IV Therapy Shortages Update 1/22/18

The IV Therapy Shortages Update is your way to keep up-to-date on the latest IV shortage and allocation information. If you have a question regarding something you don't see covered, please post it in the PremierConnect IV Therapy Community.

Recent IV news

New **Baxter announces irrigation solution allocation update.** Learn more.
New **Baxter implements allocation for 1 liter evacuated containers.** Learn more.
New **Baxter announces allocation increase for Mini Bag Plus.** Learn more.
New **Baxter announces IV drug temporary importation update.** Learn more.

Shortage updates by supplier within this document: B. Braun | Baxter.
For previous IV supplier information and resources see the IV Therapy Community.
The FDA continues to monitor shortages across suppliers.

IV Fluid Conservation Strategies

- Conservation strategies: The American Hospital Association believes that the Intravenous Solution Conservation Strategies document published by the American Society of Health-System Pharmacists (ASHP) offers practical strategies that hospitals and health care systems might consider adopting in order to better manage their supply of IV fluids during the current shortage.
- ASHP worked with the University of Utah Drug Information Service to compile management and conservation strategies for small volume parenteral solutions.
- Oral Rehydration Therapy (ORT): With IV fluid shortages, some facilities are establishing protocols to use oral rehydration as a first line treatment as an alternative to using some IV fluids in certain patients. Please refer to facility protocols prior to using oral rehydration therapy. See the launch materials in supply Chain Advisor for contracted suppliers in this area.
- The Institute for Safe Medication Practices (ISMP) released an article regarding safe alternatives during the IV shortage. The article discusses alternative solutions, bag sizes, extended "hang" times, compounding and extending expiration dates.
- Medpage Today released an article concerning alternatives for IV nitroglycerin.
- See the IV Therapy Community for additional conservation strategy resources and policy examples.

IV conservation strategy poster available
Premier has created a poster for member use in their facilities to encourage employees to think of conservation strategies when considering IV solutions. There are spaces on the poster for the member to customize with contact information and the facility logo.

Advocacy

- Premier speaks with the Office of Drug Shortages (ODS) on a regular basis regarding the drug shortages, including IV products.
- A Premier advisory team submitted letters to the ODS discussing the impact of drug/IV shortages on patient care. They also asked for increased attention to fluid importation into the U.S.
- Premier staff meet with the U.S. Food and Drug Administration (FDA) to discuss shortages, pricing, delay of drugs coming to market, the need to increase importation and increased competition.
- The FDA has recently approved importation of additional products.

Related resources

- MedPage Today article on IV nitroglycerin alternatives
- ASHP strategies for conservation
- Critical Intravenous Shortages. The view from the FDA
- FDA drug shortage webpage
- ASHP Drug Shortages Bulletin discusses fluid shortage and includes conservation information
- ISMP safe alternatives during the IV shortage
- CDC Situation Update: Summary of Weekly FluView
- Premier white paper on drug shortages

IV Shortage Update archive

Previous IV Shortage Updates can be found on the IV Therapy Community on PremierConnect.

Recent updates:

- December 21, 2017 update
- November 21, 2017 update
- November 7, 2017 update

IV Therapy Shortages Update 1/22/18

Shortage updates by supplier

B. Braun

B. Braun issues urgent drug recall for one batch of 0.25% acetic acid irrigation 500 mL plastic irrigation container
In a customer letter dated December 15, 2017, B. Braun announced it was conducting a voluntary recall of one batch (J7N965) of 0.25% acetic acid irrigation USP, 500mL plastic irrigation container (PIC), catalog number R6601-01. 0.25% acetic acid irrigation is indicated as a constant or intermittent bladder rinse to help prevent the growth and proliferation of susceptible urinary pathogens in the management of patients who require prolonged placement of an indwelling urethral catheter.

B. Braun identified that some of units in batch J7N965 may contain white particulate matter. This particulate matter has been identified as polyethylene, which is consistent with the material used to manufacture the container cap. B. Braun has conducted a risk assessment to determine potential impact of the presence of particulate matter and determined that the particulate matter has the potential to occlude urinary catheters with small lumen, which would require catheter replacement. Particles that enter the bladder during irrigation treatment may cause irritation of the mucosa and potentially result in the formation of local granuloma.

Determine your current inventory of the affected lot within your facility. Do not destroy any affected product. Using the "Product Recall Acknowledgement" form, record the total number of individual units (within partial cases) and the number of full unopened cases. If you have no inventory remaining, please enter zero (0) on the form. Return the completed "Product Recall Acknowledgement" form to B. Braun by mail using the enclosed envelope or by fax to 610.849.5430 even if the total inventory in your possession is zero (0).

B. Braun releases allocation update to customers for PAB and Excel product codes
In a customer letter date November 1, 2017, B. Braun announced that inventory improvements are expected in the coming weeks and months, but they acknowledge that supply will not meet member's comprehensive needs over the short term. They advise you to continue sourcing a portion of your product demand from alternative manufacturers for all PAB® (SVP) and the following four Excel® codes (L7500, L8000, L8001 and L8002) through the first quarter of 2018. Allocations were previously adjusted as needed.

As a result of current supply availability constraints with LVP and SVP products, it is now anticipated that all Excel and PAB codes will experience inconsistent supply through first quarter of 2018. Please reference the list of affected products in the customer letter.

Previous allocation update:
In a customer letter dated August 22, 2017, B. Braun releases allocation update to customers for all PAB (SVP) and four Excel codes (L7500, L8000, L8001 and L8002). Starting with the October allocation period, allocations will be adjusted as needed and the final percentage will be communicated by your sales representative. Please reference the list of affected products in the letter.

B. Braun allocation updates
As of December 7, 2017, B. Braun released an updated supply allocation list. Please reach out to your local B. Braun representative for questions or help coordinating needs. Your local representative is better equipped to answer allocation impacts for your facility.

As of October 23, 2017, B. Braun has made Premier aware of an updated supply allocation list. Please reach out to your local B. Braun representative for questions or help coordinating needs. Your local representative is better equipped to answer allocation impacts for your facility.

In October 2017, B. Braun released a clinical nutrition cross reference. B. Braun has also built a cross reference for total parental nutrition (TPN) and peripheral parental nutrition (PPN). The TPN/PPN cross reference includes a fact sheet with clinical considerations. All cross references were developed and provided by B. Braun.

In September 2017, B. Braun released a supply allocation list and pharmacy cross reference for IV products. The allocation list includes three tabs: Supply allocation, protective allocation and removed from allocation. All cross references were developed and provided by B. Braun.

B. Braun directions for failure to supply reimbursement available
Members need to submit the below information to their local B. Braun representative for reimbursement when purchasing from other IV solution suppliers due to failure to supply.

- Customer account number and name
- Contact person and phone number
- List of products not available with competitive substitute purchased
- Copies of invoices covering the 90 day coverage period with the competitive substitutes highlighted

IV Therapy Shortages Update 1/22/18

Baxter

New Baxter announces allocation increase for Mini Bag Plus
Effective January 16, 2018, Baxter announced they have increase monthly allocation to 50% for Mini Bag Plus products. Allocations remain monthly and only end-customer are allocated. Only customers with current allocations are eligible for the increase. Amounts purchased during the current allocation period were carried forward and count against the increased amount. The allocation will reset to the full monthly amount with the refresh on January 23, 2018. Please speak with your local Baxter representative for allocation quantities and additional details.

New Baxter implements allocation for 1 liter evacuated containers
Effective January 12, 2018, Baxter implemented an allocation for 1 liter evacuated containers (1A8504). The allocation will be 100% of average monthly usage for the timeframe of July 2017 through December 2017. Please speak with your local Baxter representative for allocation quantities and additional details.

New Baxter announces irrigation solution allocation update
Effective January 9, 2018, Baxter announced a protective allocation on irrigation products. Member allocation amounts have been set a historical usage using the timeframe of July 2017 through December 2017. Please speak with your local Baxter representative for allocation quantities and additional details.

Baxter approved for temporary importation of intravenous drug products to address drug shortages
Baxter announced that it is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of products. These products have not been tested for aluminum content and this should be taken into consideration, especially when administering to preterm and term infants less than one month of age and patients with renal impairment. There are some key differences in the labeling between the U.S. marketed products and the imported products – see the comparison tables in the customer letters for more details.

New In a customer letter dated January 15, 2018, Baxter announced it has initiated temporary importation of the below products manufactured by Baxter's manufacturing facility in Brazil. The two product codes will be added to the "ST MINI" allocation group and any orders will count against customer allocations.

Product name and description	Size	Product code	Pack Factor	NDC code
0.9% Sodium Chloride Injection (VIAFLEX Container)	100 mL	FZB1307	72	0338-9517-72
5% Dextrose Injection (VIAFLEX Container)	100 mL	FZB0087	72	0338-9523-72

In a customer letter dated November 8, 2017, Baxter announced it has initiated temporary importation of CLINIMIX (N9G15E, N9G20E and N9G30E) solution for infusion. The three imported CLINIMIX products may not be appropriate alternatives for all of the US-approved CLINIMIX products. Each formulation contains a different mixture of amino acids and glucose. The expression of the concentrations is different for individual ingredients on the imported CLINIMIX products. The imported products state the ingredient concentrations contained within each chamber of the CLINIMIX dual-chamber bags **before** mixing. In comparison, the product names for the U.S. marketed CLINIMIX E sulfite-free injections indicate the amino acid and dextrose concentrations **after** mixing the two chambers.

In a customer letter dated November 3, 2017, Baxter announced it has initiated temporary importation of SYNTHAMIN 17 without Electrolytes 10% Amino Acid Intravenous Infusion. The imported SYNTHAMIN 17, 10% Amino Acid and TRAVSOL 10% contain the same amino acid profile and are therapeutically equivalent formulations.

In a customer letter dated October 31, 2017, Baxter announced it has initiated temporary importation of Heparin Sodium 2,000 IU/L in 0.9% w/v Sodium Chloride IV Infusions in VIAFLEX container. During this temporary period, Baxter will offer the imported products in 1,000 units/500 mL and 2,000 units/1,000 mL sizes. The imported products are labeled in IU/L, whereas the FDA-approved heparin products are labeled in units per mL. The imported products and FDA-approved products contain the same Heparin Sodium concentration of 2 units per mL.

Baxter announces allocation adjustments for frozen premix
As a result of the extended nature of production disruptions from Puerto Rico facilities, Baxter is making adjustments to frozen premix allocations effective November 7, 2017. Allocations for existing customers will be adjusted to 100% of average monthly purchases directly from Baxter based on purchases during March through August 2017. Existing customers include those with a purchase history during July 1, 2017 to September 30, 2017. Any new customers to frozen post September 30, 2017 will be set at 25% to 50% allocation. The impacted codes are 2G3503, 2G3504, 2G3505, 2G3508, 2G3578 and 2G3579.

IV Therapy Shortages Update 1/22/18

Baxter issues safety notification for adhered bags in one lot of 0.9% sodium chloride injection 100 ML in VIAFLEX quad pack
In a customer letter dated October 23, 2017, Baxter announced it had received reports of individual bags of the product listed below being adhered together. When customers have pulled the adhered bags apart, a tear in the bag has resulted. Customers are advised to discard any solution bags that are found to be adhered together in order to prevent the possibility that separating the bags may create a tear or leak in the solution bags, compromising the sterility of the product. The affected lot was distributed between April 12, 2017 and August 18, 2017 in the United States.

Product code	Product description	Lot number	Expiration date	NDC
2B1302	0.9% sodium chloride injection, 100 mL VIAFLEX plastic container quad pack	P359984	8/31/2018	0338-0049-18

Baxter has supplied a list of Premier members affected by this safety notification.

Baxter approved to import products in response to hurricane
In customer letters dated October 9, 2017, Baxter announced that in coordination with the U.S. Food and Drug Administration, Baxter has increased availability to products from Baxter's manufacturing facilities in Ireland and Australia. Baxter has initiated temporary importation of sodium chloride 0.9%, glucose 5% and Metronidazole. Customers are encouraged to use the letters to verify that these products meet their clinical needs and plan how they could be implemented in the facility.

These codes will not available in the wholesaler channel and must be purchased directly from Baxter. While the import of these products will help mitigate some of the projected shortfall in supply, they will not be adequate to fully bridge the gap in the near term.

If you have any questions about the information contained in the customer letters or the use of the imported products, please contact Baxter's medical information service at 800.933.0303.

Baxter announces protective allocation for three large volume parenteral products codes
Baxter announced in late October 2017 that it is implementing a protective allocation due to significant spikes in demand on all three large volume parenteral 5% dextrose (D5) product codes below. The allocation will be equivalent to 100% of each customers average monthly usage over prior thee completed months (July through September). Allocation will include all direct customers and trading partners. Your local representative will provide allocation impacts for your facility.

Product code	Description
2B0062Q	250 mL D5
2B0063Q	500 mL D5
2B0064X	1L D5

Baxter announces dual Luer lock cap (2C6250) will be unavailable until further notice
In late October 2017, Baxter announced its Dual Luer Lock Cap ("dead end cap") has been impacted by Hurricane Maria and will be unavailable until further notice. Current backorders will be canceled. Baxter provided the below list of competitive products to help support alternative supply arrangements.

Supplier	Product number	Description
B. Braun	R2000B	Dual function red cap with male and female end
B. Braun	B2000B	Dual function blue cap with male and female end
Smiths Medical	MX491	Dual function white Luer lock cap for male and female ports
Smiths Medical	MX49101	Dual function red Luer lock cap for male and female ports
Smiths Medical	MX491B	Dual function blue Luer lock cap for male and female ports

Baxter announces protective allocation for empty EXACTAMIX (EM) bags due to increased demand
On October 20, 2017, Baxter announced it was experiencing increased demand for empty EXACTAMIX (EM) bags from distributors and non-EM customers, who are using them as alternatives for empty INTRAVIA bags that are not available from Puerto Rico. The protective allocation applies to product codes: H938735, H938737, H938738, H938739, H938740, H938741, H938742, H938743, H938901 and H938905.

The allocation is 110% of average monthly usage (AMU) for the baseline period of January to September 2017. Backorders above AMU will be cancelled. Orders exceeding the allocation amount will be cancelled.

IV Therapy Shortages Update 1/22/18

Baxter issues urgent device correction for certain Sigma Spectrum pumps
In a customer letter dated October 6, 2017, Baxter issued an urgent device correction for certain V6 Spectrum infusion pumps due to the potential that a small number of these pumps may exhibit excessive wear of the pumping mechanism caused by a lack of lubrication. Specifically, unlubricated cams and actuator fingers may wear down to the point that the tubing does not properly occlude, potentially resulting in over- or under-infusion. Baxter will be inspecting potentially affected pumps for this issue and providing any necessary corrections. All V6 devices manufactured prior to December 12, 2012 that have not been returned to Baxter-Medina for service after that date are potentially affected by this issue. If you have additional questions, please contact your Baxter sales representative, or Baxter Healthcare Medina at 800.356.3454 (choose option 1).

Baxter recalls one lot of INTRALIPID 20% IV fat emulsion
On October 5, 2017 Baxter announced a voluntary recall on one shipment from a single lot (#10LE9597) of INTRALIPID 20% IV fat emulsion, 100 mL, distributed between August 11, 2017 and August 31, 2017. The product was exposed to subfreezing temperatures during transit to a distribution facility. The subfreezing temperature is outside of the acceptable storage range listed on the product labeling. Other shipments of this lot are not affected by this issue. Baxter has informed customers affected by this particular shipment to locate and remove all affected product. Recalled product should be returned to Baxter for credit

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Baxter hurricane update
In a customer letter dated October 27, 2017, Baxter provided an update on our recovery efforts in Puerto Rico. Baxter has been working with FDA and recently was granted regulatory discretion for temporary special importation of certain products from Baxter facilities in Ireland, Australia, Canada, Mexico and England to help support product supply for the U.S. market. These products include MINI-BAG Plus container systems, small volume parenteral solutions (SVPs), amino acids and certain pre-mixed products. Please be aware that *not all customers* will receive special import products. For those customers who do, these imported products *will not be incremental* to existing allocations.

Baxter is creating other solutions to help mitigate supply constraints. They have increased production of the Frozen Premix portfolio of products as a potential substitute for certain products currently manufactured in Puerto Rico. Baxter will continue in its commitment to ramp up production in Puerto Rico, and elsewhere around the globe, to help address product demand in the U.S. Baxter currently expects that they will return to normal supply levels by the end of the year for several product categories produced in Puerto Rico.

Previous Baxter hurricane updates:
In a customer letter dated October 11, 2017, Baxter announced they closely monitor and assess the projected supply of certain products and will take proactive actions to adjust previously established allocations in order to serve their existing customers to the best of their ability. These actions will help prevent unusual and excessive purchasing, thus helping to responsibly manage and optimize inventory levels.

Product allocation amounts are being recalculated for nutrition products addressed in the letter, based on average monthly purchase history from March through August, 2017. The specific allocation amounts will be available from your Baxter sales representative or via your eServices account.

Baxter does not manufacture large volume sterile solutions, such as 1 liter intravenous solutions, in Puerto Rico. Production of these products were not impacted by the hurricanes and are available to contracted customers.

In a customer letter dated September 29, 2017, Baxter announced that as they continues assessments, the projected supply of certain products requires them to adjust previously established allocations and remove some products from the distributor/ wholesaler channel for the foreseeable future. Baxter is taking these proactive steps to responsibly manage and optimize inventory levels in order to serve existing customers to the best of their ability. It will also prevent unusual and excessive purchasing, thus helping to support equitable product distribution. The customer letter includes a list indicating which products will be removed from the channel and available only through direct purchase from Baxter, effective immediately. The table also indicates which product allocations are being adjusted. The previous customer letter was dated September 22, 2017.

Baxter announces backorders on IV solutions
In the August 2017 Solutions Supply Outlook, Baxter announced backorders to product codes 2B2324X and 2B1322Q. Baxter has experienced a few process efficiency issues on the lactated ringer's injection, USP, 1000 mL VIAFLEX Plastic Container (product code: 2B2324X). As a result, members will experience intermittent backorders through the end of August on this code. Baxter has also experienced yield issues on the lines that produces 250 mL 0.9% sodium chloride injection, USP (product code: 2B1322Q). As a result, members will experience intermittent backorders on this code. Baxter expects to return to adequate supply on this code by November. For additional details, see the August 2017 Solutions Supply Outlook.

Baxter supply outlook newsletter
Baxter has introduced a newsletter focused on the solutions space. Previous editions include April 2017, May 2017, August 2017

IV Therapy Shortages Update 1/22/18

Baxter issues urgent drug recall on 5% dextrose injection and 0.9% sodium chloride injection
In a letter dated July 6, 2017, Baxter announced a voluntary product recall for specific product codes due to the potential presence of leaks. The affected lots were distributed between April 14, 2017 and June 1, 2017 in the United States. A leak of the solution bag may allow for delay or interruption of therapy, under-delivery, unintended drug exposure and microbial contamination. Contact Baxter to arrange for return and credit. Baxter can be reached at 888.229.0001.

In a letter dated July 6, 2017, Baxter announced a voluntary product recall for product code 2B1322Q (lot number Y229153) due to the potential presence of leaks. The affected lot was distributed between April 4, 2017 and May 18, 2017 in the United States. A leak of the solution bag may allow for delay or interruption of therapy, under-delivery, unintended drug exposure and microbial contamination. Contact Baxter to arrange for return and credit. Baxter can be reached at 888.229.0001.

IV suppliers: Direct order process

Having challenges ordering fluids directly from a supplier? Suppliers ask that you do the following:
Note: Organizations should continue with their current ordering process, unless there is severe issue with getting their "allocation" from the distributor and direct may be their only option.

1. Contact their supplier representative and inform them of the need to order direct.
2. Work with the supplier representative to determine "Allocation" or "PAR" levels for their hospital.
   Note: Each hospital has allocation set at their distributor. The distributor is not able to add additional "Allocation" unless the facility demonstrates the increase in supply demand. If the supply demand is increased, (new hospital, increase census, etc.), the "Allocation will be increased" via the supplier representative.
3. Work with your supplier representative to assure all documentation is complete for ordering direct and the supplier customer service has established a facility account number you may order direct from the supplier.
4. Place direct order.
   Note: Allocation levels go with the member and will not double if you are ordering via both distribution and direct.

B. Braun position on ordering: During the allocation period, customers need to stay with their normal means of receiving product. This action is to avoid additional product shortages and insure that committed customers receive their allocations. Braun is concerned that customers will try to "double-dip" by receiving product through distribution and direct.

Additional IV supplier updates

BD/CareFusion issues safety notification on Alaris™ syringe and PCA models
In a letter dated November 17, 2017, BD/CareFusion issued a safety notification for Alaris Syringe module model 8110 and Alaris PCA module model 8120. BD/CareFusion received reports of syringe and PCA plunger grippers not closing automatically during maintenance or service when the gripper control knob was closed. It is important to note that the syringe plunger gripper can be manually closed by the user. If the user follows the Alaris system user manual and ensures the syringe plunger gripper is closed, there is no risk of harm to the patient.

If the user experiences the issue above, contact BD Support Center at 888.562.6018 or email supportcenter@carefusion.com to schedule service of the device at the BD Service Depot. BD/CareFusion has supplied a list of Premier members affected.

BD/CareFusion issues medical device recall notification
In a letter dated September 1, 2017, BD/CareFusion released an urgent medical device recall for the Alaris™ Pump Module Model 8100. The component of the Alaris Pump module mechanical assembly of concern is the bezel assembly, specifically the bezel posts. The separation of one or more posts that connect the mechanism frame to the bezel assembly may prevent the device from delivering an accurate amount of fluid flow through the pumping cycle resulting in an over or under infusion condition. In addition, it may prevent the pump from alarming for an upstream or downstream occlusion condition.

BD/CareFusion has assessed the risk of this issue and determined that the affected product can still be used until it is remediated. However, clinicians should remove the pump from service if it shows signs of infusion at an unexpected rate. BD/CareFusion will replace the mechanical assembly on the affected serial numbers at no charge. BD/CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the remediation. For more information, see the Frequently Asked Questions document.

Smiths Medical issues recall for Medfusion® syringe pump model series 3500 and 4000
In a letter dated August 3, 2017, Smiths Medical issued a voluntary recall of Medfusion syringe pump model series 3500 and 4000 due to the barrel clamp mechanism requiring repair. An ineffective thread lock material on a fastening screw may result in the pump's ability to accurately detect the outside diameter measurement of a syringe barrel, causing an "Invalid Syringe Size" alarm to occur.