

MSHP PHARMASCRIP^T

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mshprx@gmail.com
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Email: MSHP.PublicationsMarketing@ gmail.com

Artificial Intelligence in Healthcare: Patient Safety Considerations

Written by: Renee Mott, PharmD, MPH, DPLA, CPPS, Medication Safety Pharmacy Specialist, MedStar Washington Hospital Center, Lyndsy P. Beckman, PharmD, MS, MHM, CPPS, Pharmacy Medication Safety Specialist, Kaiser Permanente Mid-Atlantic States, and Evan Buzgo, PharmD, MBA, PGY2 Health System Pharmacy Administration and Leadership Resident, University of Maryland Medical Center

Artificial Intelligence (AI), defined as “the capability of computer systems or algorithms to imitate intelligent human behavior”¹, is revolutionizing the world. However, the risks of implementing such technology are not clear.² As such, healthcare organizations must weigh the benefits and consequences of adopting AI technology.

The potential benefits of AI in healthcare include: elevating diagnostic certainty³, optimizing treatment regimens³, improving coordination of care through documentation accuracy⁴, predicting disease development^{3,5}, preventing and controlling spread of diseases³, improving surgical outcomes³, supporting mental health treatment³, providing cost savings³, and alleviating workload burden on healthcare professionals.^{3,6,7,8} However, while promising, safety concerns must be considered prior to implementation.^{2,3,9}

Alert fatigue is a significant source of concern for healthcare providers where well-intentioned clinical decision support rules fire warnings and messages at a constant rate, but may not be acted upon (as documented by high override rates) due to patient-specific variables.¹⁰ To support patient and medication safety efforts, alerts highlighting drug-drug interactions, drug-disease interactions, duplicate therapy warnings, etc. are developed based on discrete rules - many from drug vendors or developed internally by an organization pursuant to a harm event. AI offers the ability for an electronic health record to consider large data sets, recognize patterns and provide predictions that can be applied to a specific patient's current and future health variables.^{10,11,12} By incorporating these features, there lies an opportunity to reduce noisy medication warnings and reduce alert fatigue.

Additionally, clinicians may initially struggle to effectively utilize and interpret results from AI tools, which may pose additional safety threats.³ To address these concerns, organizations should consider strategies to enhance transparency (e.g., explainable AI models) and provide comprehensive training to clinicians so they can interpret AI-driven recommendations safely and effectively.¹³ Furthermore, integration and regular utilization of AI tools may lead to

clinician overreliance on the technology², which may result in clinicians losing key skills essential to providing quality patient care.

How can healthcare organizations interested in adopting AI into practice safely move forward? First and foremost, organizations should form multidisciplinary teams, including data scientists, clinicians, ethicists, regulatory experts, healthcare executives, and health information technology experts^{2,14}, to oversee a coordinated approach to implementation.² Second, organizations should exercise caution when adopting AI ensuring all technology is validated, regulated, and closely monitored.² Third, periodic review of AI models is essential. Regular audits and performance checks help identify shifts in data that could degrade AI accuracy (model drift), ensuring that patient safety benefits are maintained over time.² Finally, organizations should engage frontline team members in all integration efforts to ensure any additions are value-added.²

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New Oral Antimicrobial Agents for Urinary Tract Infections: Key Take-Aways

Written by: Laura Lehman, PharmD, BCPS Clinical Pharmacist, Sinai Hospital of Baltimore

Resistance to common antibiotics for urinary tract infections (UTI) creates a need for additional effective therapies. Two oral agents FDA-approved in 2024 will soon be on the market in the United States. While not a complete review, the following information is intended to provide a brief overview and considerations regarding their place in therapy.

Sulopenem etzadroxil/probenecid (Orlynvah™) 500 mg/500 mg tablets		
Background	Unique Cautions ^{1,*}	Key Benefits
- A penem antibiotic FDA-approved in October 2024 for treatment of uncomplicated UTI (uUTI) caused by <i>Escherichia coli</i> (<i>E. coli</i>), <i>Klebsiella pneumoniae</i>, or <i>Proteus mirabilis</i> in adult women with limited or no alternative oral options. - Dose: 1 tablet twice daily x 5 days. - Not effective in clinical trials for primary or stepdown treatment of complicated UTI (cUTI) or complicated intraabdominal infections (cIAI).^{1, 2, 3} - Sulopenem etzadroxil is a prodrug that is hydrolyzed to the active sulopenem which binds to several penicillin binding proteins (PBPs). Probenecid decreases sulopenem clearance through inhibition of OAT3 resulting in increased sulopenem serum levels¹. - Similar spectrum of activity to carbapenems but structurally different. <i>In vitro</i> spectrum includes gram-positive and gram-negative aerobes and anaerobes. This includes Enterobacterales that produce extended spectrum beta-lactamases (ESBLs) and certain beta-lactamases such as AmpC, CTX-M, TEM, and SHV (but not carbapenem-resistant Enterobacterales)¹.	- Avoid in CrCl <15 mL/min - Contraindications: - Blood dyscrasias - Known uric acid kidney stones - Concomitant ketorolac - Increases risk of uric acid kidney stones and exacerbation of gout - Drug and lab interactions: - Can lead to supratherapeutic levels of ketorolac, indomethacin, naproxen, methotrexate, rifampin, lorazepam, and sulfonyleureas. - May result in a false positive glycosuria test	Remaining Questions
		- Potential additional indications - Pediatrics safety/efficacy - Pregnancy/lactation safety/efficacy - Cost and insurance coverage

*See product labeling for a complete list of cautions.

Pivmecillinam (Pivya™) 185 mg tablets		
Background	Unique Cautions ^{4,*}	Key Benefits
- Pivmecillinam, a prodrug of mecillinam, is a penicillin agent FDA-approved in 2024 for treatment of uncomplicated urinary tract infections (uUTI) caused by <i>E. coli</i>, <i>Proteus mirabilis</i>, or <i>Staphylococcus saprophyticus</i> in adult women.⁴ - Dose: 1 tablet three times daily x 3-7 days as clinically indicated. Each 185 mg tablet is equivalent to 200 mg pivmecillinam hydrochloride.⁴ - In use long term in Canada and parts of Europe and is included in guidelines for treating uUTI (at European dose of 400 mg PO TID).^{5,6} - Binds to PBP-2 but is synergistic with other beta-lactams on additional PBPs and, when combined, may block ESBLs.⁷ - In addition to the labeled organisms, <i>in vitro</i> activity includes <i>Klebsiella</i> spp and other Enterobacterales, although only ~30% of <i>Serratia marcescens</i> and <i>Morganella morganii</i> were susceptible in European studies.^{7,8} - Studies demonstrate activity against ESBL-producing <i>E. coli</i> and <i>Klebsiella</i> (>80% susceptible), but these involved 400 mg TID dosing. Certain carbapenem-resistant strains of <i>E. coli</i> and <i>E. cloacae</i> (associated with OXA-48-like and NDM mechanisms) may be susceptible.⁷	- Dose may be confusing as strength is labeled as the base equivalent rather than the hydrochloride product (200 mg) used outside the U.S. - Contraindications⁴: - Serious hypersensitivity reactions to pivmecillinam or other beta-lactams (including penicillins and cephalosporins) - Carnitine deficiency - Acute porphyria - Can deplete carnitine – consider alternative agent in patients with significant renal impairment, low muscle mass, or need for prolonged treatment - When taken by pregnant patient, may cause a false positive test for isovaleric acidemia in the newborn - Drug and lab interactions⁴: - Generates pivalate which can lead to carnitine deficiency. Concomitant pivalate-generating drugs (e.g., valproate drugs) increase this risk. If coadministration cannot be avoided, patients should monitor for symptoms of carnitine depletion (e.g., hypoglycemia, muscle aches, fatigue, and confusion) - Decreased methotrexate clearance - Newborn screening test interference	- Oral option for uUTI with little propensity for resistance - Oral option for including ESBL-producing Enterobacterales and some carbapenem-resistant <i>E. coli</i>. Note: the off-label, higher European dosing may be needed in these cases. - Widely used abroad with limited resistance development - Can be used in pregnancy with the noted consideration for the newborn screening test^{4,9}
		Remaining Questions
		- Potential additional indications - Pediatrics safety/efficacy (hypocarnitinemia has been reported with prolonged use in pediatric patients) - Cost

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Ensifentrine: A Novel COPD Medication

Written by: Daniel Butz, PharmD Candidate 2026, Zachary Geesaman, PharmD Candidate 2026

University of Maryland School of Pharmacy

Kathleen Pincus, PharmD, BCPS, BCACP

University of Maryland School of Pharmacy, Department of Pharmacy Practice, Sciences, and Health Outcomes Research

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease characterized by dyspnea, limited airflow, and chronic airway inflammation¹. COPD severity is classified using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. Lower forced expiratory volume in 1 second (FEV₁) scores compared to predicted values of a similar healthy patient correlate to increasing severity. Often caused by exposure to harmful chemicals through smoking or air pollution, COPD affects nearly 16 million adults in the United States². Globally, COPD is the third leading cause of death which drives continuous effort to improve treatment¹.

Approved by the FDA in June 2024, ensifentrine (Ohtuvayre™) is a nebulized selective dual phosphodiesterase (PDE) 3 and PDE4 inhibitor. While roflumilast, an oral PDE4 inhibitor, has previously been approved to reduce exacerbations in patients with severe COPD, ensifentrine is the first approved product with dual PDE3/4 inhibition. The current standard of care for patients with COPD consists of inhaled short acting and long acting β_2 agonists (SABAs and LABAs), long-acting muscarinic antagonists (LAMAs), and inhaled corticosteroids (ICS), used in various combinations depending on severity.

Ensifentrine was evaluated simultaneously in two phase III randomized, placebo-controlled trials: ENHANCE-1 and ENHANCE-2. The ENHANCE trials evaluated the efficacy of ensifentrine compared with placebo in 1,549 participants with moderate COPD. At a dose of 3 mg twice a day, both trials showed a significant improvement in average FEV₁ at 12 weeks, as well as decreased exacerbation rate at 24 weeks³. Symptom improvement was also measured, but only noted in the ENHANCE-1 trial³. One notable limitation of the studies is that patients on dual LAMA/LABA or LAMA/LABA + ICS therapy were excluded, limiting data on using ensifentrine as an add-on to current standard-of-care. Additionally, patients with asthma, who may have a higher risk of exacerbations, were also excluded^{1,4}.

Currently, ensifentrine has been approved by the FDA for the use as maintenance therapy in adult patients with COPD. The 2025 GOLD report now includes recommended use cases for ensifentrine. The report recognizes the evidence supporting increased lung function but also notes the mixed results on symptomatic improvements and incomplete evidence of reduction in exacerbation rates¹. As a result, the report only recommends considering the addition of ensifentrine in patients with uncontrolled dyspnea despite a dual LABA/LAMA regimen¹.

At an average wholesale price of \$3540.00 for a 30-day supply of Ohtuvayre™, it may be difficult to justify inclusion on a hospital formulary for such a modest benefit⁵. Even with this high price tag, ensifentrine represents an exciting advancement in the treatment of COPD. The ENHANCE trials have shown that PDE3 and PDE4 inhibitors have the potential to improve parameters such as FEV₁, but consistent improvements in clinical endpoints remain to be seen. To accurately determine its place in therapy, further research is needed to investigate ensifentrine both as an add-on to dual LAMA/LABA therapy ± ICS, and as a treatment compared to this current standard regimen. For now, pharmacists and practitioners must carefully weigh the costs versus benefits when recommending ensifentrine.

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Legislative Day 2025

Approximately 200 student pharmacists and pharmacists from across the state of Maryland converged on Annapolis for Pharmacy Legislative Day on Thursday, February 20th. In just a few hours, participants conducted nearly 150 meetings with representatives and senators from all 47 legislative districts. Legislative Day is a collaborative effort brought forth by several different pharmacy organizations in Maryland under the umbrella of the Maryland Pharmacy Coalition (MPC), which is made up of representatives from Maryland Society of Health System Pharmacy (MSHP), Maryland Pharmacists Association (MPHA), the Maryland Pharmaceutical Society (MPhS), and the Maryland Chapter of the American Society of Consultant Pharmacists (MDASCP), along with student representatives from Notre Dame, University of Maryland, Baltimore (UMB), and University of Maryland, Eastern Shore (UMES). This year, rotating leadership of MPC was the responsibility of none other than our own legislative committee, led by Courtney Henry!

The purpose of Legislative Day is to advocate for the advancement of pharmacists and pharmacy practice by voicing our support, disfavor, or concerns about bills being proposed during the state legislative session. By meeting with legislators face to face and providing them with our thoughts on proposed legislation, we help shape which bills are passed and how pharmacy is practiced across our state.



This year, MPC elected to focus advocacy efforts on three sets of bills:

- **SB111/HB382** – would remove step therapy/PA requirements from Medicaid for medications used to treat serious mental health conditions

- **SB303/HB321** – would prohibit PBMs from restricting pharmacists discussing certain cost-saving interventions with patients; clarifies that certain other existing regulations apply to PBMs, limits PBMs from reimbursing other pharmacies less than they reimburse their own pharmacies for the same prescription
- **SB438/HB813** – would require Medicaid PBMs to reimburse pharmacies with the same dispensing fee (approx. \$10.70) as Medicaid Fee-For-Service

As of March 11th, **SB111/HB382** and **SB438/HB813** were awaiting advancement out of committee in both the House and Senate, and **SB303/HB321** had passed the House and was awaiting advancement out of committee in the Senate.

While we won't know the ultimate fate of the above bills until the legislative session ends in early April, we are confident that the efforts of our student pharmacists and pharmacists in preparation for and on Legislative Day have had a positive impact on the practice of pharmacy in our state through continued advocacy and contact with our legislators, no matter the outcome of any specific bill. We encourage all readers to consider participating directly with future Legislative Day efforts and to contact your own representatives so that your voice is heard.

CALENDAR

Upcoming Events	
April 8, 2025	Medication safety Webinar
April 24 and 25, 2025	Spring Reverse Expo and Seminar at Hotel at Arundel Preserve

Diversity, Equality, & Inclusion Calendar

April

This Month:

- 4/2: World Autism Awareness Day
- 4/6: Tartan Day
- 4/7: World Health Day
- 4/9: Eid al-Fitr
- 4/13: Vaisakhi
- 4/22: Earth Day
- 4/22: Passover
- 4/21-27*: Black Maternal Health Week

All Month:

- Celebrate Diversity Month
- National Arab American Heritage Month
- Autism Acceptance Month
- National Deaf History Month
- National Minority Health Month
- Sexual Assault Awareness and Prevention Month
- National Child Abuse Prevention Month
- Alcohol Awareness Month

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May

This Month:

- 5/5: Holocaust Remembrance Day (Yom HaShoah)
- 5/5: Orthodox Easter
- 5/11-17: National Women's Health Week
- 5/17: International Day Against Homophobia, Biphobia and Transphobia
- 5/19: Malcolm X Day
- 5/21: World Day for Cultural Diversity for Dialogue and Development.
- 5/23: Vesak (Buddha Day)
- 5/27: Memorial Day
- 5/28: World LGBTQ Domestic Violence Awareness Day

All Month:

- Mental Health Awareness Month
- National Asian American and Pacific Islander Heritage Month
- Indian Heritage Month
- Jewish-American Heritage Month
- National Foster Care Month
- Older Americans Month
- National Physical Fitness and Sports Month
- Speech and Hearing Awareness Month

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June

This Month:

- 6/8: Family Health and Fitness Day
- 6/9: Race Unity Day
- 6/14: World Elder Abuse Awareness Day
- 6/16: Eid al-Adha
- 6/18: International Day of Countering Hate Speech
- 6/19: Juneteenth
- 6/19: World Sickle Cell Day
- 6/27: National HIV Testing Day

All Month:

- LGBTQ Pride Month
- Caribbean American Heritage Month
- PTSD Awareness Month
- Men's Health Month
- Alzheimer's and Brain Awareness Month

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