Acentra HEALTH

West Virginia rDUR NEWSLETTER

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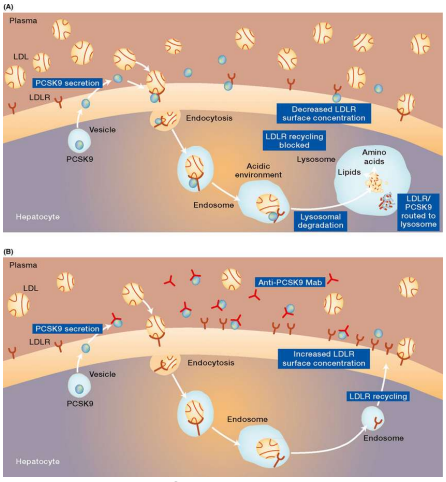
FDA APPROVAL SPOTLIGHT

LEROCHOL® (lerodalcibep-liga) Injection 300 mg/1.2 mL

Cardiovascular disease remains the leading cause of morbidity and mortality in the United States, with elevated low-density lipoprotein cholesterol (LDL-C) continuing to be one of the most significant modifiable risk factors. While statins remain first-line therapy, many patients either do not reach goal LDL-C levels or are unable to tolerate high-intensity statins. As a result, additional lipid-lowering therapies have become essential in managing high-risk patients.



Lerochol (lerodalcibep-liga)* is a novel PCSK9 inhibitor designed to significantly lower LDL-cholesterol and reduce cardiovascular risk that was approved by the U.S. Food and Drug Administration (FDA) on December 15, 2025 as adjunct therapy to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). Unlike monoclonal antibody PCSK9 inhibitors that require frequent dosing, lerodalcibep utilizes a small-binding protein technology that allows for sustained LDL reduction with less frequent administration.

By targeting PCSK9, lerodalcibep prevents degradation of LDL receptors in the liver, leading to increased clearance of circulating LDL cholesterol. Lerodalcibep 300mg demonstrated a sustained reduction of LDL-C by 50% to 55% compared to placebo over 52 weeks in the LIBerate-CVD and LIBerate-HR trials when used as an adjunct to maximally tolerated statin therapy, particularly in patients with established atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia.

Dosing	300 mg subcutaneously every 4 weeks
Adverse Effects	Injection site reaction Nasopharyngitis Diarrhea, Nausea Peripheral edema
Contraindication(s)	Pregnancy
Place in therapy	Offers an additional option for patients requiring aggressive LDL-C lowering, particularly those unable to reach guideline-directed targets on the maximally tolerated statins alone. The monthly dosing schedule may improve adherence compared with other injectable lipid-lowering agents.

**Prior authorization may be required for approval*

imaavy™ (nipocalimab-aahu)

Generalized myasthenia gravis (gMG) is a chronic autoimmune neuromuscular disease that leads to muscle weakness and fatigue. Many gMG patients continue to have disease breakthrough and limited symptom control with the standard-of-care. The primary therapies used to treat gMG are pyridostigmine, an acetylcholinesterase inhibitor, for symptomatic relief, followed by corticosteroids and nonsteroidal immunosuppressants such as mycophenolate mofetil, cyclosporine, azathioprine, methotrexate and tacrolimus for underlying immune dysregulations. Rescue options include intravenous immunoglobulin (IVIG), plasma exchange and thymectomy when thymoma is present. Biologic treatment options are available for patients in need of chronic immunotherapy with acetylcholine receptor (AChR) antibody-positive gMG or muscle-specific kinase (MuSK) antibodies.

Imaavy (nipocalimab-aahu)* is a first in class neonatal Fc receptor (FcRn) inhibitor, within the biologic therapy class, designed to reduce pathogenic autoantibodies that drive gMG offering an even more targeted approach to disease control. FcRn normally prevents immunoglobulin G (IgG) breakdown by recycling antibodies back into circulation. Blocking this receptor lowers IgG levels, including pathogenic autoantibodies such as AChR and MuSK, without affecting other immunoglobulin types.

Nipocalimab showed statistically significant improvements in myasthenia gravis activities of daily living (MG-ADL) and quantitative myasthenia gravis (QMG) scores with a favorable safety profile over six months in the ongoing vivacity-MG3 study. The primary outcome of MG-ADL score was -4.7 in the nipocalimab group versus -3.25 in the placebo group, a difference of -1.45 (95% CI, -2.38 to -0.52; p=0.0024), and the QMG score improved -4.86 versus -2.05, with a difference of -2.81 (95% CI, -4.22 to -1.41; p=0.00012). The absolute change did not reach the minimal clinically important difference in MG-ADL score of ≥2 point reduction or the QMG score of ≥3 point reduction. Nipocalimab demonstrated a sustained reduction in autoantibody levels from the first dose and throughout a 24-week period of monitoring, representing a sustained response.

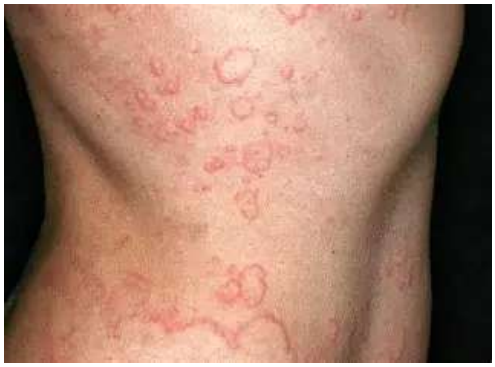
Dosing	30mg/kg loading dose, followed by 15mg/kg every 2 weeks as maintenance
Adverse Effects	Peripheral edema Respiratory tract infection Infectious disease Hypersensitivity reaction Muscle Spasms
Contraindication(s)	None. Precautions for active infection(s).
Place in therapy	New treatment option for refractory gMG patients for possible sustained disease response.

**Prior authorization may be required for approval*

Rhapsido® (remibrutinib) 25mg tablets

Chronic spontaneous urticaria (CSU) is a relapsing inflammatory skin disorder characterized by recurrent wheals and angioedema. Thought to be mediated via both IgE allergic and IgG autoimmune pathways, the activation of mast cells and basophils triggers the release of proinflammatory mediators, such as histamine, leading to the recurrent symptoms. CSU may also significantly impact the patient's quality of life by disturbing sleep patterns, productivity, and mental health. Until now, no oral targeted therapies have been available for patients with CSU.

Rhapsido (remibrutinib)* is a novel bruton's tyrosine kinase (BTK) inhibitor that reduces the mast cell and basophil activation which contributes to the release of histamine and other proinflammatory mediators. Approved by the FDA on September 30, 2025 for the treatment of CSU in adult patients who remain symptomatic despite histamine 1-antihistamine therapy. BTK inhibition may potentially have immunomodulatory effects in a subset of CSU patients.



Remibrutinib was approved based on phase three REMIX-1 and REMIX-2 trials, which demonstrated a significantly greater and sustained improvement from baseline to week 12 in urticaria activity score during a 7-day period (UAS7) compared with placebo. Just under one-third of patients in the remibrutinib group had a UAS7 score of 0, effectively showing no signs or symptoms of itching or hives at week 12. While the disease-modifying effects remain unknown, remibrutinib is the only oral therapy available after inadequate response to antihistamines.

Dosing	25 mg orally twice daily with or without food
Adverse Effects	Petechiae Headache Nasopharyngitis Abdominal pain, Nausea Hemorrhage, contusion
Contraindication(s)	None
Place in therapy	Novel ORAL treatment option for self-administration

**Prior authorization may be required for approval*

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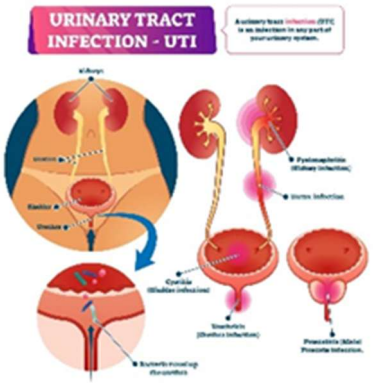
GUIDELINE UPDATES

2025 IDSA COMPLICATED UTI GUIDELINES



Urinary tract infections (UTIs) are among the most common infections treated in both outpatient and inpatient settings. While many patients present with classic lower urinary symptoms, those with structural or functional abnormalities may have more severe infections requiring broader-spectrum therapy. It is critical to differentiate between uncomplicated and complicated UTIs because this distinction directly impacts antibiotic selection, route of administration, and treatment duration.

The 2025 Infectious Diseases Society of America (IDSA) guidelines shift the focus from anatomical classification to patient-specific risk factors. Misclassification of a UTI can lead to unnecessary broad-spectrum antibiotic exposure or inadequate treatment of serious infections. These updates aim to improve clinical decision-making and support antimicrobial stewardship. urinary catheter.

Classification: Uncomplicated vs. Complication

	Uncomplicated UTI	Complicated UTI (cUTI)
Clinical Presentation	• **Infection confined to the bladder** in afebrile women or men • Local bladder signs: dysuria, urgency, frequency, and suprapubic pain.	• **Infection beyond the bladder** in men and women • Febrile or bacteremic (UTI) • Signs or symptoms of systemic illness (chills, rigors, or hemodynamic instability) • Flank pain
Population	• Females or males • Patients with underlying urologic abnormalities • Patients with immunocompromise and diabetes. • Recurrent UTI	• Catheter-Associated Urinary Tract Infection • Pyelonephritis • Neurogenic bladder, urinary obstruction, urinary retention as an underlying condition.

Pathogens

The most frequent pathogen is Escherichia coli which is approximately 75-95% of cases. Others include Proteus, Klebsiella, Staphylococcus saprophyticus (uUTI), Pseudomonas, Enterococcus (cUTI)

What's NEW in the 2025 IDSA guidelines

The 2025 IDSA guidelines introduce several changes to the diagnosis and management of complicated urinary tract infections (cUTIs), aiming to improve precision, reduce overtreatment, and reinforce stewardship.

cUTI Criteria

- Previous: cUTI was defined by anatomical location or male sex
- Current: cUTI defined by host risk factors such as urinary obstruction, catheters, transplant status, and immunosuppression, allowing for more clinically relevant categorization

Emphasis on Cultures

- Previous: did not require a urine culture before treatment
- Current: Obtain a culture prior to initiating antibiotics in all suspected cUTIs. Supporting more targeted and effective therapy

Shorter Duration of Therapy

- Previous: 10–14 days was the standard regardless of clinical course
- Current: 5–7 days for fluoroquinolones and 7 days for other agents, if patient is clinically improving. Longer durations are reserved for more complex scenarios like abscess or prostatitis.

Therapy

- Previous: fluoroquinolones widely used empirically
- Current: fluoroquinolones discouraged unless no safer options are available and the pathogen is susceptible, due to rising resistance and serious adverse effects

Treatment

Parameter	Uncomplicated UTI	Complicated UTI
First Line Agents	• Nitrofurantoin 100 mg BID x 5 days • TMP-SMX 160/800 mg BID x 3 days • Fosfomycin 3 g PO x1 dose	• Cefepime 1-2g every 8 to 12 hours • Ceftriaxone 1-2g daily13,14 Ertapenem 1g daily • Meropenem 1g every 8 hours • Piperacillin-tazobactam 4.5g every 8 hours
Route	Oral	IV initially- Switch to oral once stable
Duration	3-5 days	5–7 days (if improving) 7 days (bacteremia) 10–14 days (abscess, prostatitis, poor response)
Culture Needed?	Not routinely	Always before antibiotics
Step-Down	Not usually needed	Recommended once stable *Fluoroquinolones Oral x 5-7 days if no safer option
Considerations	Avoid fluroquinolones if possible	Replace/remove catheter in Catheter-Associated Urinary Tract Infection (CAUTI)

Sepsis

When the Patient Has Sepsis

If patient is septic, there is a higher risk for serious complications, so use broad IV antibiotics right away. That includes cefepime, piperacillin-tazobactam, or a carbapenem like meropenem. Sometimes, fluoroquinolones or aminoglycosides are also options. Aiming to cover a wide range of possible pathogens, including those that might be resistant. Once cultures come back, we can narrow the treatment based on what the labs show.

When the Patient Does Not Have Sepsis

If patient has a cUTI but isn't septic, start with a more targeted antibiotic depending on their risk factors and the setting. IV antibiotics are still common at first, but may be able to switch to oral medications sooner if doing well. Options like TMP-SMX or ceftriaxone will work if the pathogen is sensitive. The main goal is to treat the infection effectively while also avoiding overuse of broad-spectrum antibiotics.

Monitoring & Deprescribing

Monitoring Parameters	Deprescribing Plan
• **Resolution of symptoms (dysuria, urgency, fever)** • Vital signs: temperature, blood pressure, heart rate • Urinalysis: leukocyte esterase, nitrites, WBCs • Renal function: SCr, CrCl (especially if using nephrotoxic agents • Follow-up culture if bacteremia or recurrent infection	• **Discontinue empiric broad-spectrum IV antibiotics once cultures result** • Step down to narrow-spectrum oral therapy if appropriate • Reassess antibiotic duration based on clinical response (5–7 days is sufficient) • Discontinue antibiotics if symptoms resolve and culture is negative

Clinical Impact

- More precise classification
- Shorter, evidence-based durations
- Culture-guided therapy

Overall, the 2025 IDSA guideline reinforces antimicrobial stewardship while optimizing patient outcomes for the treatment of complicated UTI.