

PHARMACY FOCUS

JOURNAL OF THE VALLEY HOSPITAL PHARMACY

FORMULARY UPDATES



Flurpiridaz F 18 (Flyrcado)

FDA-approved radioactive diagnostic drug for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress in adult patients with known or suspected coronary artery disease to evaluate for myocardial infarction or ischemia. Compared with Tc-99m SPECT MPI, Flurpiridaz F 18 had higher specificity and accuracy, especially in patients where Tc-99m SPECT is limited (obese, women, pharmacologic stress). It also showed better detection of single- and multivessel CAD.

Eltrombopag (Promacta)

TPO-receptor agonist that induces proliferation and differentiation of megakaryocytes, leading to increased platelet production. FDA-approved for chronic immune thrombocytopenia in patients who have had an insufficient response to corticosteroids, IVIG, or splenectomy. Supplied as an oral medication and considered equipotent to an alternative treatment, romiplostim, which is only available as a subcutaneous injection. Approved for ambulatory and inpatient formulary with restrictions to providers with hematology/oncology credentials.

Linvoseltamab-gcpt (Lynozyfic)

FDA-approved bispecific B-cell maturation antigen-directed CD3 T-cell engager for the treatment of relapsed or refractory multiple myeloma in patients who have received at least four prior lines of therapy, including a proteasome inhibitor, immunomodulatory agent, and an anti-CD38 mAb. Requires registration with the REMS program. Approved for ambulatory and inpatient formulary with restrictions to providers with hematology/oncology credentials.

AMBULATORY FORMULARY UPDATES

Amivantamab and hyaluronidase-lpuj (Rybrent Faspro)

Subcutaneous version of the bispecific antibody amivantamab that targets EGFR and MET receptors to block cancer growth. This injection is FDA-approved for the treatment of non-small cell lung cancer with EGFR 19 deletions, Exon 21 L858R substitution mutations, or Exon 20 insertion mutations. The subcutaneous formulation showed a longer median duration of response, better disease control, and longer overall survival in comparison to the intravenous formulation.

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WELCOMING OUR NEW DIRECTOR



Mina Millad-Aziz, PharmD
Director of Pharmacy

“My goal is to build one unified pharmacy department where every team member feels valued, supported, and empowered to grow. Together, we will focus on professional development, open communication, operational excellence, and a culture of accountability, collaboration, and patient-centered care. By working as one team, we can continue to elevate our practice and provide exceptional care to every patient we serve.”

Mina is a graduate of the Philadelphia College of Pharmacy and brings a wealth of experience from a diverse and accomplished pharmacy career. He began his professional journey as a retail pharmacist with CVS Pharmacy before transitioning into long-term care with PharmScript LLC. He subsequently served as an Emergency Department and Intensive Care Unit pharmacist at NYU Langone Medical Center and later as Pharmacy Operations Manager at Memorial Sloan Kettering Cancer Center. Before joining Valley Health System, Mina served as Pharmacy Operations Manager for Inpatient and Outpatient Infusion Services at New York-Presbyterian. With his extensive clinical and operational leadership experience across multiple healthcare settings, Mina brings valuable expertise and vision to our organization. We are thrilled to have him join the Valley Health team and look forward to his leadership and contributions.

When Mina is not working, he enjoys staying active in the gym, spending time at the beach, and making the most of his time with family and friends. One highlight from his year has been welcoming his new niece. He is excited to start making lasting memories as she grows. Those moments help remind him of the importance of balance, relationships, and enjoying life outside of work. Welcome Mina to the Valley team!

PROMOTIONS



Usha Tejwaney, PharmD
Ambulatory Care Pharmacy
Manager

Over the past 8 years at Valley, Usha has continuously stepped forward to take on expanded responsibilities, lead complex initiatives, and support the evolving needs of the department and health system. In her work supporting infusion pharmacy management and operations, Usha has contributed to workforce coordination, regulatory readiness, residency development, and multidisciplinary collaboration across clinical and operational teams. Her efforts have helped advance workflow improvements, emergency preparedness initiatives, quality programs, and operational continuity within the department. In addition to her operational leadership, Usha remains deeply committed to professional growth and academic advancement.

She is also serving as a PGY-1 Pharmacy Residency Program Director. Under her leadership, the residency program has continued to grow and strengthen, achieving a 100% residency match rate and attracting highly talented candidates year after year. Usha's commitment to supporting residents, advancing pharmacy education, and creating meaningful learning experiences has made a lasting impact on both the program and the future pharmacy leaders she mentors. She is currently pursuing her MBA at Boston University Questrom School of Business and actively participating in Valley's Leadership Academy. She also serves as a Faculty Lecturer at Fairleigh Dickinson University and has contributed to several peer-reviewed publications focused on clinical medicine, healthcare innovation, and emerging technologies in patient care.



Anthony Grega, CPhT
Materials Manager
Supervisor

Anthony has 30 years' experience working in pharmacy across many different areas. He has worked in long-term care, home care, retail, and hospital pharmacy. 17 years ago, Anthony started at Valley as an inventory technician. Throughout his time here, he has always supported the team willing to step in when needed. He was later promoted to inventory coordinator, where he helped transition to the new hospital seamlessly, ensuring the team was able to continue care for our patients. He has consistently demonstrated outstanding teamwork, adaptability, resourcefulness, and a cooperative approach that has earned him the respect of colleagues across the organization. We are so excited to have him continue his growth with Valley as our new Materials Manager Supervisor. Outside of pharmacy, Anthony enjoys watching sports and attending concerts.

PRELIMINARY EVIDENCE SUPPORTS FURTHER STUDY OF GH001 IN TREATMENT-RESISTANT DEPRESSION

Kaila McIntyre, PharmD



Volcano Medic 2 Vaporization System

GH001 (Mebufotenin) is an investigational therapy currently being studied in depression subtypes. GH001 is a psychoactive molecule that is a nonselective serotonin agonist with a higher affinity for the 5-HT_{1A} receptor. It is administered using the Volcano Medic 2 Vaporization System. This system vaporizes GH001, which is then collected in a detachable balloon. The patient then inhales the medication. GH001 dosing is individualized per patient, with up to 3 escalating doses (6, 12, 18 mg). All doses are given on a single day with 1-hour intervals. GH001 recently showed early promising results in two different phase two studies: postpartum depression and treatment-resistant depression.

The Phase 2a study was a proof-of-concept open-label trial. It included 10 postpartum women, 18-45 years old, with a confirmed major depressive disorder diagnosis with peripartum onset. This study did not have a control arm. They used the Montgomery-Åsberg Depression Rating Scale (MADRS) to evaluate the patients' depression. The baseline MADRS scores ≥ 28 (moderate to severe depression) at baseline. In this study, GH001 was administered on day 1. Significant reductions in the MADRS scores were seen as soon as 2 hours post-dose. All 10 patients achieved remission by Day 8, which was defined as a MADRS score ≤ 10 . It was well tolerated, with the most frequent adverse event being a headache. Although GH001 showed early promise, conclusions are constrained by the limited evidence, including a small cohort of 10 patients and no comparator such as a placebo or standard of care.

A second Phase 2b study was also completed on GH001. This study was a 7-day randomized, double-blind, placebo-controlled trial with a 6-month open-label extension for 81 patients with treatment-resistant depression. Remission was defined as a MADRS score of ≤ 10 . On Day 8, remission was seen in 23 out of 40 patients who received GH001 and 0 patients who were given the placebo. It also showed improvements in anxiety, global illness severity, and quality of life. All patients after part 1 (first 8 days) were enrolled in the 6-month follow-up part 2. In part 2, they were eligible for 5 GH001 treatments. 20 out of the 23 patients who achieved remission on day 8 remained in remission at the 6-month completion of part 2. Improvements in depression symptoms were maintained in some patients during the 6-month open-label extension. With a slightly larger cohort than the Phase 2a trial, more side effects were noted: nausea, salivary hypersecretion, feeling of pins and needles.

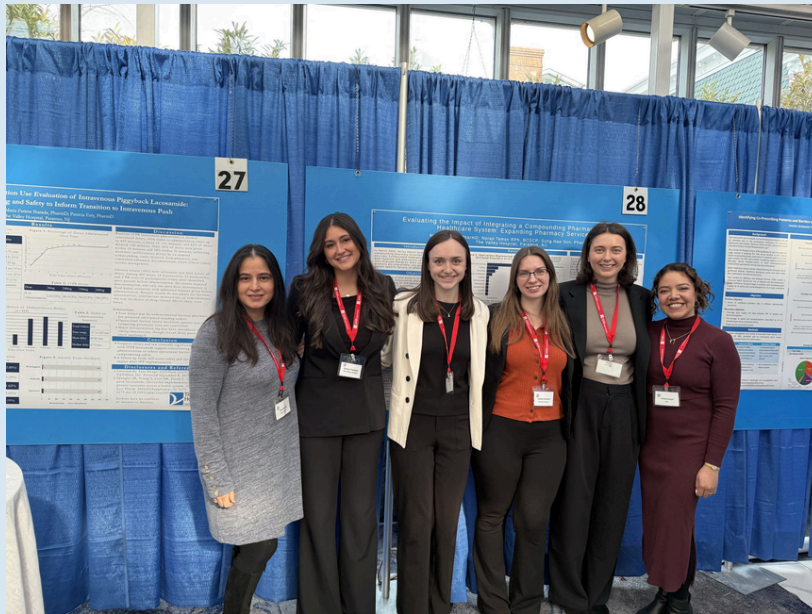
Despite the seemingly promising results, these are still very early studies with many limitations. GH001 requires a large phase 3 trial evaluating efficacy and safety compared to a control.

References

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ANNUAL MEETING



The Annual Meeting Recap:

In March the residents had the opportunity to showcase their research at the New Jersey Society of Health-System Pharmacists (NJSHS) Annual Meeting. In addition, they attended continuing education sessions on leadership and guideline updates. Along with round table discussions on hot topics: artificial intelligence, GLP-1 in perioperative care, and more!

World Pharmacist Day!

September 25th

There are **100** Pharmacists working for Valley Health System! Thank you to our pharmacists for all the work you do



TEBIPENEM PIVOXIL: THE NEXT BIG THING?

Gabriella Lamantea, PharmDc 2027; Kaila McIntyre, PharmD

Complicated urinary tract infections (cUTIs), including pyelonephritis, occur frequently in the United States due to multidrug-resistant pathogens. In the US, there are more than 3 million cUTI cases yearly. Adult patients may experience symptoms such as fever, nausea, vomiting, and lower back pain. Tebipenem pivoxil (Utebzi) is the first oral carbapenem drug to receive FDA approval on June 17, 2026. It is used to treat complicated urinary tract infections (cUTIs), including pyelonephritis caused by susceptible bacteria: *Enterobacter cloacae* species complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, and *Enterococcus faecalis*. Tebipenem pivoxil is a prodrug that converts to tebipenem. It binds to and inhibits penicillin-binding proteins, disrupts cell wall biosynthesis, and triggers bacterial death.

Tebipenem pivoxil is an antibiotic that can be taken with or without food, at a dose of 600 mg by mouth every 6 hours for 7 to 10 days in adult patients. The dose is adjusted for patients with an eGFR less than 60 mL/min. Tebipenem pivoxil lowers valproic acid and divalproex sodium concentrations, potentially increasing breakthrough seizure risk. Additionally, organic anion transporter inhibitors (OAT) 1 and 3 increase tebipenem concentrations.

Tebipenem pivoxil is a new treatment for patients who have limited oral options. The intravenous (IV) carbapenems for cUTIs are used in an inpatient hospital setting, requiring admission. PIVOT-PO is a phase 3, randomized, double-blind clinical trial in which 1,690 participants with cUTIs, including pyelonephritis, received either oral tebipenem pivoxil or intravenous imipenem-cilastatin for 7-10 days. Tebipenem pivoxil was non-inferior to imipenem-cilastatin, achieving an overall response rate of 58.5% vs. 60.2% (treatment difference: -1.3%; 95% CI: -7.5 to 4.8) and clinical cure rates exceeding 93% with both medications.

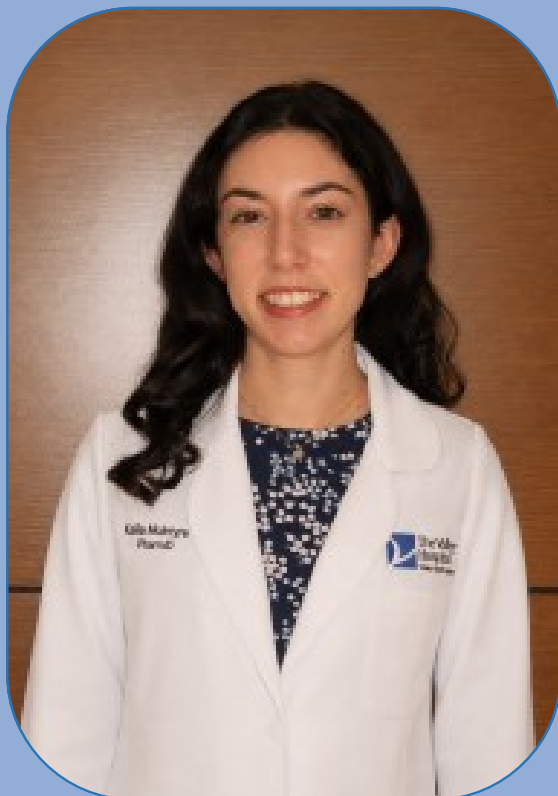
PIVOT-PO Adverse Reaction Comparison Rates		
	Tebipenem Pivoxil (Oral)	Imipenem-Cilastatin (IV)
Diarrhea	8%	3%
Headache	3%	3%
Nausea	1%	1%
Abdominal Pain	1%	1%
Increased Hepatic Enzymes	1%	1%
C.diff infection	1%	2%
Treatment-Related Adverse Event Discontinuation Rates	0.6%	0.8%

References

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MEET THE RESIDENTS

PGY-1 Traditional Pharmacy



Kaila McIntyre, PharmD

Kaila McIntyre is from Paramus, New Jersey, and earned her Doctor of Pharmacy degree from Ernest Mario School of Pharmacy, Rutgers University in May 2026. She is excited to start her PGY1 residency with Valley Hospital to strengthen her clinical skills and work with other healthcare professionals. She wants to learn more about the different areas of pharmacy, specifically patient safety. At the end of residency, she hopes to continue her training with a PGY2 in medication safety and continue to make a positive impact on patients' lives. Outside of work, Kaila enjoys reading, trying new crafts, and traveling. A fun fact is that she was born at the Valley Hospital.



Andrea Neporanny, PharmD

Andrea Neporanny is from Washingtonville, New York, and earned her Doctor of Pharmacy degree from Fairleigh Dickinson University, College of Pharmacy and Health Sciences in May 2026. She is looking forward to expanding her clinical knowledge and collaborating with an interdisciplinary team. She has a particular interest in oncology. She hopes to pursue a PGY2 in oncology, with future opportunities to precept and teach student pharmacists. Outside of work, Andrea enjoys going to the gym, cooking and baking, exploring new coffee shops, and reading. A fun fact is that she speaks Ukrainian.

MEET THE RESIDENTS

PGY-1 Community Pharmacy



Joyce Lee, PharmD

Joyce Lee is from Fort Lee, New Jersey, and recently graduated with her Doctor of Pharmacy degree from Rutgers University, Ernest Mario School of Pharmacy in May 2026. Joyce is excited to be involved with community outreach events, interact with patients with diverse backgrounds, and to help make an impact within the local community. After completing her PGY-1, Joyce hopes to continue working with patients as a transitions of care (TOC) pharmacist to improve health outcomes. When not working, Joyce enjoys playing video games, crocheting, and hanging out with her friends. A quick fun fact is that she grew up in Oklahoma!



Hanifa Aktar, PharmD

Hanifa Aktar is from Totowa, New Jersey. She received her bachelor's degree in biology from New Jersey City University. She continued her education at Shenandoah University for her Doctor of Pharmacy and Master of Business Administration. Hanifa is excited to develop her clinical pharmacy skills with an interest in oncology. At the end of residency, she plans to work as a clinical pharmacist to provide patient-centered care and improve patient health outcomes. Outside of the pharmacy, she enjoys traveling, ziplining, and discovering new restaurants. A fun fact about her is that she can speak three languages.

FIRST ORAL PCSK9 INHIBITOR APPROVED: WHAT ENLICITIDE MEANS FOR CHOLESTEROL MANAGEMENT

Mariam Habib, PharmDc 2027; Kaila McIntyre, PharmD

Enlicitide (Lipfendra) was approved in July 2026 to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH). It is the first oral agent in the proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor class; previously available as a subcutaneous injection given every two to four weeks.

Cholesterol is essential for building cell membranes and synthesizing hormones, but increased levels of LDL, the "bad" cholesterol, deposit in arterial walls and accelerate atherosclerosis, raising the risk of heart attack and stroke. HeFH is a common inherited disorder that produces markedly elevated LDL-C from birth, placing patients at high lifetime cardiovascular risk and frequently requiring more medications.

Enlicitide is a macrocyclic peptide that binds PCSK9 and blocks its interaction with the LDL receptor. By preventing PCSK9-mediated receptor degradation, more LDL receptors remain available on the hepatocyte surface to clear circulating LDL-C. The recommended dose is one 20 mg film-coated tablet once daily, taken on an empty stomach in the morning with water, black coffee, or plain tea.

Two 52-week, multicenter, randomized, double-blind, placebo-controlled phase 3 trials supported approval. Trial 1 CORALreef Lipids (NCT05952856), enrolled 2,904 adults with hypercholesterolemia, with and without HeFH, who had either a history of a major atherosclerotic cardiovascular disease (ASCVD) event or elevated risk for a first event, and who required additional LDL-C lowering despite stable moderate- or high-intensity statin therapy. Trial 2 CORALreef HeFH (NCT05952869), applied the same design in 303 adults with HeFH diagnosed by clinical criteria or genotyping. Both trials produced a statistically significant and clinically meaningful result at week 24.

Enlicitide is now a new option to consider for people struggling with high cholesterol whose next step in therapy is a PCSK9 inhibitor.

Endpoint	CORALreef Lipids	CORALreef HeFH
LDL-C vs Placebo at Week 24	-56% (95% CI: -61, -51; p<0.001)	-59% (95% CI: -66, -53; p<0.001)
LDL-C Change from Baseline	-57%	-58%
Placebo Change from Baseline	+3%	+3%

Reference

1. Navar AM, Mikhailova E, Catapano AL, et al; CORALreef Lipids Investigators. A placebo-controlled trial of the oral PCSK9 inhibitor enlicitide. N Engl J Med. 2026;394(6):529-539. doi:10.1056/NEJMoa2511002.
2. Merck's Lipfendra® (enlicitide) is the First and Only Once-Daily Oral PCSK9 Inhibitor Approved by the U.S. FDA to Reduce LDL-C in Adults with Hypercholesterolemia. Merck.com. July 16, 2026. Accessed September 4, 2026. <https://www.merck.com/news/mercks-lipfendra-enlicitide-is-the-first-and-only-once-daily-oral-pcsk9-inhibitor-approved-by-the-u-s-fda-to-reduce-ldl-c-in-adults-with-hypercholesterolemia/>.
3. Lipfendra (enlicitide) . Package insert. Merck & Co.; 2026

RETIREMENTS



Scott Crawford retired after nearly 25 years with Valley! He served as our inventory supervisor, always ensuring we were able to care for our patients



William (Bill) Cinnante served as the pharmacist in charge at the Valley Health Pharmacy at Luckow Pavilion since its opening in 2002. He was dedicated to his patients, building lasting relationships

FORMULARY UPDATES CONTINUED



Anakinra (Kineret)

Anakinra was approved in support of the development of the CAR-T therapy program. Restricted to hematology/oncology and intensivists treating immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) or cytokine release syndrome (CRS) grade 3 or 4.

Cetirizine (Zyrtec)

Cetirizine tablets and oral solution for pediatric patients are approved for patients 2 years of age and older.

Cabergoline (Dostinex)

The strength available is 0.5 mg; 1 mg by mouth once for lactation inhibition.

Doxepin (Silenor)

3 mg and 6 mg have been added, with the removal of 50 mg

Emapalumab-lzsg (Gamifant)

Emapalumab-lzsg is an interferon gamma antagonist FDA-approved for primary HLH and is being proposed for off-label use as third-line therapy for immune effector cell hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS). Emapalumab-lzsg is approved for life-threatening IEC-HS, with prescribing limited to providers with Hematology/Oncology credentials or intensivists.

Ethiodized Oil (Lipiodol)

The agent is an FDA-approved radiopaque iodinated poppy seed oil contrast agent, with labeled indications including hysterosalpingography, lymphography, and selective hepatic intra-arterial imaging in hepatocellular carcinoma (HCC). Approve ethiodized oil to the inpatient formulary.

Glofitamab-gxbm (Columvi)

Glofitamab-gxbm is a CD20-CD3 T-cell engager bispecific antibody indicated for the treatment of diffuse large B-cell lymphoma after two or more prior lines of therapy. Approve glofitamab-gxbm for the inpatient formulary.

Insulin Regular U-500

Has been added to the inpatient formulary

Pancrelipase (Creon)

Creon was approved to replace Zenpep with strengths of 3,000 units, 12,000 units, and 36,000 units for the treatment of exocrine pancreatic insufficiency (EPI) in adult and pediatric patients. Creon is a porcine-derived pancreatic enzyme replacement therapy containing lipase, protease, and amylase, available in multiple delayed-release capsule strengths that allow individualized dosing.

Ruxolitinib (Jakafi)

Ruxolitinib was approved in support of the development of the CAR-T therapy program. It is approved for the inpatient formulary but restricted to hematology/oncology and intensivists treating immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS).

Tranexamic Acid (Lysteda) 650 mg Tablets

Indicated for patients in the emergency department with confirmed hip and femur fractures and post-operative hip, knee, and shoulder order set

ISMP UPDATES

In July, ISMP noted that potential errors can occur from using diluted EPINEPHrine. Diluted IV EPINEPHrine is commonly used in anesthesia practice to rapidly correct hypotension. It does not treat hypotension but acts as bridging therapy for further care. It is administered as an IV push every 1 to 5 minutes. However, it is not commercially available, typically being made urgently at the bedside. Diluted EPINEPHrine is dosed in micrograms (mcg) compared to epinephrine that is used for cardiac arrest or anaphylaxis, which is dosed in milligrams (mg). Products for cardiac arrest are available in 1 mg/10 mL compared to an anaphylaxis product that is dosed at 1 mg/mL. The different products available to compound diluted EPINEPHrine can lead to dosing errors that are 10-fold greater than intended. They also can be confused with a prefilled flush syringe if they are diluted in 0.9% sodium chloride flushes. Here at Valley, we have PHENYLEphrine 1,000 mcg/10 mL (100 mcg/mL) syringes ready to use as an alternative. PHENYLEphrine onset is 1 minute, dosed every 2-5 minutes. It increases coronary perfusion, thus improving cardiac output, but will not increase heart rate.

In August, ISMP reported on the continued challenges with smart pumps. They provided tips on how to prevent errors. A quick way to start improving safety is to limit verbal orders. In an emergency, if a verbal order is needed, use closed-loop communication by repeating what you heard or what you will do. As a health system, we can stay up to date with annual competencies and training regarding smart pumps. Additionally, creating a culture of safety that encourages reporting events is important. Reporting smart pump events can lead to medication library changes, contacting the manufacturer, or clarifying any confusion.

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