

# **West Virginia RDUR**

2025 Quarter 3 Newsletter

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# FDA APPROVAL SPOTLIGHT

Blujepa (gepotidacin)



On March 25, 2025 the Food and Drug Administration (FDA) approved Blujepa (gepotidacin) for the treatment of uncomplicated urinary tract infections (uUTI) caused by a susceptible microorganism (Escherichia coli, Klebsiella pneumoniae, Citrobacter

freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis) in female adult and pediatric patients 12 years and older weighing 40kg or more. Gepotidacin is an antibiotic with a novel mechanism of action in which it inhibits DNA replication by inhibiting type II topoisomerases including bacterial topoisomerase II and topoisomerase IV.

Gepotidacin is recommended to be taken as 1500 mg orally twice daily after a meal for five days. The medication should be avoided in patients with a history of QTc prolongation, with relevant pre-existing cardiac disease, severe hepatic impairment (Child-Pugh Class C), severe renal impairment (estimated glomerular filtration [eGFR] <30mL/min), or medical conditions that may be exacerbated by acetylcholinesterase inhibition. Concomitant use of gepotidacin should be avoided with strong CYP3A4 inhibitors, drugs that prolong the QTc interval, succinylcholine-type neuromuscular blocking agents, systemic anticholinergic medications, or non-depolarizing neuromuscular blocking agents.

Two non-inferiority trials compared gepotidacin to nitrofurantoin and found it to be noninferior in the microbiological intent to treat nitrofurantoin-susceptible (micro-ITTS) population. Due the the unique mechanism of action, gepotidacin may offer antibacterial activity against certain antibiotic resistant uropathogens and be less likely to lead to bacterial resistance than other antibiotics commonly recommended for uUTIs. Gepotidacin is significantly higher in cost than the generic antibiotics currently recommended for uUTI, which remain effective in most cases. Therefore, gepotidacin should be reserved for patients with uUTIs who are unable to use alternative first-line agents or those who have not responded to other agents.

#### References:

• GlaxoSmithKline; Durham, NC. Bluejepa [package insert]. U.S. Food and Drug Administration website.

 $\underline{\text{https://www.accessdata.fda.gov/drugsatfda\_docs/label/2025/218230s000lbl.pd}} \\ \text{f}$ 

## **GUIDELINE UPDATES**

# 2025 AHA/ACC HIGH BLOOD PRESSURE GUIDELINES

The AHA/ACC Guideline for the prevention, detection, evaluation and management of high blood pressure in adults was updated in August 2025 to reflect and incorporate the most recent hypertension evidence in clinical practice. The following information is a summary of the newest recommendations and updated terminology found in the updated clinical guidelines.

#### **Blood Pressure Categories**

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (top/upper number)	and/or	DIASTOLIC mm Hg (bottom/lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
STAGE 1 HYPERTENSION (High Blood Pressure)	130 – 139	or	80 – 89
STAGE 2 HYPERTENSION (High Blood Pressure)	140 OR HIGHER	or	90 OR HIGHER
, -	140 OR HIGHER HIGHER THAN 180	or and/or	90 OR HIGHER HIGHER THAN 120

<sup>\*</sup>symptoms: chest pain, shortness of breath, back pain, numbness, weakness, change in vision or difficulty speaking

**New terminology**: <u>Severe hypertension</u>, previously known as hypertensive urgency, is a systolic blood pressure higher than 180 mmHg and/or a diastolic blood pressure higher than 120 mmHg.

#### **UPDATED GUIDELINE RECOMMENDATIONS**

#### **PRIMARY ALDOSTERONISM**

**New recommendation:** Screen all adults with resistant hypertension regardless of potassium level and continue most antihypertensives (except MRAs) before screening.

#### LIFESTYLE APPROACHES

**New recommendation:** Potassium-based salt substitutes are recommended to lower BP (except in CKD or those on potassium-sparing drugs). Old recommendation: Focus was on sodium restriction, DASH diet, and exercise; potassium-based substitutes were not specifically recommended.

#### **RISK-BASED INITIATION**

**New recommendation:** Start medications at  $\geq 130/80$  mmHg in adults with diabetes, CKD, or  $\geq 7.5\%$  10-year CVD risk (PREVENT tool). In lower-risk adults (<7.5%), start if BP remains  $\geq 130/80$  mmHg after 3–6 months of lifestyle therapy.

#### **DIABETES**

New recommendation: ACEi or ARB are recommended for patients with diabetes and hypertension who also have CKD (eGFR <60 or albuminuria ≥30 mg/g) and should be considered even with mild albuminuria.

#### **CHRONIC KIDNEY DISEASE**

New recommendation: For hypertension with CKD and albuminuria ≥30 mg/g, RAAS inhibition with either ACEi or ARB (not both) is recommended to reduce CVD risk and slow kidney disease progression.

#### ACUTE INTRACEREBRAL HEMORRHAGE AND ISCHEMIC STROKE

**New recommendation:** In acute ICH with SBP 150–220 mmHg, lower BP to 130–139 mmHg for at least 7 days, with careful titration to avoid variability. After reperfusion therapy for ischemic stroke, avoid lowering SBP<140 mmHg in the first 24–72 hours.

#### **COGNITIVE HEALTH**

**New recommendation:** Target SBP P <130 mmHg to prevent mild cognitive impairment and dementia due to stronger proof now that high blood pressure is linked to increased risk of these outcomes.

#### **PREGNANCY**

New recommendation: Treat if SBP ≥160 or DBP ≥110 mmHg on repeat measurements within 30–60 minutes; treat chronic hypertension patients to <140/90 mmHg; recommend low-dose aspirin for preeclampsia prevention; avoid atenolol, ACEi, ARB, direct renin inhibitors, nitroprusside, and MRAs.

#### **RESISTANT HTN AND RENAL DENERVATION**

**New recommendation:** Stronger emphasis on secondary cause evaluation and medication review. Patients being considered for RDN should undergo multidisciplinary evaluation, with shared decision-making about risks and benefits.

#### HYPERTENSIVE EMERGENCIES

**New recommendation:** Do not acutely lower BP in nonpregnant and nonstroke hospitalized patients with severe hypertension (>180/120 mmHg) if no target organ damage is present.

#### References:

Jones DW. 2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC ... (Living Guidelines on High Blood Pressure). Circulation. 2025;152:e00–e00. doi:10.1161/CIR.000000000001356. [cited 2025 Sept 21]. Available from: https://www.ahajournals.org/doi/10.1161/CIR.000000000001356

## **LEGISLATIVE NEWS**



In April 2025, West Virginia Senate Bill (SB) 526 was signed into law giving pharmacists prescribing authority. The bill expands pharmacist's scope of practice by allowing the prescribing of drugs or devices that are prescribed for Food and Drug Administration (FDA) approved indications.

Pharmacists are given the authority to prescribe non-controlled substances for conditions that do not require a new diagnosis, can be identified by federal Clinical Laboratory Improvement Amendments of 1988 (CLIA)-waived tests (for example, influenza, COVID-19, RSV), are minor and self-limiting, or are deemed an emergency by the pharmacist. The prescriptions must be limited to a 30-day supply within a 6-month period, and if more than a 10-day supply is issued, then the patient's primary care provider must be notified.

West Virginia is facing a critical shortage of healthcare providers, while the population is aging and the demand for healthcare providers is increasing. Appropriate and easy access is essential for West Virginia patients, as the rates of chronic health conditions (for example, asthma, cardiovascular disease, depression) is significantly higher than other states. SB 526 has the potential to fill the gap and increase healthcare access for patients, particularly Medicaid members, especially in rural areas that are affected more critically by the provider shortages.

#### References:

- *SB 526 Text*. (2025). Wylegislature.gov. https://www.wylegislature.gov/Bill\_Status/bills\_text.cfm?billdoc=sb526%20sub1%20eng .htm&yr=2025&sesstype=RS&billtype=B&i=526
- Bridge Initiative for S&T Policy, Leadership, & Communications | Medical Personnel Shortage in West Virginia. (2024, November). Wvu.edu. <a href="https://scitechpolicy.wvu.edu/science-and-technology-notes-articles/2024/10/31/medical-personnel-shortage-in-west-virginia">https://scitechpolicy.wvu.edu/science-and-technology-notes-articles/2024/10/31/medical-personnel-shortage-in-west-virginia</a>