Supply Continuity for IV Solutions:

In follow-up to Baxter’s communication on Nov. 11 regarding anticipated increases in allocations for U.S. IV products, today Baxter confirmed with customers new allocation levels for several IV product groups, effective today, 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.

Barring any unanticipated developments, Baxter expects to share details on 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.

[November 25, 2024 Update: Product Allocations for U.S. IV Products](#)

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

- **Oct 2024 - 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.*

- *Oct 2024 - 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.*

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.*
 - **Oct 2024 -** *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.*
 - **Oct 2024 -** *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.*

3. FDA's Information and Updates on CDER-Regulated Drug and Biological Products

- [Hurricane Helene: Baxter's manufacturing recovery in North Carolina](#) – 10/28/24
 - FDA's Temporary Importation sources to mitigate shortages – this information is located midway through the link above.
- [FDA's drug shortages list](#)

4. U.S. Department of Health and Human Services

- [HHS Informational Briefing on IV Fluid Conservation Best Practices](#) 10/28/24
- [Statement from Secretary Xavier Becerra on IV Fluid Increase](#) 10/24/24

5. Centers for Disease Control and Prevention

- [Health Alert Network \(HAN\) Health Advisory – 10/12/24](#)