Supply chain disruption report

Baxter North Cove Plant

Situation

On September 26, 2024, Hurricane Helene made landfall on the Florida coast as a Category 4 hurricane. On September 29, 2024, Baxter announced it would be suspending operations at its North Cove facility in Marion, N.C., secondary to flooding from Hurricane Helene.

Background

According to Baxter's website, the Baxter North Cove manufacturing facility was opened in 1972 and is Baxter's largest manufacturing plant, employing over 2,500 employees.

Baxter's North Cove plant manufacturers intravenous and dialysis solutions and is the largest manufacturer of these solutions in the United States.

A Baxter press release was released on September 29, notifying customers and the public that the North Cove plant was impacted by rain and storm surging from Hurricane Helene. While current assessments of impact are still underway, Baxter has closed production due to limited access.

In addition, Baxter has announced a shipment hold of 48 hours (starting September 29), with allocations shortly following, to minimize patient care disruptions.

Baxter has announced that they were able to implement their hurricane preparedness plan, and they are leveraging their global manufacturing network to minimize potential disruptions.

Immediate Recommended Actions

Clinical providers should implement conservation strategies and protocols immediately.

- Recommendations compiled by the American Society of Health-System Pharmacists (ASHP) and The University of Utah here.
- Recommendations from Vizient's IV Push List, including adult and pediatric patient populations.

All stakeholders:

- For the most up-to-date information, please visit Baxter's website.

Assessment and recommendation

Baxter's North Cove plant was affected by a storm surge caused by Hurricane Helene. The facility experienced water damage, and the plant is closed due to limited access caused by roadway collapse and flooding.

Baxter is working with local, state and federal officials to evaluate the situation and develop a plan to restore operations as quickly as possible. Although Baxter was able to implement hurricane preparedness measures, the plant has suffered damage and remains closed with ceased operations until further assessment.

The North Cove facility produces large volume intravenous (IV) fluids (e.g, saline, dextrose, lactated ringers) as well as peritoneal dialysis solutions. This facility supplies large volume IV fluids used in the U.S., making it the primary manufacturing facility for large volume IV fluids; however, Baxter is actively analyzing leveraging their global network to minimize supply chain impact.

The End Drug Shortages Alliance (EDSA) is currently monitoring the evolving situation and is coordinating with various industry and regulatory stakeholders to minimize potential disruptions.

Manufacturers

The End Drug Shortages Alliance (EDSA) recommends that sterile injectable manufacturers and 503B compounders of impacted products and their alternatives evaluate their ability to increase production to help meet current demand levels for these products. As impacted product lists become available, 503B compounders may consider reviewing their formularies to assess production capabilities for impacted essential medications where possible.

Wholesalers

The EDSA has recommended that wholesalers communicate with manufacturers and establish protective allocations for impacted products and their alternatives to ensure the product is available for patient care. EDSA recommends that wholesalers maintain relevant allocations in place until additional information is available on product specific market impact. To our knowledge, all major distributors have implemented allocations at this time. To ensure allocations are properly utilized, the EDSA recommends the following for purchasers and for wholesalers:

- Ensure ordering of impacted products remains at consistent, historical purchasing volume, as allocations are in place to help ensure product is distributed equally
- Regularly communicate pertinent updates and information sharing when medications become available for patients
- Coordinate with manufacturers, clinical providers, and GPO partners for alternate therapies, when available
- Implement conservation and inventory stewardship best practices

Clinical Providers

It will be vital for providers and clinicians to exercise a drug shortage stewardship mindset when ordering, prescribing, and administering medications affected by supply constraints to preserve availability for vulnerable patient populations. Alert your regulatory community with any price gouging or predatory activity. The EDSA is recommending the following guidance for clinical providers to consider:

- Providers should implement conservation and practice protocols immediately.
    - Please see specific recommendations complied by the American Society of Health-System Pharmacists (ASHP) and The University of Utah here.
    - Recommendations are also available from Vizient's IV Push list that lists adult and pediatric considerations and alternatives.
- Activate internal drug shortage and mitigation review processes and committees, including communication and education for conversation and mitigation practices to multidisciplinary stakeholders
    - All providers should take caution to exercise appropriate principles of Drug Shortage Stewardship to minimize impact to patient care
- Switching or leveraging the smallest possible volume of IV fluids for the required indication, while regularly reviewing patients on IV fluids for discontinuation of therapy, and switching to alternative routes of administration if possible
- For electrolyte replenishment therapies, or other therapies involving IV fluids, consider starting patients on oral, or other alternative administration routes

- Continuously review Baxter's website for updates and implement, revise, and review conversation strategies
- Ensure ordering of fluids remains at consistent, historical volume, as allocations are in place to help ensure product is distributed equitably
- Communicate frequently with neighboring health systems and wholesalers, GPO, and distributor partners when medications are available for patients

Figure 1. Current Baxter Manufacturing Sites

Category	Description	Primary Baxter manufacturing site	Potential alternate Baxter manufacturing site(s)	
Large Volume IV Fluids	IV Fluids / Irrigation ranging from 250 mL to 5000 mL	North Carolina[a]	Mexico	Spain

[a] Facility impacted by Hurricane Helene
Abbreviations: IV = intravenous; NA = not applicable

Baxter is currently analyzing leveraging their global manufacturing network to identify if secondary and tertiary sites are eligible for US distribution. Please refer to Baxter's website for updates on manufacturing and plant status, as this situation evolves.

Appendix 1. Baxter North Cove Impacted IV Solution SKUs

All products affected at Baxter's North Cove facility are placed on allocation. Baxter has communicated that product lines typically utilized in **substitution of the impacted products will be placed on a protective allocation**. Baxter has released customer letters with allocations, please refer to Baxter's website for more information.

Product category
Brevibloc premixed injection (esmolol hydrochloride) in sodium chloride
Cardioplegic solution for cardiac perfusion
Clinimix
Intravia empty bags
Irrigation bag solutions
Mini-Bag Plus
Sterile water and dextrose for injection
ViaFlex IV solutions – large volume
ViaFlex IV solutions – small volume
Viaflo IV solutions – large volume

Table 1. Impacted IV Solution SKUs and Other Suppliers Cross-Referenced in the Market

Table 1 contains a detailed list of the top utilized IV solutions produced at Baxter North Cove plant, which was provided in Baxter's customer letter. Please reference Baxter's website for more information.

The table below also includes listed product code, NDCs, and potential cross-references of other suppliers with information derived from a compilation of various market resources and clinical input.

NDC	Baxter Product code	Description	B. Braun product code	Becton Dickinson product code	Fresenius Kabi product code	ICU Medical product code
00338001702	2B0062Q	Dextrose 5% inj, USP 250 mL migrated	L5102	1727172005	624674	07922-02
00338001703	2B0063Q	Dextrose 5% inj, USP 500 mL migrated	L5101	1727172006	624675	07922-03
00338001704	2B0064X	Dextrose 5% in, USP 1,000 mL migrated	L5100	1727172007	624610	07922-09
00338008904	2B1064X	5% dex and 0.9% sod chl inj, USP	L6100	N/A	870174	07941-09
00338008504	2B1074X	5% dex and 0.45% sod chl inj, USP	L6120	N/A	869110	07926-09
00338004902	2B1322Q	Sod chlor 0.9% inj, USP ViaFlex plastic 250 mL migrated	L8002	1727170105	623174	07983-02
00338004903	2B1323Q	Sod chlor 0.9% inj, USP ViaFlex plastic 500 mL migrated	L8001	1727170106	623175	07983-03
00338004904	2B1324X	Sod chlor 0.9% inj, USP ViaFlex 1,000 mL migrated	L8000	1727170107	623176	07983-09
00338011702	2B2322Q	Lactated ringer's inj, USP	L7502	1727171005	964174	07953-02
00338011703	2B2323Q	Lactated ringer inj, USP via flex plastic container 500 mL	L7501	1727171006	964175	07953-03
00338011704	2B2324X	Lactated ringer inj, USP 1,000 mL ViaFlex container	L7500	1727171007	964176	07953-09
00338022104	2B2544X	Plasma-Lyte A inj, pH 7.4 multiple	L7070	N/A	389100	07670-09
00338004747	2B7127	0.9% sod chl irrig, USP 3,000 mL Uromatic container	R8206	N/A	N/A	07972-08
00338004727	2B7477	0.9% sod chl irrig, USP, 3,000 mL Arthromatic	R8206	N/A	N/A	07972-08
00338013727	2B7487	Lactated ringers irrig, 3,000 mL Arthromatic	R8306	N/A	N/A	07828-08

Appendix 2. Baxter North Cove Impacted Dialysis Solution SKUs

The product list below in Appendix 2 was included in Baxter's customer letter. Please refer to Baxter's website for more information.

NDC	Baxter Product Code	Description
0941067952	5B4984	Extraneal PD-2 2l/2l UltraBag
0941067953	5B4986	Extraneal PD-2 2.5l/3.0l UltraBag
0941042455	5B9757	Dianeal low ca 1.5% dex 3l/5l UltraBag (2.5 meq/l)
0941043055	5B9758	Dianeal low ca 2.5% dex 3l/5l UltraBag (2.5 meq/l)
0941043355	5B9759	Dianeal low ca 4.25% dex 3l/5l UltraBag (2.5 meq/l)
0941042451	5B9765P	Dianeal low ca 1.5% dex1.5l/2l UltraBag (2.5 meq/l)
0941042452	5B9766	Dianeal low ca 1.5% dx 2l/2l UltraBag (2.5 meq/l)
0941042453	5B9768P	Dianeal low ca 1.5% dex2.5l/3l UltraBag (2.5 meq/l)
0941043051	5B9775P	Dianeal low ca 2.5% dex 1.5l/2 l UltraBag(2.5meq/l)
0941043052	5B9776	Dianeal low ca 2.5% dex 2l/2l UltraBag (2.5 meq/l)
0941043053	5B9778P	Dianeal low ca 2.5% dex 2.5/3l UltraBag (2.5 meq/l)
0941043351	5B9795P	Dianeal low ca 4.25% dex 1.5l/ 2l UltraBag (2.5meq/l)
0941043352	5B9796	Dianeal low ca 4.25%dex 2l/2l UltraBag (2.5 meq/l)
0941043353	5B9798P	Dianeal low ca 4.25% dex 2.5/ 3l UltraBag (2.5 meq/l)
0941042655	5B9857	Dianeal PD-2 solution 1.5% dex 3l/5l UltraBag
0941042755	5B9858	Dianeal PD-2 solution 2.5% dex 3l/5l UltraBag
0941-0429-55	5B9859	Dianeal PD-2 solution 4.25% dex 3l/5/l UltraBag
0941042652	5B9866	Dianeal PD-2 solution 1.5% dex 2l/2l UltraBag
0941042653	5B9868P	Dianeal PD-2 solution 1.5% dex 2.5l/3l UltraBag
0941042752	5B9876	Dianeal PD-2 solution 2.5% dex 2l/2l UltraBag
0941042753	5B9878P	Dianeal PD-2 solution 2.5% dex 2.5l/3l UltraBag
0941042952	5B9896	Dianeal PD-2 solution 4.25% de x 2l/2l UltraBag
0941042953	5B9898P	Dianeal PD-2 solution 4.25% dex 2.5l/3l UltraBag
0941040906	L5B4825	Dianeal low cal 1.5% dex 2l/2 l PD solution
0941040907	L5B4826	Dianeal low cal 1.5% dex 5l/6l (sys 2)
0941067906	L5B4974	Extraneal PD-2 (icodextrin) pd soln (2l/3l)
0941067905	L5B4976	Extraneal PD-2 (icodextrin) pd soln (2.5l/3l)
0941041105	L5B5163	Dianeal PD-2 1.5% dex 1l/1l (sys 2)
0941041106	L5B5166	Dianeal PD-2 1.5% dex 2l/3l (sys 2)

NDC	Baxter Product Code	Description
0941041104	L5B5169	Dianeal PD-2 1.5% dex 3l/3l (sys 2)
0941041305	L5B5173	Dianeal PD-2 2.5% dex 1l/1l (sys 2)
0941041306	L5B5177	Dianeal PD-2 2.5% dextrose (2l/2l)
0941041304	L5B5179	Dianeal PD-2 2.5% dex 3l/3l (sys 2)
0941041505	L5B5183	Dianeal PD-2 4.25% dex 1l/1l (sys 2)
0941041506	L5B5187	Dianeal PD-2 4.25% dex 2l/3l (sys 2)
941041504	L5B5189	Dianeal PD-2 4.25% dex 3l/3l (sys 2)
0941041107	L5B5193	Dianeal PD-2 1.5% dextrose (5l/6l)
0941-0413-07	L5B5194	Dianeal PD-2 2.5% 5l/6l (sys 2)
0941041507	L5B5195	Dianeal PD-2 4.25% dex 5l/6l (sys 2)
0941045705	L5B5202	Dianeal low cal 2.5% dex 5l/6l (sys 2) (2.5 meq/l)
0941045905	L5B5203	Dianeal low ca 4.25% dex 5l/6l (sys 2) (2.5% meq/l)
0941041111	L5B9710	Dianeal PD-2 1.5% dex 6l/6l (sys 2)
0941041301	L5B9711	Dianeal PD-2 2.5% dex 6l/6l (sys 2)
0941041501	L5B9712	Dianeal PD-2 4.25% dex 6l/6l (sys 3)
0941045708	L5B9727	Dianeal low cal (2.5 meq/l) pd soln 2.5% dex (2l/3l)
0941045908	L5B9747	Dianeal low cal 4.25% dex 2l/3 l pd solution
0941040901	L5B9770	Dianeal low ca 1.5% dex 6l/6l (sys 2) (2.5 meq/l)
0941045701	L5B9771	Dianeal low cal 2.5% dex 6l/6l (sys 2) (2.5 meq/l)
0941045901	L5B9772	Dianeal low ca 4.25% dex 6l/6l (sys 2) (2.5 meq/l)
0941-0409-05	L5B9901	Dianeal low ca 1.5% 3l/3l (sys 2) (2.5 meq/l)
0941045702	L5B9902	Dianeal low cal 2.5% dex 3l/3l (sys 2) (2.5 meq/l)
0941045902	L5B9903	Dianeal low cal 4.25% dex 3l/3l (sys 2) (2.5 meq/l)

Special thank you to the End Drug Shortages Alliance (EDSA) Advisory Board and Rapid Response Team for their collaborative response to assess the disruption to the supply chain following this natural disaster. The information provided in this document was compiled on behalf of the EDSA Rapid Response Team (RRT). The Rapid Response Team is a group of Subject Matter Experts (SMEs) across the entire industry, volunteering their time to end drug shortages, and serving to respond with timely and correct information during supply chain disruptions. Some notable mentions for the RRT include the Vizient®, the United States Pharmacopeia (USP), American Society of Health System Pharmacists (ASHP), and Children's Hospital Association (CHA).

Formed in December 2021, the End Drug Shortages Alliance brings together health systems, manufacturers, and other industry stakeholders across the supply chain who are dedicated to solving pharmaceutical supply challenges by collaborating to increase visibility, access, and advocacy. Collectively we will end drug shortages through focus on transparency, communication, quality, redundancy, and supply readiness to achieve measurable and sustainable results.

To learn more, please visit enddrugshortages.com, or contact us at info@enddrugshortages.com.

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