Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Frequently Revision:
Antibiotic and Antifungal - Parenteral Therapy in the Home Setting	**MP-OTHER-FP-01-25**	☒ **MMM MA** ☒ **MMM MultiHealth**	**10/01/2025** **Last Review Date:** **12/12/2025**	**Annual** **Page: 1 of 45**

Service Category:

☐ **Anesthesia**
☐ **Surgery**
☐ **Radiology Procedures**
☐ **Pathology and Laboratory Procedures**
☐ **Medicine Services and Procedures**
☐ **Evaluation and Management Services**
☐ **DME/Prosthetics or Supplies**
☒ **Other: Drugs Administered Other than Oral Method**

Service Description:

This policy addresses the administration of parenteral antibiotic and antifungal medications in the home setting for the management of acute or chronic infectious conditions when oral therapy is not feasible, not tolerated, or clinically ineffective. This policy applies to parenteral antimicrobial therapies in the home setting that require prior authorization based on medical necessity, FDA-approved indications, and applicable utilization management criteria.

A. Parenteral Antifungals:

• Antifungal agents administered intravenously, as detailed in Section A, including FDA-approved indications, dosing parameters, and monitoring requirements.

B. Parenteral Antibiotics:

• Penicillins
• Cephalosporins
• Carbapenems
• Monobactams
• Aminoglycosides
• Lipopeptides
• Oxazolidinones
• Lincosamides
• Glycylcyclines
• Other intravenous antibacterial agents commonly used in home infusion therapy

***Special Note*:** This policy applies only to parenteral administration of antibiotics and antifungals in the home setting. It does not address oral therapy, non-antimicrobial infusions, or hospital management, all of which are governed by separate policies. In addition, any use of the medications listed in this policy that does not correspond to the expressly established indications must be evaluated in accordance with current Medical Policies and/or pharmacy utilization management requirements, including applicable benefit determinations.

Background Information:

According to the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 7, Section 50.4 'Reasonableness and Necessity'), drugs and biologicals must be approved for marketing by the FDA to be considered safe and effective for coverage. Therefore, only antimicrobial agents with a valid FDA-approved prescribing information may be eligible under this Home Parenteral Antimicrobial Therapy policy [1].

Home parenteral therapy has become a safe, effective, and cost-efficient alternative for patients requiring extended antimicrobial treatment outside the hospital (IDSA, 2018) [2].

- Clinical effectiveness: Reduces hospital stays, lowers nosocomial infection risk, and improves patient satisfaction (CDC, 2016; NHIA, 2024) [3-4]
- Patient selection: Requires correct diagnosis, hemodynamic stability, functional venous access, and a safe home environment with trained caregiver support (Norris et al., 2019) [5].
- Interdisciplinary coordination: Therapy requires involvement of prescriber, pharmacist, skilled nurse, and laboratory monitoring (IDSA, 2018; NHIA, 2024) [2-4].
- Stewardship and safety: Therapy must follow evidence-based guidelines for agent selection, dose, frequency, duration, monitoring, and step-down to oral therapy when appropriate (CDC, 2016) [3].

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The most recent National Home Infusion Association (NHIA) standards state that parenteral antibiotic management at home requires an interdisciplinary approach, including physician, pharmacist, skilled nursing, and laboratory monitoring coordination (NHIA, 2024).

This policy summarizes FDA-approved dosing parameters for parenteral antimicrobial drugs [15-54]. These parameters are provided for coverage reference, not as a substitute for clinical judgment. Final dosing requires prescriber assessment, patient-specific factors, and current clinical guidelines.

CDC Antibiotic Stewardship:
This policy aligns with the CDC Core Elements of Outpatient Antibiotic Stewardship to ensure the proper and safe use of antibiotics, including appropriate agent selection, correct dosage, minimum effective duration, review of cultures, transition to oral therapy when clinically possible, and ongoing monitoring to prevent antimicrobial resistance [5].

Classification of services:
There are injectable medications that are classified under different cpt codes even though they share the same amount of active substance [52,53]. This occurs when formulations are not considered equivalent, or when the presentation corresponds to a specific manufacturer. For compliance and billing purposes, the code that corresponds to the exact presentation administered, according to product labeling and clinical documentation, must be used.

Conversion from Parenteral to Oral Therapy:
Certain antimicrobials with high oral bioavailability (e.g., fluoroquinolones, oxazolidinones, metronidazole, clindamycin, trimethoprim-sulfamethoxazole, fluconazole, voriconazole) may be converted from intravenous to oral therapy once the patient meets predefined clinical stability criteria. This strategy reduces duration of IV therapy, lowers risk of catheter-related complications, shortens hospital stay, and decreases healthcare costs without compromising treatment effectiveness. A formal, institutional IV-to-oral conversion program is therefore an essential component of a responsible antimicrobial stewardship strategy [56].

Medicare Benefit Policy Manual:
The Centers for Medicare & Medicaid Services (CMS) allows coverage for the IV home service as broken down in Chapter 7: Home Health Services Therapies and indicates that the service have medically necessary, clinically appropriate, and included in a plan of care supervised by a qualified provider. According to the Medicare Benefit Policy Manual, Chapter 7, intravenous, intramuscular, subcutaneous, hypodermoclysis, or nutrition medication administration services parenteral in-home setting They require the involvement of qualified clinical staff, such as a registered nurse, for safe and effective administration or teaching [6-7].

Coverage and Benefit Considerations:
While this policy summarizes FDA-approved dosing parameters and clinical considerations for parenteral antimicrobial therapy in the home setting, it is intended solely to define clinical eligibility and medical necessity. Coverage determinations, including benefit assignment and pharmacy utilization management requirements (such as prior authorization under Medicare Part D), are administered independently in accordance with the member's benefit plan and applicable CMS regulations. This policy does not supersede pharmacy benefit determinations or utilization management criteria maintained by the Department of Pharmacy.

Coverage under this policy is limited to FDA-approved indications. Off-label use is not considered medically necessary unless separately reviewed and approved in accordance with applicable medical and pharmacy policies.

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Medical Necessity Guidelines:

The following medical necessity criteria apply to both parenteral antibiotic and antifungal therapies unless otherwise specified in the medication-specific tables. The indication of parenteral antibiotics and/or antifungals In Home Settings should be supported by a documented medical necessity, and their administration should be conducted according to standardized protocols for preparation, follow-up, and transition to oral therapy [7-9]. It is considered medically necessary when it meets all the following:

1. **Eligible clinical diagnosis, application must meet all the following [2-3]:**
   - A. Severe bacterial infections requiring parenteral treatment (e.g., but not limited, osteomyelitis, endocarditis, complicated pneumonia, skin and soft tissue infections, severe intra-abdominal or urinary tract infections).
   - B. Diagnosis documented by the treating physician by culture, susceptibility testing, or other valid microbiological evidence (IDSA, 2018 [3]; CDC, 2023 [2]).

   and;

2. **Impossibility or ineffectiveness of oral therapy, application must comply with all the following [3 –7]:**
   - A. The patient has intolerance, contraindication, or documented failure to appropriate oral antibiotics.

   and;

3. **Medical stability, application must meet (1) the following [3 –7]:**
   - A. The patient has achieved sufficient clinical stability to receive treatment outside the hospital setting. **or;**
   - B. Does not require continuous monitoring or advanced life support.

   and;

4. **Documented Treatment Plan [3 –7]:**
   - C. Prescription by a qualified physician, specifying the antimicrobial agent, estimated duration, frequency of administration, and required clinical monitoring.

   and;

5. **Appropriate clinical support: [3 –7]:**
   - A. Functional venous access (peripheral or central catheter).
   - B. Supervision by competent clinical staff or self-administration with documented training.
   - C. Availability of drug-based laboratory monitoring (serum levels, kidney or liver function, blood count, etc.).

   and;

6. **Ordered Drug [15-54]:**
   - A. The ordered drug must meet FDA-approved indications, adult and pediatric doses, Renal/hepatic adjustments, contraindications, warnings, caution, adverse reactions and limitations described in the FDA's Drug-Specific Requirements section.

Not Medical Necessity:

Home therapy is not medically necessary if ANY of the following apply:

1. Oral therapy is appropriate [3].
2. Insufficient clinical documentation for diagnosis, dose, or rationale [4].
3. Use outside FDA-approved or guideline-supported therapy [2-3].
4. Does not meet CMS “reasonable and necessary” criteria [1-4]

— END OF MEDICAL NECESSITY GUIDELINES —

Medication-Specific FDA Requirement:

A. PARENTERAL ANTIFUNGALS						
Medication (generic-brand)	**Route**	**Clinical Indications**	**Adult Dose**	**Pediatric Dose**	**Adjustments**	**Source**
A.1.Antifungals						
Anidulafungin - ERAXIS®	**Route** Intravenous (IV) only, lyophilized powder for infusion.	**Clinical Indications** •Candidemia •Other invasive Candida infections (including intra-abdominal abscess & peritonitis) •Esophageal candidiasis	**Adult Dose** • Candidemia / Invasive Candida: – Day 1: 200 mg IV (loading) – Then: 100 mg IV once daily • Esophageal candidiasis: – Day 1: 100 mg IV – Then: 50 mg IV once daily	**Pediatric Dose** **Pediatric Dosing** (≥ 1 month) • Candidemia / Intra-abdominal Candida: – Day 1: 3 mg/kg IV (max 200 mg) – Then: 1.5 mg/kg IV once daily (max 100 mg) • Esophageal candidiasis: – Not approved in pediatrics.	**Adjustments** **Renal / Hepatic Adjustments** • Renal impairment: No dose adjustment required. • Hepatic impairment: No defined adjustments; use caution in severe hepatic dysfunction (limited data).	[15]
Caspofungin acetate - CANCIDAS®	**Route** Only IV in infusion, not bolus.	**Clinical Indications** •Esophageal candidiasis. •Candidemia and other *Candida* infections (e.g., intra-abdominal abscess). • Empirical therapy of fungal infections in febrile neutropenic patients. •Invasive aspergillosis in adults and pediatrics (≥ 3 months) refractory or intolerant to other therapies.	**Adult Dose** [18 years and older] •Administer a single loading dose of 70 mg on day 1, followed by 50 mg once daily for all indications except esophageal candidiasis. For esophageal candidiasis, use 50 mg once daily without loading dose.	**Pediatric Dose** Pediatric Patients [3 Months to 17 Years] • The dose should be based on the patient's body surface area. • For all indications, administer a single loading dose of 70 mg/m² on day 1, followed by 50 mg/m² once daily thereafter. •The maximum loading dose and daily maintenance dose should not exceed 70 mg, regardless of the	**Adjustments** Adjustments for renal/hepatic function •Renal: no adjustment required. •Moderate hepatic (Child-Pugh B): adult maintenance dose 35 mg/day. •There are insufficient data on severe liver failure.	[16]

				dose calculated for the patient		
Fluconazol-DIFLUCAN® Injection	**Route** IV (iso-osmotic solution in sodium chloride or dextrose).	**Clinical Indications** • Oropharyngeal and esophageal candidiasis • Systemic candidiasis, including candidemia • Cryptococcal meningitis • Prophylaxis in bone marrow transplant patients at risk of fungal infections.	**Adult Dose** Adult (IV) dose • 200–400 mg/day IV as indicated. •Cryptococcal meningitis: loading dose 400 mg, then 200–400 mg once daily.	**Pediatric Dose** •3–12 mg/kg/day IV, depending on the severity and type of infection; do not exceed adult dose.	**Adjustments** Adjustment for renal function: • Requires dose reduction when ClCr ≤ 50 mL/min (e.g., 50% of maintenance dose). • Adjustment by liver function • Caution in liver failure; the label does not provide a numerical adjustment scheme but recommends monitoring liver function tests.	[17]
Voriconazole-NVFEND®	**Route** Intravenous (IV)	**Clinical Indications** • Azole antifungal indicated for adults and pediatric patients ≥2 years Treatment of: • Invasive aspergillosis. • Candidemia in nonneutropenic patients and other deep *Candida infections*. • Esophageal candidiasis. •Severe fungal infections with *Scedosporium apiospermum* and *Fusarium spp.* in patients who are intolerant or refractory to other therapies.	**Adult Dose** Invasive aspergillosis: • Load: 6 mg/kg IV every 12 h for 2 doses. • Maintenance: 4 mg/kg IV every 12 hr. •Candidemia and other Candida infections: • Load: 6 mg/kg IV every 12 h for 2 doses. • Maintenance: 3–4 mg/kg IV every 12 hr. • Escedosporiosis and Fusarium: • Loading: 6 mg/kg IV every 12 h for 2 doses. • Maintenance: 4 mg/kg IV every 12 hr. • Candidiasis esofágica: • Intravenous infusion - Not Evaluated	**Pediatric Dose** Pediatric (≥2 years): • Invasive aspergillosis / Candida infections, Scedosporium, Fusarium: • Load: 9 mg/kg IV every 12 h for 2 doses. • Maintenance: 8 mg/kg IV every 12 h. • Esophageal candidiasis: • Maintenance: 4 mg/kg IV every 12 hr. • In patients aged 12–14 years ≥50 kg, use adult doses.	**Adjustments** In patients with moderate or severe renal impairment (CrCl <50 mL/min), it is recommended to avoid the intravenous formulation of voriconazole due to accumulation of the excipient SBECD (sulfobutyl ether beta-cyclodextrin). •In these patients, systemic exposure (AUC) of SBECD increases approximately 4 times and the maximum concentration (Cmax)	[18]

			• Reduce doses in adults <40 kg: 100 mg PO every 12 hr.		increases by about 50% compared to subjects with function renal normal. • Intravenous use should be avoided whenever possible; Consider alternative routes of management.	

B. PARENTERAL ANTIBIOTICS

Antibiotic Classes by Spectrum of Activity

- 🔵 High-Spectrum (Broad-Spectrum) Antibiotics
- 🟢 Medium-Spectrum Antibiotics
- 🟡 Low-Spectrum (Narrow-Spectrum) Antibiotics

Medication (generic brand)	Route	Clinical Indications	Adult Dose	Pediatric Dose	Adjustments	Source
B.1. Penicillins						
🟡 **Penicillin G Potassium-Pfizerpen ®**	**Route** Intravenous (IV)	**Clinical Indications** Serious infections caused by susceptible microorganisms, including: •Streptococci (including *Streptococcus pneumoniae*). •Sensitive staphylococci (non-penicillinase producing). •*Neisseria meningitidis, Neisseria gonorrhoeae.* •*Clostridium*spp., *Corynebacterium diphtheriae, Listeria monocytogenes*.	**Adult Dose** Usually 5–24 million units/day, IV, divided every 4–6 h, depending on infection. • Meningitis and endocarditis may require 18–24 million U/day.	**Pediatric Dose** Approximately 100,000–400,000 U/kg/day IV, divided depending on the indication (the label gives specific ranges by entity).	**Adjustments** Adjustments for renal function: In severe renal impairment, it is recommended to reduce the dose or prolong the interval and monitor for toxicity (seizures, electrolytes).	[19]

		•*Treponema pallidum* (syphilis) and other spirochetes.				
🟡 **Penicillin G Benzathine - Bicillin® L-A**	**Route** Intramuscular (IM)	**Clinical Indications** Penicillin G benzathine IM is indicated for infections caused by penicillin G-sensitive microorganisms, compatible with the low and prolonged serum levels produced by this formulation. • Therapy should be guided by bacteriological studies (including sensitivity tests) and by the clinical response of the patient. • Infections that generally respond to adequate doses of penicillin G benzathine IM include: • Mild to moderate upper respiratory tract infections with susceptible streptococci. • Venereal infections — for example, syphilis, and other sensitive treponemal diseases. • It is also indicated as prophylaxis under certain conditions, when indicated.	**Adult Dose** a single injection of 1,200,000 units. • Primary, secondary and latent syphilis: 2,400,000 units (1 dose). • Late (tertiary and neurosyphilis): 2,400,000 units every 7 days for three doses. • Congenital, under 2 years of age: 50,000 units/kg of body weight. • Ages 2 to 12 years: adjust doses according to the adult schedule. • Yaws, Bejel and Pinta: 1 injection of 1,200,000 units. • Prophylaxis — for rheumatic fever and glomerulonephritis. • After an acute attack, parenteral benzathine penicillin G may be administered at doses of 1,200,000 units once a month or 600,000 units every 2 weeks.	**Pediatric Dose** Older pediatric patients: a single injection of 900,000 units. • Infants and pediatric patients weighing <60 pounds: 300,000 to 600,000 units	**Adjustments** Levels by decreasing the apparent volume of distribution and slowing the rate of excretion by competitively inhibiting renal tubular secretion of penicillin.	[20]
🟢 **Ampicillin 500 mg inj-Ampicillin for Injection, USP**	**Route** Intravenous (IV) or Intramu	**Clinical Indications** Used for infections caused by susceptible organisms, including:	**Adult Dose** Respiratory and Soft Tissue Infections • ≥40 kg: 250–500 mg q6h	**Pediatric Dose** Bacterial Meningitis • 150–200 mg/kg/day, divided q3–4h	**Adjustments** Ampicillin requires dose reduction or extension of dosing interval	[21]

	scular (IM)	•Respiratory tract infections *S. pneumoniae, S. aureus, H. influenzae, Group A Streptococcus* •Meningitis *E. coli, Group B Streptococcus, L. monocytogenes, N. meningitidis* • Sepsis and endocarditis *Streptococcus spp., penicillin-sensitive staphylococci, enterococci, E. coli, Proteus mirabilis, Salmonella spp.* • Urinary tract infections *E. coli, P. mirabilis* • Gastrointestinal infections *Salmonella spp., Shigella spp.* Note: May be combined with an aminoglycoside for enhanced Gram-negative coverage. Switch to oral ampicillin when clinically appropriate.	• <40 kg: 25–50 mg/kg/day, divided q6–8h GI and GU Infections (incl. female gonorrhea) • ≥40 kg: 500 mg q6h • <40 kg: 50 mg/kg/day, divided q6–8h • Severe or chronic infections: higher doses, prolonged therapy, and close monitoring. Gonococcal Urethritis (Men) • 500 mg, repeat 500 mg in 8–12 h • Extended therapy for prostatitis or epididymitis • If syphilis suspected: dark-field exam + monthly serology × 4months Bacterial Meningitis (Adults) •150–200 mg/kg/day, divided q3–4h • Start IV; may continue IM Sepsis (Adults) •150–200 mg/kg/day • Start IV ≥3 days, then IM q3–4h	• Start IV; continue IM as needed Sepsis (Children) • 150–200 mg/kg/day Neonatal Dosing (≤28 days) Based on gestational and postnatal age: • ≤34 weeks GA & ≤7 days: 100 mg/kg/day, q12h • ≤34 weeks GA & 8–27 days: 150 mg/kg/day, q12h • >34 weeks GA & ≤28 days: 150 mg/kg/day, q8h	in renal impairment according to creatinine clearance (CrCl). Recommended Adjustments: • CrCl ≥ 50 mL/min: Use usual dosing (no adjustment). • CrCl 30–49 mL/min: Extend interval to q6–8h instead of q4–6h. • CrCl 10–29 mL/min: Administer every 12 hours. • CrCl < 10 mL/min: Administer every 12–24 hours, depending on severity. Monitor closely for neurotoxicity (e.g., seizures). • Hemodialysis: Give a supplemental dose after dialysis (drug is dialyzable).	
Ampicillin sodium 1.5 g - UNASYN®	**Route** Intravenous (IV) or Intramuscular (IM).	**Clinical Indications** Same indications as ampicillin — bacterial infections by susceptible organisms; surgical prophylaxis in certain surgeries.	**Adult Dose** Adults1.5 g (1 g ampicillin + 0.5 g sulbactam) to 3 g (2 g ampicillin + 1 g sulbactam) every 6 hours. Maximum dose of sulbactam: 4 g/day.	**Pediatric Dose** Pediatric (≥1 year) • 300 mg/kg/day (200 mg ampicillin + 100 mg sulbactam/kg/day), in divided doses every 6 h. • IM administration in	**Adjustments** Creatinine clearance (mL/min) Half-life (h) Recommended dose≥30 1 1.5–3 g every 6–8 h15–29 5 1.5–3 g every 12 h5–14 9 1.5–3 g every 24 h	[22]

				children is not recommended. • If the weight ≥40 kg, use adult doses (not to exceed 4 g/day of sulbactam). •Usual duration of IV therapy: ≤14 days.	•Administer less frequently in severe renal impairment.	
Nafcillin sodium-Nallpen®	**Route** Intravenous (IV) or Intramuscular (IM).	**Clinical Indications** Treatment of susceptible penicillinase-producing staphylococci infections, for example: • Sepsis. • Endocarditis. • Skin and soft tissue infections. • Bone and joint infections. • Respiratory, urinary and other infections caused by sensitive staphylococci.	**Adult Dose** Usual adult dose (IV/MI) • Moderate-severe infections: 1–2 g IV every 4 h (4–12 g/day depending on severity) .• MI may be used for less severe infections or as a continuation.	**Pediatric Dose** Usual dose in the pediatric population • Usually 25–50 mg/kg/day in divided doses every 4–6 h for mild/moderate infections. • For severe infections: 100–200 mg/kg/day divided every 4–6 h.	**Adjustments** •Adjustments for renal/hepatic function •The label indicates that nafcillin is eliminated primarily by the hepatic route. • It is usually not adjusted for renal impairment alone; caution is advised when renal and hepatic dysfunction coexist.	[23]
Piperacillin/Tazobactam-ZOSYN®	**Route** Intravenous (IV) as an infusion.	**Clinical Indications** Complicated intra-abdominal infections. •Complicated infections of skin and skin structures .•Community-acquired pneumonia. •Nosocomial pneumonia (including ventilator-associated, with specific recommendations). •Gynaecological infections (e.g. postpartum	**Adult Dose** Usual adult dose (IV) • Usual dose: 3.375 g (3 g piperacillin / 0.375 g tazobactam) IV every 6 h (total 13.5 g/day). •Nosocomial pneumonia: 4.5 g IV every 6 h • Infusion: about 30 minutes.	**Pediatric Dose** Pediatric (IV) dose • 2 months–12 years, complicated intra-abdominal infections: • 80 mg/kg piperacillin + 10 mg/kg tazobactam every 6–8 h (max. adult dose).	**Adjustments** Adjustments for renal function (adult) • ClCr 20–40 mL/min: 2.25 g IV every 6 h • ClCr < 20 mL/min: 2.25 g IV every 8 h. • Hemodialysis: 2.25 g IV every 12 h with an additional dose of 0.75 g after each dialysis.	[24]

		endometritis, pelvic infections).				
B.2. Cephalosporins						
● **Cefazolin sodium - Ancef®**	**Route** 2g/vial: IV infusion or IV bolus. *Not for IM use.* 3g/vial: IV infusion only. *Not for IV bolus or IM use.*	**Clinical Indications** Cefazolin for Injection is a cephalosporin antibacterial indicated for: • Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients 1 month of age and older for whom appropriate dosing with this formulation can be achieved: •Respiratory tract infections (1.1) •Urinary tract infections (1.2) •Skin and skin structure infections (1.3) o Biliary tract infections (1.4) •Bone and joint infections (1.5) •Genital infections (1.6) • Septicemia (1.7) Endocarditis (1.8) •Perioperative prophylaxis in adult patients (1.9)	**Adult Dose** Mild infections (gram-positive cocci): 250–500 mg every 8h • Moderate to severe infections: 500 mg–1 g every 6–8 h • Acute, uncomplicated UTI: 1 g every 12 h • Pneumococcal pneumonia: 500 mg every 12 h • Serious or life-threatening infections (e.g., endocarditis, sepsis): 1–1.5 g every 6 h	**Pediatric Dose** Pediatric Dosing (CLcr ≥ 70 mL/min) • Mild to moderate infections: 25–50 mg/kg/day, divided q6–8h (3–4 doses) • Severe infections: Up to 100 mg/kg/day, divided q6–8h (3–4 doses)	**Adjustments** Dose Adjustments • Adults: Reduce dose when creatinine clearance (CLcr) < 55 mL/min • Pediatrics: Reduce dose when CLcr < 70 mL/min	[25]
● **Cefuroxime - DUPLEX®**	**Route** Intravenous (IV)	**Clinical Indications** Infections of the respiratory tract, urinary tract, skin/soft tissues, meningitis (in some cases), and others due to susceptible organisms according to label.	**Adult Dose** •Usual: 750 mg – 1.5 g every 8 h for 5–10 days. •Severe infections: 1.5 g every 8 h. •Bone/joint infections: 1.5 g every 8 h.	**Pediatric Dose** Usual dose: 50–100 mg/kg/day, divided every 6–8 hours, effective for most cefuroxime-susceptible infections. • Severe infections: 100 mg/kg/day, not	**Adjustments** Renal impairment: adjust dose by creatinine clearance. Pediatrics: Renal insufficiency: adjust dosing	[26]

			•Life-threatening: 1.5 g every 6 h. •Meningitis: ≤3 g every 8 h.	exceeding maximum adult dose. • Bone and joint infections: 150 mg/kg/day, divided every 8 hours, not exceeding maximum adult dose .• Bacterial meningitis: 200–240 mg/kg/day IV, divided every 6–8 hours.	frequency as per adult recommendations.	
🟢 **Ceftriaxone - ROCEPHIN**	**Route** Intravenous (IV)	**Clinical Indications** • Lower respiratory tract infections • Acute bacterial otitis media • Skin and skin structure infections • Urinary tract infections • Pelvic inflammatory disease • Bacterial sepsis • Bone and joint infections •Intra-abdominal infections • Meningitis • Surgical prophylaxis	**Adult Dose** For intravenous use only, given over approximately 30 minutes. Use this formulation only in patients requiring the full dose of 1 g or 2 g (not for fractionated doses). Recommended dosages: • Usual adult dose: 1 g to 2 g once a day or divided every 12 hours. The total daily dose should not exceed 4 g. Surgical prophylaxis: 1 g administered 1/2 to 2 hours before surgery. • Infections of the skin and skin structures: 50 mg/kg to 75 mg/kg every 12 hours, not to exceed 2 g daily. • Patients with significant hepatic and renal impairment should not receive	**Pediatric Dose** Ceftriaxone for Injection and Dextrose Injection in the DUPLEX® Container is designed to deliver a 1 g or 2 g dose of ceftriaxone. To prevent unintentional overdose, this product should not be used in pediatric patients who require less than the full adult dose of ceftriaxone. [see Use in Specific Populations (8.4)]	**Adjustments** Does not fit in renal insufficiency (noticeable biliary excretion) — beware of neonatal bilirubin Adjustment in renal impairment (estimated CrCl): • >50 mL/min: Full dose (1.5 g IV every 8 hours) .• 30–50 mL/min: 750 mg (500/250 mg) IV every 8 hours. • ESRD on hemodialysis: Starting dose of 750 mg (500/250 mg) IV, then 150 mg (100/50 mg) IV every 8 hours after dialysis.	[27]

			more than 2 g per day of ceftriaxone.			
🟢 **Cefotaxime – Claforan®**	**Route** Intramuscular (IM) or Intravenous (IV)	**Clinical Indications** Cefotaxime is used for the treatment of infections caused by susceptible organisms, including: • Lower respiratory tract infections • Genitourinary infections, including uncomplicated gonorrhea • Gynecologic infections (PID, endometritis, pelvic cellulitis) • Bacteremia/Septicemia • Skin and soft tissue infections • Intra-abdominal infections • Bone and joint infections • Central nervous system infections (meningitis, ventriculitis) Note: No activity against *Chlamydia trachomatis*; add appropriate therapy if suspected.	**Adult Dose** AdultDosing •Uncomplicated infections: 2 g/day (1 g every 12 h IM/IV) • Moderate to severe infections: 3–6 g/day (1–2 g every 8 h IM/IV) • Sepsis or infections requiring high doses: 6–8 g/day (2 g every 6–8 h IV) • Life-threatening infections: Up to 12 g/day (2 g every 4 h IV) • Gonococcal urethritis/cervicitis (men/women): 0.5 g IM single dose • Rectal gonorrhea: Women: 0.5 g IM once Men: 1 g IM once	**Pediatric Dose** Neonates (0–1 month): • First week: 50 mg/kg every 12 h IV • Weeks 1–4: 50 mg/kg every 8 h IV Infants/Children (1 month–12 years): • <50 kg: 50–180 mg/kg/day in 4–6 divided doses (use higher doses for severe infections/meningitis) • ≥50 kg: use adult dosing • Maximum daily dose: 12 g	**Adjustments** Renal Impairment • Drug accumulation may occur in patients with reduced urinary output. • Reduce total daily dose when creatinine clearance <20 mL/min/1.73 m² (suggested: 50% reduction). • Dose should be individualized based on: • degree of renal dysfunction • severity of infection • organism susceptibility	[28]
🔵 **Ceftazidime-FORTAZ®**	**Route** Intramuscular (IM) or Intravenous (IV)	**Clinical Indications** Indications FORTAZ is indicated for infections caused by susceptible organisms, including: Lower respiratory tract infections (incl. pneumonia) *P. aeruginosa, H. influenzae, Klebsiella spp., Enterobacter spp., Proteus spp., E. coli, Serratia spp.,*	**Clinical Indications** Adult Dosing Usual dose: • 1 g IV/IM every 8–12 h Other dosing based on infection Condition Dose Uncomplicated UTI 250 mg IV/IM q12h Complicated UTI 500 mg IV/IM q8–12h	**Pediatric Dose** Pediatric Dosing • Neonates (0–4 weeks): 30 mg/kg IV q12h • 1 month–12 years: 30–50 mg/kg IV q8h (max 6 g/day) • Higher doses may be required in: immunocompromised patients,	**Adjustments** Renal Impairment Ceftazidime is eliminated almost entirely by glomerular filtration. Dose adjustment required when: • GFR < 50 mL/min General	[29]

			Citrobacter spp., S. pneumoniae, MSSA Skin and skin structure infections *P. aeruginosa, Klebsiella spp., E. coli, Proteus spp., Enterobacter spp., Serratia spp., MSSA, Group A streptococcus* Urinary tract infections (complicated/uncomplicated) *P. aeruginosa, Enterobacter spp., Proteus spp., Klebsiella spp., E. coli* Bacterial septicemia *P. aeruginosa, Klebsiella spp., H. influenzae, E. coli, Serratia spp., S. pneumoniae, MSSA* Bone and joint infections *P. aeruginosa, Klebsiella spp., Enterobacter spp., MSSA* Gynecological infections *Endometritis, pelvic cellulitis; caused primarily by E. coli* Intra-abdominal infections *E. coli, Klebsiella spp., MSSA; mixed aerobic/anaerobic infections (variable activity vs. Bacteroides spp.)* Central nervous system infections (meningitis) *H. influenzae, N. meningitidis; limited success in P.*	Bone and joint infections 2 g IV q12h Uncomplicated pneumonia / mild skin infections 500 mg–1 g IV/IM q8h Serious gynecologic / intra-abdominal infections 2 g IV q8h Meningitis 2 g IV q8h Severe infections / immunocompromised 2 g IV q8h Pulmonary Pseudomonas (cystic fibrosis) 30–50 mg/kg IV q8h (max 6 g/day)	cystic fibrosis, or meningitis	guidance (based on CLcr): • 50–31 mL/min: Standard dose at extended intervals • 30–16 mL/min: Reduced dose • 15–6 mL/min: Further reduction; therapeutic monitoring recommended • <6 mL/min: Individualized dosing based on infection severity and organism susceptibility	

		aeruginosa and S. pneumoniae				
🔵 **Ceftazidime /Avibactam - Avycaz®**	**Route** Intravenous (IV)	**Clinical Indications** •Approved indications (patients ≥18 years of age): • Complicated intra-abdominal infections (cIAI), used with metronidazole. •Complicated urinary tract infections (UTIs), including pyelonephritis. •Hospital-associated bacterial pneumonia (HABP) and ventilator-associated pneumonia (VABP). •Use directed at susceptible Gram-negative microorganisms. •It should be used only in proven or strongly suspected infections to reduce bacterial resistance.	**Adult Dose** AVYCAZ 2.5 g (ceftazidime 2 g + avibactam 0.5 g). IV administration in 2 hours, every 8 hours. For patients ≥18 years with CrCl >50 mL/min.	**Pediatric Dose** Safety and effectiveness in patients less than 18 years of age have not been established.	**Adjustments** CrCl 31–50 mL/min: AVYCAZ 2.25 g every 8 h. CrCl 16–30 mL/min: AVYCAZ 1.5 g every 12 h. CrCl 6–15 mL/min: AVYCAZ 0.94 g every 12 h. CrCl ≤5 mL/min: AVYCAZ 0.94 g every 48 h. Haemodialysis: three times a week, after haemodialysis on the days that correspond.	[30]
🔵 **Cefepime-MAXIPIMET M®**	**Route** Intravenous (IV) or Intramuscular (IM)	**Clinical Indications** Cefepime is indicated for infections caused by susceptible organisms, including: • Moderate to severe pneumonia *S. pneumoniae (including bacteremia), P. aeruginosa, K. pneumoniae, Enterobacter spp.* • Febrile neutropenia (empiric therapy) • Can be used as monotherapy • In high-risk patients (bone marrow transplant, hypotension, hematologic	**Adult Dose** Adult Dosing (CLcr > 60 mL/min) • Moderate to severe pneumonia: 1–2 g IV every 12 h × 10 days • Febrile neutropenia: 2 g IV every 8 h × 7 days • Mild to moderate UTI: 0.5–1 g IV/IM every 12 h × 7–10 days • Severe UTI: 2 g IV every 12 h × 10 days • Moderate to severe skin infections: 2 g IV every 12 h × 10 days	**Pediatric Dose** Pediatric Dosing (2 months–16 years) • Skin infections, pneumonia, ICU patients: 50 mg/kg/dose every 12 h • Febrile neutropenia: 50 mg/kg/dose every 8 h • Duration: same as adult indications • Maximum pediatric dose must not exceed adult dose • Renal impairment: adjust	**Adjustments** Renal Impairment (Adults) • CLcr 30–60 mL/min: Extend dosing interval (every 24 h) • CLcr 11–29 mL/min: Reduce dose + extend interval to every 24 h • CLcr <11 mL/min: Reduce dose further + every 24 h • Peritoneal dialysis: Dose every 48 h • Hemodialysis:	[31]

		malignancy, severe or prolonged neutropenia), monotherapy may be insufficient • Urinary tract infections (uncomplicated and complicated) *E. coli, K. pneumoniae, P. mirabilis* • Uncomplicated skin and skin structure infections *MSSA, Streptococcus pyogenes* • Complicated intra-abdominal infections (with metronidazole) *E. coli, Streptococcus viridans, P. aeruginosa, K. pneumoniae, Enterobacter spp., B. fragilis* **Note:** Use only when infection is proven or strongly suspected to involve susceptible bacteria.	• Complicated intra-abdominal infections (with metronidazole): 2 g IV every 12 h × 7–10 days	proportionally, using adult guidance (no precise pediatric data available)	• 1 g on day 1, then 500 mg every 24 h • Administer after hemodialysis **Pediatric renal dosing:** adjust proportionally to adult recommendations.	
🔵 **Ceftolozane/tazobactam - Zerbaxa®**	**Route** Intravenous (IV)	**Clinical Indications** Complicated intra-abdominal infections (in combination with metronidazole). • Complicated urinary tract infections, including pyelonephritis. • To reduce the development of resistant bacteria, it should only be used in infections that are proven or strongly suspected to be caused by susceptible microorganisms.	**Adult Dose** Standard dosage: 1.5 g (ceftolozan 1 g / tazobactam 0.5 g) IV every 8 hours, infused in 1 hour. •15–29 mL/min: 375 mg (250/125 mg) IV every 8 hours.	**Adult Dose** ZERBAXA has not been studied in pediatric patients.	**Adjustments** Adjust for renal impairment (reduced dose by CrCl) • Adjustment in renal impairment (estimated CrCl): • >50 mL/min: Full dose (1.5 g IV every 8 hours). • 30–50 mL/min: 750 mg (500/250 mg) IV every 8 hours. • ESRD on hemodialysis: Starting dose of 750 mg (500/250 mg) IV, then 150	[32]

					mg (100/50 mg) IV every 8 hours after dialysis.	
🔵 **Ceftaroline fosamil -Teflaro ®**	**Route** Intravenous (IV)	**Clinical Indications** Teflaro is indicated for the treatment of: 1. Acute bacterial infections of skin and skin structure (ABSSSI). 2. Community-acquired pneumonia (CABP).	**Adult Dose** • 600 mg IV every 12 hours • Infusion given over 1 hour • For adults ≥18 years	**Pediatric Dose** Safety and effectiveness in pediatric patients have not been established.	**Adjustments** Creatinine clearance (mL/min) Teflaro > 50 No adjustment required > 30 to ≤ 50 400 mg IV (about 1 hour) every 12 hours ≥ 15 to ≤ 30 300 mg IV (about 1 hour) every 12 hours End-stage renal disease (ESRD), including hemodialysis 200 mg IV (about 1 hour) every 12 hours	[33]
🟢 **Cefoxitin sodium-MEFOXIN®**	**Route** Intravenous (IV)	**Clinical Indications** Indications • Serious infections caused by susceptible organisms. • Lower respiratory infections (pneumonia, lung abscess). • Urinary tract infections. • Intra-abdominal infections (peritonitis, abscess). • Gynecologic infections (PID, endometritis, pelvic cellulitis). • Sepsis. • Bone and joint infections. • Skin and soft tissue infections. • No activity against Chlamydia trachomatis; add anti-chlamydial	**Adult Dose** Adult Dosing • Usual dose: 1–2 g every 6–8 hours. • Uncomplicated infections: 1 g every 6–8 hours (3–4 g/day). • Moderate to severe infections: 1 g every 4 hours or 2 g every 6–8 hours (6–8 g/day). • Severe infections (e.g., gas gangrene): 2 g every 4 hours or 3 g every 6 hours (up to 12 g/day). • Group A streptococcal infections: treat ≥10 days. • Staphylococcal abscesses may require surgical drainage.	**Pediatric Dose** Pediatric Dosing (≥3 months) • 80–160 mg/kg/day, divided into 4–6 doses. • Higher doses for severe infections. • Maximum: 12 g/day. •No recommendations for infants <3 months. • Renal adjustments: proportional to adult reductions.	**Adjustments** Renal Impairment (Adults) • Give 1–2 g loading dose, then adjust maintenance dosing. • CLcr 50–30 mL/min: 1–2 g every 8–12 hours. • CLcr 29–10 mL/min: 1–2 g every 12–24 hours. • CLcr 9–5 mL/min: 0.5–1 g every 12–24 hours. • CLcr <5 mL/min: 0.5–1 g every 24–48 hours.	[34]

		therapy if suspected.				
B.3. Carbapenems						
🔵 **Meropenem - MERREM® IV**	**Route** Intravenous (IV)	**Clinical Indications** Indications • Complicated skin and skin structure infections (adults; pediatrics ≥3 months). • Complicated intra-abdominal infections (adults and pediatrics). • Bacterial meningitis (pediatric patients ≥3 months).	**Adult Dose** • Skin and soft tissue infections: 500 mg every 8 hours. • Intra-abdominal infections: 1 g every 8 hours. • Complicated skin infections caused by *Pseudomonas aeruginosa*: 1 g every 8 hours. • Administration: IV infusion over 15–30 minutes or IV bolus over 3–5 minutes.	**Pediatric Dose** Pediatric Dosing (≥3 months) • Complicated skin and soft tissue infections: 10 mg/kg every 8 hours (max 500 mg). • Intra-abdominal infections or meningitis: 20 mg/kg every 8 hours (max 2 g). • If >50 kg, use adult dose. • Administration: IV infusion 15–30 min or IV bolus 3–5 min. Infants <3 months (GA = gestational age; PNA = postnatal age) • GA < 32 wks & PNA < 2 wks: 20 mg/kg every 12 hours • GA < 32 wks & PNA ≥ 2 wks: 20 mg/kg every 8 hours • GA ≥ 32 wks & PNA < 2 wks: 30 mg/kg every 8 hours • GA ≥ 32 wks & PNA ≥ 2 wks: 30 mg/kg every 8 hours	**Adjustments** Renal Dose Adjustments (Adults) • CLcr > 50 mL/min: Full recommended dose every 8 hours. • CLcr 25–50 mL/min: Full dose every 12 hours. • CLcr 10–25 mL/min: Half dose every 12 hours. • CLcr < 10 mL/min: Half dose every 24 hours. Pediatric Renal Impairment • Limited clinical experience. • Reported dose: 40 mg/kg every 8 hours (limited data). • Reduce dose when creatinine clearance ≤50 mL/min.	[35]
🔵 **Doripenem Doribax ®**	**Route** IV (powder for infusion solution)	**Clinical Indications** •Complicated intra-abdominal infections (cIAI) •Complicated urinary tract infections, incluyendo pyelonephritis (cUTI)	**Adult Dose** 500 mg IV every 8 h, infused in 1 hour, for cIAI and cUTI (adjust for renal function).	**Pediatric Dose** There is no pediatric regimen approved on the DORIBAX® label. (Not established).	**Adjustments** CrCl 30–50 mL/min: 250 mg IV every 8 h• CrCl 10–29 mL/min: 250 mg IV every 12 h• Hemodialysis: 250 mg IV after dialysis, then every 24 h	[36]

Imipenem and cilastatin for injection - PRIMAXIN® IV	**Route** IV (there is also IM formulation in some products, but the label of PRIMAXIN IV is for intravenous infusion.	**Clinical Indications** PRIMAXIN IV is indicated for serious infections caused by susceptible bacteria, including: • Lower respiratory tract infections • Urinary tract infections • Intra-abdominal infections • Gynecological infections • Bacterial sepsis • Bone and joint infections • Skin and skin structure infections • Endocarditis Therapy should be guided by suspected or confirmed pathogen susceptibility.	**Adult Dose** (Normal Renal Function) • 500 mg IV every 6 hours, or • 1000 mg IV every 8 hours, or • 1000 mg IV every 6 hours Infusion requirements: • Doses ≤500 mg: infuse over 20–30 minutes • Doses >500 mg: infuse over 40–60 minutes • If nausea occurs, slow the infusion rate.	**Pediatric Dose** • 15–25 mg/kg IV every 6 hours • Maximum imipenem dose: 4 g/day Not recommended in pediatric patients with CNS infections due to seizure risk. Not recommended in certain pediatric populations per safety warnings.	**Adjustments** Renal Impairment (Adults) Dose adjustments based on creatinine clearance (CLcr): When infection is due to susceptible organisms CLcr (mL/min) Dose ≥90 500 mg q6h <90–60 400 mg q6h <60–30 300 mg q6h <30–15 200 mg q6h When infection is due to organisms with intermediate susceptibility CLcr (mL/min) Dose ≥90 1000 mg q6h <90–60 750 mg q8h <60–30 500 mg q6h <30–15 500 mg q12h Additional notes: • Discard any unused portion of the infusion solution. • Dosing interval extends as renal function declines.	[37]

🔵 **Ertapenem-INVANZ®**	**Route** IV or IM (lyophilized powder for reconstitution).	**Clinical Indications** •Complicated intra-abdominal infections • Complicated skin and skin structure infections • Community-acquired pneumonia • Complicated urinary tract infections (included pyelonephritis) • Acute pelvic infections (incluyendo endometritis posparto, aborto séptico, infecciones ginecológicas posquirúrgicas)	**Adult Dose** 1 g once a day IV or IM.	**Pediatric Dose** 3 months – 12 years: 15 mg/kg IV twice daily (max. 1 g/day). • 13–17 years: 1 g IV once daily.	**Adjustments** • Adjustment for renal function • CrCl ≤ 30 mL/min and in hemodialysis: 500 mg IV once daily. • Adjustment for liver function • No dose adjustment is required in hepatic impairment.	[38]
B.4. Aminoglycosides						
🟢 **Gentamicin (gentamicin injection, USP) - GARAMYCIN® (different parenteral presentations).**	**Route** Intravenous (IV) (must be diluted for infusion) • IM	**Clinical Indications** • Serious infections by susceptible bacteria, including sepsis, respiratory tract infections, CNS infections (including meningitis, as part of combination therapy), intra-abdominal, complicated urinary, bone and joint infections, skin and soft tissue infections, and infected burns. Approved indications (parenteral)	**Adult Dose** Usual adult dose (IV/IM) 3–5 mg/kg/day divided every 8 h (e.g., 1–1.7 mg/kg every 8 h), or single-dose daily regimens according to label.	**Pediatric Dose** • Neonates and infants: 2.5–3 mg/kg every 12 h.• Older children: 6–7.5 mg/kg/day divided every 8 h.	**Adjustments** • Adjustment for renal function • Requires prolonging the interval or decreasing doses according to creatinine, with monitoring of serum levels (label da tables/equations). • Adjustment for liver function • No numerical adjustment is specified; caution mainly for renal function.	[39]
🟢 **Tobramycin (tobramycin for injection, USP)- Aminoglycoside.**	**Route** IM or IV (after reconstitution and dilution for	**Clinical Indications** Serious infections by susceptible Gram-negative bacteria, including: • Sepsis. • Lower respiratory tract infections	**Adult Dose** Usual adult dose (IV/IM) In patients with normal renal function: 3–5 mg/kg/day divided every 8 h (≈ 1–1.7 mg/kg q8h).	**Pediatric Dose** Usual dose in the pediatric population • Children: 6–7.5 mg/kg/day divided every 8 h. • Neonates: higher doses	**Adjustments** Requires dose and/or interval adjustment in renal impairment according to creatinine and monitoring of serum levels (the	[40]

	infusio n)	.• CNS infections (meningitis) as part of combination therapy. • Intra-abdominal infections. • Infections of the skin, subcutaneous tissue, bone, and joints. • Complicated and recurrent urinary tract infections. • Typical pathogens: *Pseudomonas aeruginosa*, *E. coli*, *Klebsiella*, *Enterobacter*, *Serratia*, *susceptible Staphylococcus aureus*, etc.	• There are single-dose daily schedules of 5–7 mg/kg (according to label).	mg/kg with longer intervals (label gives specific tables).	label includes tables/equations). • Adjustments for liver function • No specific adjustment is described; main concern is renal function and serum levels.	
🟢 **Amikacin sulfate injection, USP - Amikin® (and injectable generics).**	**Route** Intrave nous (IV) (infusio n)or Intramu scular (IM).	**Clinical Indications** •Short-term treatment of severe susceptible Gram-negative bacilli infections (*Pseudomonas*, *E. coli*, *Proteus*, *Klebsiella*, *Enterobacter*, *Serratia*, *Acinetobacter*). • Usable in complicated and recurrent urinary tract infections, sepsis, respiratory, intra-abdominal, bone, and skin/soft tissue infections caused by these organisms • It can be used in severe sensitive staphylococcal infections when there is an allergy to other antibiotics or mixed infection.	**Adult Dose** Normal renal function: 15 mg/kg/day in total, divided into 2–3 doses (e.g., 7.5 mg/kg every 12 h or 5 mg/kg every 8 h). • Typical duration: 7–10 days.	**Pediatric Dose** Neonates and infants: 10 mg/kg load dose, then 7.5 mg/kg every 12 h (example of the label). • Children: 15–20 mg/kg/day divided into 2–3 doses.	**Adjustments** • Requires dose reduction and/or interval increase according to CrCl; serum levels and renal function should be monitored. • Adjustments for liver function • No specific numerical adjustment; main care for renal function.	[41]
B.5. Fluoroquinolones						
🔵 **Ciprofloxacin-CIPRO® I.V.**	**Route** Intrave nosa (IV)	**Clinical Indications** •Complicated urinary tract infections (cUTI) • Pyelonephritis	**Adult Dose** • 200–400 mg IV every 12 hours depending on the indication• Nosocomial pneumonia: 400	**Pediatric Dose** 10 mg/kg IV every 12 hours (maximum 400 mg per dose) for:	**Adjustments** • CrCl 30–50 mL/min: • 200–400 mg IV every 12 hours •	[42]

		• Lower respiratory tract infections caused by susceptible organisms • Skin and skin structure infections • Bone and joint infections • Intra-abdominal infections (in combination with metronidazole) • Nosocomial pneumonia • Infections caused by *E. coli* O157:H7 and *Shigella* •Post-exposure inhalational anthrax (*Bacillus anthracis*) • Plague (*Yersinia pestis*)	mg IV every 8 hours • Intra-abdominal infections (with metronidazole): 400 mg IV every 12 hours • Anthrax post-exposure: 400 mg IV every 12 hours for 60 days	•Complicated UTI • Pyelonephritis• 15 mg/kg IV every 8 hours for plague • 10–15 mg/kg IV every 12 hours for inhalational anthrax *(The FDA label indicates that pediatric is limited to these indications.)*	CrCl 5–29 mL/min: • 200–400 mg IV every 18–24 hours • Hemodialysis/CAPD: • 200–400 mg IV every 24 hours (after dialysis)	
🔵 **Levofloxacin-LEVAQUIN® Injection**	**Route** Intravenous (IV): premix solution to dilute.	**Clinical Indications** (IV): • Community-acquired pneumonia (7–14 day and 5-day regimens) • Acute exacerbation of chronic bronchitis • Acute bacterial sinusitis • Complicated infections of skin and skin structures • Uncomplicated skin infections • Chronic bacterial prostatitis • Complicated urinary tract infections • Uncomplicated urinary tract infections • Acute pyelonephritis • Inhalation anthrax (post-exposure) • Plague (treatment and prophylaxis)	**Adult Dose** Usual IV dose in adults (as indicated):• 750 mg IV every 24 h (eg, pneumonia 5 days, complicated skin, pyelonephritis). • 500 mg IV every 24 h (pneumonia 7–14 days, skin 10 days, prostatitis, some respiratory). • 250 mg IV every 24 h (uncomplicated UTI). • Infusion: 60–90 minutes depending on dose.	**Pediatric Dose** • Limited to: • Inhaled anthrax (post-exposure) • Plague • Weight/age regimens. • Safety >14 days not studied.	**Adjustments** Adjustment for renal function (adults):• Requires adjustment if ClCr < 50 mL/min. If usual dose = 750 mg q24h:• CrCl 20–49: 750 mg every 48 h• CrCl 10–19 or hemodialysis/CAPD: 750 mg starting dose → 500 mg every 48 h If usual dose = 500 mg q24h:• CrCl 20–49: 500 mg initial → 250 mg q24h• CrCl 10–19 or hemodialysis/CAPD: 500	[43]

					mg initial → 250 mg every 48 h	
🔵 **Moxifloxacin-AVELOX®**	**Route** Intravenous (IV), infusion-ready solution.	**Clinical Indications** •Community-acquired pneumonia • Complicated skin and skin structure infections. • Complicated intra-abdominal infections.	**Adult Dose** • 400 mg IV once daily. • Infusion in approximately 60 minutes.	**Pediatric Dose** • Safety and efficacy not established in pediatrics; not recommended for use in children and adolescents.	**Adjustments** No adjustment for renal impairment (including hemodialysis) is required. • It is not recommended in moderate-severe hepatic impairment.	[44]
B.6. Macrolides						
🟢 **Erythromycin lactobionate-ErythrocinTM Lactobionate - IV**	**Route** Intravenous (IV infusion)	**Clinical Indications** Treatment of infections by susceptible strains in: • Respiratory tract infections • Skin and soft tissue infections • Erythrasma • Syphilis, when penicillin is contraindicated • *Mycoplasma pneumoniae* infections • Diphtheria (as an adjuvant) • Pertussis (whooping cough) • *Neisseria gonorrhoeae pelvic inflammatory disease* (followed by oral therapy)	**Adult Dose** Usually 15–20 mg/kg/day of equivalent base erythromycin, divided every 6 h (by IV), according to severity and type of infection (label details specific regimens by indication).	**Pediatric Dose** 30–50 mg/kg/day divided every 6 h (IV), depending on indication and severity.	**Adjustments** The label emphasizes caution in hepatic dysfunction (erythromycin is eliminated mainly by the liver); It does not define a standard renal adjustment numerical scheme.	[45]
🟢 **Azithromycin (IV) - Zithromax**	**Route** Intravenous (IV)	**Clinical Indications** Approved indications (IV) • Community-acquired pneumonia (PDA) caused by: *Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila,*	**Adult Dose** 500 mg IV once daily for at least 2 days• Continue with 500 mg PO once daily until 7–10 days total. PID:• 500 mg IV once a day for 1–2 days• Continue with 250 mg PO	**Pediatric Dose** • No safety or efficacy has been established in IV for <16 years. • In studies, it has only been administered orally to children 6 months–16	**Adjustments** Adjustments for kidney function • No adjustment required with GFR ≤ 80 mL/min. • En GFR <10 mL/min: AUC ↑ 35% → use	[46]

		Moraxella catarrhalis, *Mycoplasma pneumoniae*, *Staphylococcus aureus*, *Streptococcus pneumoniae* in patients requiring initial IV therapy. •Pelvic inflammatory disease (PID) caused by: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma hominis* in patients requiring initial IV therapy Important clinical notes: • If anaerobes are suspected, → be combined with antimicrobial with anti-anaerobic activity. • IV treatment should be followed by oral azithromycin according to clinical response. • Cultures and susceptibility tests should be performed before initiating treatment. • Use should be limited to proven or strongly suspected infections to avoid resistance.	once a day to complete 7 days total. Transition IV → VO: • According to clinical judgment and patient response. • If anaerobes are suspected, administer in combination with anti-anaerobic drug.	years. • Pediatric IV use not recommended due to lack of data.	with caution.	
B.7.Lipopeptides						
🟢 **Daptomycin-CUBICIN®**	**Route** Injection - for intravenous use	**Clinical Indications** Daptomycin is indicated for the treatment of: • Complicated skin and skin structure infections (cSSSI) • Staphylococcus aureus bloodstream infections	**Adult Dose** Route: IV injection over 2 minutes or IV infusion over 30 minutes •cSSSI: 4 mg/kg once every 24 hours, for 7–14 days •S. aureus	**Pediatric Dose** – S. aureus Bacteremia (1–17 years) Route: IV infusion (not by IV push) • 12–17 years: 7 mg/kg q24h (30-	**Adjustments** Renal impairment (CLcr < 30 mL/min or on hemodialysis) • 4 mg/kg (cSSSI) or 6 mg/kg (bacteremia)	[47]

		(bacteremia) in adults, including right-sided infective endocarditis • S. aureus bacteremia in pediatric patients (1–17 years)	bacteremia: 6 mg/kg once every 24 hours, for 2–6 weeks.	min infusion) • 7–11 years: 9 mg/kg q24h (30-min infusion) • 2–6 years: 12 mg/kg q24h (60-min infusion) Duration: Up to 42 days Note: No established dose adjustments for renal impairment. Pediatric Dosing – cSSSI (1 month–17 years) Route: IV infusion 30–60 minutes, depending on age • 12–17 years: 5 mg/kg q24h (30-min infusion) • 7–11 years: 7 mg/kg q24h (30-min infusion) • 2–6 years: 9 mg/kg q24h (60-min infusion) • 1 month–<2 years: 10 mg/kg q24h (60-min infusion) Duration: Up to 14 days Note: No dose adjustment established for renal impairment.	once every 48 hours • Administer after hemodialysis when possible	
B.8. Oxazolidinones						
● **Linezolid - Zyvox®**	**Route** Intravenous (IV)	**Clinical Indications** Linezolid is indicated for the treatment of: Nosocomial pneumonia • Community-Acquired Pneumonia	**Adult Dose** 600 mg IV every 12 hours.	**Pediatric Dose** • Pediatric patients (birth to 11 years): • 10 mg/kg intravenously every 8 hours	**Adjustments** •No dose adjustment required in mild, moderate, or severe renal impairment.	[48]

		• Complicated Skin and Structure Infections • Vancomycin-Resistant Enterococcus faecium Infections Linezolid is not indicated for the treatment of infections caused by gram-negative bacteria		• Adults and adolescents (12 years and older): • 600 mg intravenously every 12 hours Recommended duration of treatment (consecutive days) • Nosocomial pneumonia, community-acquired pneumonia, and complicated skin infections: • 10 to 14 days • Vancomycin-resistant Enterococcus faecium infections: • 14 to 28 days	• Metabolites can accumulate in patients with renal impairment, especially in ESRD with hemodialysis. • Hemodialysis removes about 30% of metabolites. • Administer the dose after hemodialysis. • The accumulation of metabolites usually does not produce clinical symptoms but should be considered in prolonged treatments.	
B.9.Nitroimidazoles						
Metronidazole - Metronidazole Injection, USP	**Route** Intravenous (IV)	**Clinical Indications** Treatment of serious infections caused by susceptible anaerobic bacteria (intra-abdominal, skin and skin structures, gynecological, septicemia, bone and joint infections, CNS, lower respiratory tract, endocarditis).	**Adult Dose** • 500 mg IV every 8 h (usually infused within 30–60 minutes).	**Pediatric Dose** • 7.5 mg/kg IV every 6 h (not to exceed 4 g/day).	**Adjustments** Adjustment for renal function • Adjustment is generally not required in mild-moderate renal failure; consider reducing or prolonging interval in severe failure or hemodialysis according to label. • Adjustment for liver function • In severe hepatic dysfunction: consider dose reduction; the label recommends monitoring levels or signs of toxicity.	[49]

B.10. Sulfonamides						
🟢 **Sulfamethoxazole and trimethoprim - BACTRIM® Injection.**	**Route** Intravenous (IV) solution, for infusion after dilution.	**Clinical Indications** Indications (IV) • Enteritis due to Shigella flexneri or Shigella sonnei (adults and children) • Severe or complicated urinary tract infections when the oral route is not possible • Acute exacerbations of chronic bronchitis • Pneumocystis jirovecii pneumonia (PCP) – treatment and prophylaxis.	**Adult Dose** Dosage (expressed as trimethoprim – TMP) • Severe infections/UTI, Shigella, bronchitis: 8–10 mg/kg/day TMP (40–50 mg/kg/day SMX), divided every 6–8 hours • PCP treatment: 15–20 mg/kg/day TMP (75–100 mg/kg/day SMX), divided every 6 hours	**Pediatric Dose** Pediatric dosing: similar mg/kg ranges adjusted by weight (label contains specific tables) • Contraindicated in infants <2 months	**Adjustments** Renal Adjustment • CrCl 15–30 mL/min: give half the usual dose • CrCl <15 mL/min: generally not recommended unless close monitoring is available Hepatic Adjustment • No numeric adjustment scheme; the label warns of hepatotoxicity → use with caution and monitoring.	[50]
B.11. Monobactams						
🟡 **Aztreonam 100 mg - Azactam**	**Route** Intravenous (IV) or Intramuscular (IM)	**Clinical Indications** Aztreonam is indicated for the treatment of infections caused by susceptible Gram-negative organisms, including: • Urinary tract infections (cystitis, pyelonephritis) • Lower respiratory tract infections (pneumonia, bronchitis) •Sepsis • Skin and soft-tissue infections (wounds, ulcers, burns) •Intra-abdominal infections (including peritonitis) • Gynecologic infections (endometritis, pelvic cellulitis) • Adjunctive therapy in surgical infections (abscesses, GI perforation).	**Adult Dose** Urinary tract infections: 500 mg–1 g every 8–12 h • Moderately severe systemic infections: 1–2 g every 8–12 h • Severe or life-threatening infections: 2 g every 6–8 h • Pseudomonas infections: 2 g every 6–8 h (recommended initial dose) Maximum daily dose: 8 g/day IV route is preferred for: • Single doses >1 g • Sepsis • Parenchymal abscesses • Peritonitis or life-threatening	**Pediatric Dose** Pediatric Dosing • Mild to moderate infections: 30 mg/kg every 8 h • Moderate to severe infections: 30 mg/kg every 6–8 h • Maximum: 120 mg/kg/day	**Adjustments** Renal Impairment • CLcr 10–30 mL/min/1.73 m²: After standard loading dose (1–2 g), reduce maintenance dose by 50%. • CLcr <10 mL/min/1.73 m² or hemodialysis: • Give usual initial dose (500 mg–2 g) • Maintenance dose: ¼ of usual dose at usual intervals • For severe infections: add ⅛ dose after each hemodialysis session	[51]

		Important notes: • In critically ill patients, additional coverage may be needed for Gram-positive and anaerobic bacteria. • Avoid combining with beta-lactamase–inducing antibiotics (e.g., cefoxitin, imipenem).	infections Duration: Continue at least 48 h after symptom resolution or confirmed bacterial eradication. Persistent infections may require prolonged therapy.			
B.12. Lincosamides						
Clindamycin CLEOCIN PHOSPHATE (Another Presentation) -	**Route** Intravenous (IV infusion) or Intramuscular (IM)	**Clinical Indications** • Severe infections caused by susceptible anaerobic bacteria in adults and pediatrics. • Infections caused by susceptible streptococci, pneumococci, and staphylococci in adults and pediatrics when appropriate doses can be achieved. • Lower respiratory tract infections: pneumonia, lung abscess, empyema. • Severe skin and skin structure infections. • Severe gynecologic infections: endometritis, tubo-ovarian abscess, pelvic cellulitis, post-surgical vaginal cuff infections. • Severe intra-abdominal infections: peritonitis, intra-abdominal abscess. • Severe septicemia. • Bone and joint infections: acute	**Adult Dose** Adult Dosage (IV/IM) • 600–1200 mg/day, divided into 2–4 doses, for severe aerobic gram-positive cocci and susceptible anaerobes. • Infusion guidance: • 300 mg → infuse over 10 minutes • 600 mg → 20 minutes • 900 mg → 30 minutes	**Pediatric Dose** Pediatrics: • First dose example: 5–7 mg/kg IV over 1 hour • General pediatric dosing: 20–40 mg/kg/day divided into 3–4 doses (higher doses for severe infections)	**Adjustments** Renal Adjustments • No renal dose adjustment required. • Clindamycin is not significantly eliminated by the kidneys; dose modification is not necessary in mild, moderate, or severe renal impairment, including patients on hemodialysis. Supplemental post-dialysis dosing is not required.	[52]

		hematogenous osteomyelitis due to *S. aureus*; adjunct therapy in chronic bone/joint infections.				
Clindamycin phosphate-CLEOCIN PHOSPHATE® (and other presentations)	**Route** Intravenous (IV infusion) or Intramuscular (IM)	**Clinical Indications** Indications • Severe infections caused by susceptible anaerobic bacteria in adults and pediatrics. • Infections caused by susceptible streptococci, pneumococci, and staphylococci in adults and pediatrics when appropriate doses can be achieved. • Lower respiratory tract infections: pneumonia, lung abscess, empyema. • Severe skin and skin structure infections. • Severe gynecologic infections: endometritis, tubo-ovarian abscess, pelvic cellulitis, post-surgical vaginal cuff infections. • Severe intra-abdominal infections: peritonitis, intra-abdominal abscess. • Severe septicemia. • Bone and joint infections: acute hematogenous osteomyelitis due to *S. aureus*; adjunct therapy in chronic bone/joint infections.	**Adult Dose** Adult Dosage (IV/IM) • 600–1200 mg/day, divided into 2–4 doses, for severe aerobic gram-positive cocci and susceptible anaerobes. • Infusion guidance: • 300 mg → infuse over 10 minutes • 600 mg → 20 minutes • 900 mg → 30 minutes	**Pediatric Dose** Pediatrics: • First dose example: 5–7 mg/kg IV over 1 hour • General pediatric dosing: 20–40 mg/kg/day divided into 3–4 doses (higher doses for severe infections)	**Adjustments** Renal Adjustments • No renal dose adjustment required. • Clindamycin is not significantly eliminated by the kidneys; dose modification is not necessary in mild, moderate, or severe renal impairment, including patients on hemodialysis. • Supplemental post-dialysis dosing is not required.	[53]

B.13.Tetracyclines						
🔵 **Tigecycline - TYGACIL® and other formulations of tigecycline for injection.**	**Route** Intravenous (IV) after reconstitution and dilution.	**Clinical Indications** Indications • Complicated skin and skin structure infections • Complicated intra-abdominal infections • Community-acquired bacterial pneumonia	**Adult Dose** Adult Dosage (IV) • Loading dose: 100 mg IV • Maintenance dose: 50 mg IV every 12 hours • Infusion time: 30–60 minutes	**Pediatric Dose** Pediatric Use • Safety and efficacy not established in patients <18 years of age •Not recommended in pediatric populations	**Adjustments** Renal Adjustments • No renal dose adjustment required • Tigecycline clearance is not significantly affected by renal impairment	[54]

Policy Name:	Policy Number:	Scope:	Origination Date:	Frequently Revision:
Antibiotic and Antifungal - Parenteral Therapy in the Home Setting	**MP-OTHER-FP-01-25**	☒ **MMM MA** ☒ **MMM MultiHealth**	**10/01/2025** **Last Review Date:** **12/12/2025**	**Annual** **Page: 30 of 45**

Limits or Restrictions:

1. These services require going through the authorization process.
2. This policy applies only to parenteral antimicrobial therapy administered in the home setting when all medical necessity criteria are met.
3. Therapy provided outside the scope of this policy, including non-parenteral administration, non-home settings, or indications not expressly addressed, must be evaluated in accordance with other applicable Medical Policies and/or pharmacy utilization management requirements.
4. Table of medication for warnings / precautions warnings, adverse reactions and limitations of use per medications:

A. PARENTERAL ANTIFUNGALS				
Medication (generic-brand)	**Warning and Precautions**	**Adverse Reaction**	**Limitations of Use**	**Source**
A.1. Antifungals				
Anidulafungin - ERAXIS®	**Warnings / Precautions:** • Histamine-mediated infusion reactions (rash, flushing, dyspnea, hypotension). • Monitor for hypersensitivity; stop if severe reaction or anaphylaxis.	**Adverse Reactions:** • Rash, urticaria, flushing, pruritus, dyspnea, hypotension.	**Limitations of Use:** • Use only for **susceptible Candida infections**. • Avoid in **echinocandin hypersensitivity**.	[15]
Caspofungin acetate - CANCIDAS®	**Warnings / Precautions:** • Hypersensitivity reactions possible (class effect). • Monitor liver function during therapy.	**Adverse Reactions:** • **Adults ≥10%:** diarrhea, fever, ↑ALT/AST, ↑alkaline phosphatase, ↓potassium. • **Pediatrics ≥10%:** fever, diarrhea, rash, ↑ALT/AST, ↓potassium, hypotension, chills.	**Limitations of Use:** • Use only for **susceptible Candida** or **Aspergillus** infections.	[16]
Fluconazol- DIFLUCAN® Injection	**Warnings / Precautions:** • **Hepatotoxicity** (may be severe or fatal). • **QT prolongation / torsades de pointes**. • **Severe skin reactions** (SJS/TEN).	**Adverse Reactions:** • Nausea, abdominal pain, diarrhea, headache, ↑liver enzymes.	**Limitations of Use:** • For **susceptible fungal infections only**. • Not active against bacteria.	[17]
Voriconazole- NVFEND®	**Warnings / Precautions:** • **Hepatotoxicity** — monitor liver tests. • **Infusion reactions / anaphylaxis** — stop if severe. • **Visual disturbances** (blurred vision, photophobia). • **Photosensitivity** → sun avoidance; risk of photoaging &	**Adverse Reactions:** • Vision changes, rash, nausea/vomiting, diarrhea, headache, peripheral edema, ↑LFTs. • Severe cases: hepatotoxicity, arrhythmias, QT	**Limitations of Use:** • Monitor closely for toxicity and interactions. • Advise strict sun protection.	[18]

	skin cancer. • **Drug interactions** (major). • **Severe skin reactions** (SJS/TEN). • **Embryo-fetal toxicity** — avoid in pregnancy. • Risk of **adrenal dysfunction** or **Cushing's** with corticosteroids. • **Skeletal fluorosis** with prolonged therapy.	prolongation, renal failure, hallucinations.		

B. PARENTERAL ANTIBIOTICS

Antibiotic Classes by Spectrum of Activity

- 🔵 High-Spectrum (Broad-Spectrum) Antibiotics
- 🟢 Medium-Spectrum Antibiotics
- 🟡 Low-Spectrum (Narrow-Spectrum) Antibiotics

Medication (generic - brand)	Warning and Precautions	Adverse Reaction	Limitations of Use	Source
B.1. Penicillin's				
🟡 **Penicillin G Potassium- Penicillin G Potassium**	**Warnings / Precautions** • Severe hypersensitivity reactions, including **anaphylaxis**. • **Neurotoxicity** (e.g., seizures), especially with high doses or renal impairment. • **Electrolyte disturbances**, including **hyperkalemia** from potassium load. • Monitor renal and neurologic status during high-dose therapy.	**Side Effects** • Rash, hives, drug fever. • Diarrhea, nausea. • Phlebitis at IV site. • Seizures (dose-related, especially in renal failure).	**Usage Limits** • Use **only** for infections caused by susceptible organisms. • **Not effective** against penicillinase-producing organisms.	[19]
🟡 **Penicillin G Benzathine - Bicillin® L-A**	Warnings / Precautions • Therapy should be guided by bacteriological data and clinical response. • When culture/susceptibility data are unavailable, use local epidemiology to guide empirical selection. • Only indicated for infections requiring low and prolonged serum levels, characteristic of benzathine formulation. • Not appropriate for severe or rapidly progressive infections requiring high serum concentrations.	Side Effects • Injection-site reactions. • Hypersensitivity reactions including rash, urticaria, and anaphylaxis. • Fever, malaise. • Rare adverse reactions with inadvertent intravascular injection.	**Usage Limits** Indicated for infections due to penicillin-susceptible organisms, including: • Mild to moderate upper respiratory tract infections (susceptible streptococci). • Venereal infections (syphilis, yaws, bejel, pinta). • Prophylaxis of	[20]

			rheumatic fever, chorea, and follow-up after rheumatic heart disease or glomerulonephritis .	
Ampicillin 500 mg inj- Ampicillin for Injection, USP	• Severe hypersensitivity (including life-threatening anaphylaxis); higher risk with history of β-lactam allergy. • Clostridioides difficile–associated diarrhea (CDAD) — may occur during treatment or up to 2 months later. • Superinfection risk (bacterial or fungal overgrowth) with prolonged use. • Avoid in infectious mononucleosis due to high incidence of rash (not an allergic reaction). • 5. Use only for proven or strongly suspected bacterial infections to prevent antimicrobial resistance.	•Allergic reactions: rash, pruritus, urticaria; may progress to anaphylaxis. •Gastrointestinal effects: diarrhea, nausea, vomiting. •CDAD — potentially severe. •Injection-site reactions: pain, inflammation. •Hematologic abnormalities: eosinophilia, anemia, thrombocytopenia. •Hepatic enzyme elevations. •Seizures (mainly at high doses or with renal impairment).	Treatment should be based on cultures and susceptibility testing. • Use only in proven or strongly suspected infections of susceptible bacterial origin, to avoid antimicrobial resistance.	[21]
Ampicillin sodium 1.5 g - UNASYN®	**Warnings and Precautions:** • Risk of severe hypersensitivity reactions, including life-threatening anaphylaxis (higher in patients with a history of penicillin allergy or multiple allergens). • Hepatotoxicity: reversible hepatitis or cholestatic jaundice; rare fatal cases reported. • Severe cutaneous reactions: TEN, SJS, exfoliative dermatitis, erythema multiforme, AGEP—discontinue if lesions progress. • *Clostridioides difficile*–associated diarrhea (CDAD), ranging from mild to fatal. • High risk of rash in patients with infectious mononucleosis. • Possible superinfections with *Pseudomonas* or *Candida*. • Patient counseling: use only for bacterial infections, complete full treatment, report persistent or bloody diarrhea.	**Adverse Reactions:** • Local: IM site pain (16%), IV site pain (3%), thrombophlebitis (3%). • Systemic: diarrhea (3%), rash (<2%), pruritus, nausea, vomiting, candidiasis, headache, fatigue. • Hematologic: hemolytic anemia, agranulocytosis, thrombocytopenia, eosinophilia. • Hepatic: elevated AST, ALT, ALP, LDH; jaundice or cholestatic hepatitis. • Severe skin reactions: SJS, TEN, AGEP. • Overdose: seizures due to elevated CSF levels.	**Limitations of Use:** • Use only for bacterial infections proven or strongly suspected to be caused by susceptible organisms. • Dose adjustment required in elderly patients and those with renal impairment.	[22]

Nafcillin sodium-Nallpen®	**Warnings and Precautions:** • Risk of severe hypersensitivity reactions, including anaphylaxis. • *Clostridioides difficile*–associated diarrhea. • Neutropenia and agranulocytosis with prolonged therapy. • Hepatotoxicity, including cholestatic hepatitis.	**Adverse Reactions:** • Rash, urticaria. • Nausea, vomiting, diarrhea. • Phlebitis at IV site; pain with IM injection. • Elevated liver enzymes; cholestatic jaundice.	**Limitations of Use:** • Use only for infections caused by **penicillinase-producing, nafcillin-susceptible Staphylococcus aureus**. • Not appropriate when other more specific β-lactams are suitable for non–penicillinase-producing organisms.	[23]
Piperacillin/Tazobactam-ZOSYN®	**Warnings and Precautions:** • Serious hypersensitivity reactions, including anaphylaxis; cross-reactivity possible with other β-lactams. • *Clostridioides difficile*–associated diarrhea. • Hematologic abnormalities: leukopenia, neutropenia, thrombocytopenia. • Nephrotoxicity, especially when used with vancomycin. • Seizures in patients with renal impairment receiving high doses.	**Adverse Reactions:** • Diarrhea, nausea, vomiting. • Rash, pruritus. • Elevated AST and ALT. • Thrombocytopenia.	**Limitations of Use:** • Should be used only for infections proven or strongly suspected to be caused by susceptible bacteria, due to broad spectrum and increased resistance risk.	[24]
Cefazolin sodium -Ancef®	**Warnings and Precautions:** • Hypersensitivity reactions may occur; cross-reactivity possible in up to 10% of patients with penicillin allergy. • Risk of *Clostridioides difficile*–associated diarrhea (CDAD), which may be severe or fatal. • Possible reduction in prothrombin activity; monitor patients at risk and provide vitamin K if needed.	**Adverse Reactions:** • Most common: nausea, vomiting, diarrhea. • Allergic reactions: rash, anaphylaxis. • Local injection-site reactions.	**Limitations of Use:** • Renal excretion is inhibited by probenecid—avoid coadministration. • Use only for infections proven or strongly suspected to be caused by susceptible bacteria.	[25]
Cefuroxime - CEFTIN	**Warnings and Precautions:** • Assess history of hypersensitivity to cephalosporins or penicillins; severe allergic reactions may require epinephrine. • CDAD may occur during treatment	**Adverse Reactions:** • Local: thrombophlebitis. • GI: diarrhea, nausea, pseudomembranous colitis.	**Limitations of Use:** • The DUPLEX® container must **not** be used in pediatric patients requiring	[26]

	or up to two months afterward. • Hematologic changes: anemia, eosinophilia, rare neutropenia or thrombocytopenia. • Transient increases in liver enzymes; rare elevations in creatinine/BUN. • Postmarketing: seizures, angioedema.	• Hypersensitivity: rash, pruritus, urticaria, rare anaphylaxis. • Lab abnormalities (hematologic, hepatic, renal).	less than the full adult dose (risk of overdose).	
🟢 **Ceftriaxone - ROCEPHIN**	**Warnings and Precautions:** • Hypersensitivity reactions, including anaphylaxis and severe skin reactions. • CDAD risk. • Hematologic abnormalities: eosinophilia, anemia, thrombocytopenia; increased SGOT/SGPT. • Risk of precipitation with calcium-containing solutions.	**Adverse Reactions:** • Most common (>2%): diarrhea, rash, eosinophilia, thrombocytosis, elevated SGOT/SGPT.	**Limitations of Use:** • Do not mix or co-administer with calcium-containing IV products. • Incompatible with vancomycin, aminoglycosides, and fluconazole. • Use only for infections likely caused by susceptible organisms.	[27]
🟢 **Cefotaxime – Claforan®**	Prior to initiating **therapy with CLAFORAN**, it should be determined whether the patient has had **prior hypersensitivity reactions** to:• cefotaxime sodium• cephalosporins• penicillins• other medicinal products• Administer with **caution** in patients with **type I hypersensitivity to penicillin**.	The most frequent adverse reactions (greater than 1%) are: Local (4.3%) - Injection site inflammation with IV administration. Pain, induration, and tenderness after IM injection. Hypersensitivity (2.4%) - Rash, pruritus, fever, eosinophilia. Gastrointestinal (1.4%) - Colitis, diarrhea, nausea, and vomiting. Symptoms of pseudomembranous colitis can appear during or after antibiotic treatment. Nausea and vomiting have been reported rarely.	If **C. trachomatis** is a possible pathogen, add anti-chlamydial treatment, as cefotaxime does not cover this organism.	[28]
🔵 **Ceftazidime-FORTAZ®**	• **Hypersensitivity reactions**, including anaphylaxis, especially in patients with β-lactam allergy. • **Neurotoxicity** (seizures,	**Adverse Reactions (Most Relevant)** • Gastrointestinal: diarrhea, nausea; rare *C.*	Use only for suspected or proven infections caused by	[29]

	encephalopathy, confusion) may occur, particularly in renal impairment if doses are not adjusted. • **Clostridioides difficile–associated diarrhea** may occur; consider in any patient with diarrhea. • **Hematologic effects**: eosinophilia, leukopenia, neutropenia, thrombocytosis. • **Renal considerations**: dose adjustment required in renal impairment; risk increases when combined with nephrotoxic drugs. • **Positive direct Coombs test** may occur without hemolysis.	*difficile* colitis. • Skin: rash, pruritus, urticaria. • Hematologic: eosinophilia, neutropenia, thrombocytosis. • Liver enzymes: transient elevations in AST/ALT, ALP. • Neurologic: headache, dizziness; seizures in overdose or renal failure. • Injection-site reactions: phlebitis, inflammation, pain.	susceptible Gram-negative organisms. • Limited activity against Gram-positive organisms and anaerobes—may require additional agents for mixed infections. • Not recommended when effective oral therapy is appropriate. • Renal dose adjustment is mandatory to reduce neurotoxicity risk. • Avoid prolonged empirical therapy without clinical or microbiologic justification.	
🔵 **Ceftazidime /Avibactam - Avycaz®**	**Warnings and Precautions:** • Hypersensitivity reactions including anaphylaxis; higher risk with history of penicillin allergy. • CDAD risk. • CNS reactions (including seizures), especially with renal impairment. • Reduced efficacy in complicated intra-abdominal infections (cIAI) when CrCl ≤50 mL/min.	**Adverse Reactions (≥5%):** • cIAI: diarrhea, nausea, vomiting. • cUTI: diarrhea, nausea. • HABP/VABP: diarrhea, vomiting.	**Limitations of Use:** • Use only for susceptible Gram-negative infections. • Dose adjustment required in renal impairment.	[30]
🔵 **Cefepime-MAXIPIME®**	**Warnings and Precautions:** • Risk of hypersensitivity reactions, including cross-reactivity with penicillins. • Neurotoxicity: encephalopathy, myoclonus, and seizures—especially in renal impairment or with incorrect dosing. • CDAD risk. • Risk of superinfection with prolonged use.	**Adverse Reactions:** • Rash, pruritus. • Diarrhea, nausea, vomiting. • Positive direct Coombs test; transient lab abnormalities.	**Limitations of Use:** • Requires dose adjustment in renal impairment to avoid neurotoxicity. • Use only for infections caused by susceptible organisms.	[31]
🔵 **Ceftolozane/tazobactam - Zerbaxa®**	**Warnings and Precautions:** • Severe hypersensitivity reactions, including anaphylaxis; cross-	**Adverse Reactions (common):**	**Limitations of Use:** • Not indicated in	[32]

	reactivity with other β-lactams. • CDAD risk. • Renal dosing adjustments required; incorrect doses may reduce efficacy or increase toxicity.	• Nausea, diarrhea, headache, fever.	the pediatric population. • Use only for infections proven or strongly suspected to involve susceptible Gram-negative pathogens.	
🔵 **Ceftaroline fosamil -Teflaro ®**	**Warnings and Precautions:** • Severe hypersensitivity reactions, including anaphylaxis; caution in β-lactam–allergic patients. • CDAD risk. • Positive direct Coombs test may occur; evaluate for hemolytic anemia if anemia develops.	**Adverse Reactions (≥2%):** • Diarrhea, nausea, rash.	**Limitations of Use:** • Use according to susceptibility and clinical need; apply antibiotic stewardship principles.	[33]
🟢 **Cefoxitin sodium-MEFOXIN®**	**Warnings / Precautions:** • Serious hypersensitivity reactions, including anaphylaxis; use with caution in patients with penicillin/cephalosporin allergy. • Risk of *Clostridioides difficile*–associated diarrhea (CDAD), which may be severe or fatal. • In patients with renal impairment or reduced urine output: risk of prolonged high drug levels — adjust dose accordingly. • Superinfection or overgrowth of non-susceptible organisms if used indiscriminately; use only when indicated by susceptibility or strong suspicion.	**Adverse Reactions:** • Local: pain, irritation or thrombophlebitis at injection site. • Systemic: diarrhea, nausea, vomiting. • Allergic: rash, urticaria, pruritus — in rare cases exfoliative dermatitis or severe skin reactions. • Hematologic / lab: possible eosinophilia, leukopenia/neutropenia, positive Coombs, transient liver enzyme elevations or jaundice.	**Limitations of Use:** • Use only for infections proven or strongly suspected to be caused by susceptible bacteria. • Not effective against certain pathogens such as *Chlamydia trachomatis* (e.g. in PID) — add appropriate therapy if suspected. • Dose adjustment required in renal impairment; avoid typical dosing when urine output is reduced	[34]
🔵 **Meropenem - MERREM® IV**	• Severe hypersensitivity reactions (including anaphylaxis) in patients with allergy to β-lactams.• Seizures and other CNS events, especially in patients with neurological pathology or renal failure.• CDAD.• Interaction with valproic acid/divalproex (decreases	• Headache, nausea, diarrhea, rash .• Inflammation or pain at the infusion site.	• Use only for proven or strongly suspected infections by susceptible bacteria.	[35]

	valproate concentrations; combination is not recommended).			
🔵 **Doripenem Doribax ®**	• Severe hypersensitivity reactions • Seizures/CNS effects — higher risk with renal impairment. • *C. difficile*–associated diarrhea (CDAD).	**Adverse Reactions:** • Headache, nausea, diarrhea, rash, candidiasis, elevated liver enzymes.	**Limitations of Use:** • Use only for proven or strongly suspected susceptible bacterial infections.	[36]
🔵 **Imipenem and CILASTIN for injection - PRIMAXIN® IV**	**Warnings / Precautions:** • Hypersensitivity reactions including anaphylaxis. • Increased seizure risk—especially with valproic acid co-administration. • *C. difficile*–associated diarrhea. • Potential for selection of drug-resistant bacteria.	**Adverse Reactions:** • Nausea, vomiting, diarrhea, rash, pruritus. • Seizures (dose-related), phlebitis, liver enzyme elevation.	**Limitations of Use:** • Use only in confirmed or strongly suspected susceptible infections.	[37]
🔵 **Ertapenem-I INVANZ®**	**Warnings / Precautions:** • Severe hypersensitivity (β-lactam cross-risk). • Seizures/CNS effects in predisposed or renally impaired patients. • *C. difficile*–associated diarrhea.	**Adverse Reactions:** • Diarrhea, nausea, headache, infusion-site phlebitis, elevated transaminases.	**Limitations of Use:** • **Does NOT cover Pseudomonas or Acinetobacter.** • Use only for susceptible organisms.	[38]
🟢 **Gentamicin – Garamycin®**	**Warnings / Precautions:** • Nephrotoxicity (dose-dependent). • Ototoxicity (cochlear & vestibular). • Neuromuscular blockade - respiratory paralysis risk.	**Adverse Reactions:** • Elevated creatinine, proteinuria. • Vertigo, tinnitus, hearing loss. • Injection-site pain.	**Limitations of Use:** • Use only for serious infections when safer agents are inappropriate..	[39]
🟢 **Tobramycin (tobramycin for injection, USP)- Aminoglycoside.**	**Warnings / Precautions:** • Nephrotoxicity and ototoxicity (may be irreversible). • Neuromuscular blockade — caution in myasthenia gravis. • Requires renal monitoring and serum-level monitoring.	**Adverse Reactions:** • Elevated BUN/creatinine, proteinuria. • Hearing loss, tinnitus, vertigo. • Injection-site irritation.	**Limitations of Use:** • Use only in serious infections where safer therapies are inadequate.	[40]
🟢 **Amikacin sulfate injection, USP - Amikin® (and injectable generics).**	**Warnings / Precautions:** • Nephrotoxicity and ototoxicity. • Requires renal dose adjustment and therapeutic drug monitoring. • Neuromuscular blockade risk.	**Adverse Reactions:** • Elevated creatinine, hearing loss, dizziness. • Injection-site reactions.	**Limitations of Use:** • Reserve for serious Gram-negative infections when other drugs are unsuitable.	[41]
🔵 **Ciprofloxacin-CIPRO® I.V.**	**Warnings / Precautions:** • Tendonitis/tendon rupture. • Peripheral neuropathy. • CNS effects (seizures, psychosis). • QT prolongation.	**Adverse Reactions:** • Nausea, diarrhea, vomiting. • Rash. • CNS effects (dizziness,	**Limitations of Use:** • Pediatric use restricted to cUTI, pyelonephritis,	[42]

	• Aortic aneurysm/dissection risk. • Glucose disturbances. • CDAD. • Photosensitivity, hepatotoxicity.	headache). • Injection-site reactions.	anthrax, plague. • Reserve for patients without alternatives.	
🔵 **Levofloxacin-LEVAQUIN® Injection**	**Warnings / Precautions:** • Tendon rupture, peripheral neuropathy. • CNS effects (seizures, hallucinations). • QT prolongation. • Aortic aneurysm/dissection. • Severe glucose disturbances. • Hepatotoxicity. • CDAD.	**Adverse Reactions:** • Nausea, diarrhea, headache, insomnia, dizziness. • Elevated liver enzymes.	**Limitations of Use:** • Reserve for patients without alternatives for certain indications.	[43]
🔵 **Moxifloxacin-AVELOX®**	**Warnings / Precautions:** • Potentially irreversible tendon, muscle, nerve, and CNS toxicity. • QT prolongation and arrhythmia risk. • Hepatotoxicity. • CDAD. • Dysglycemia.	**Adverse Reactions:** • Nausea, vomiting, diarrhea, abdominal pain. • Headache, dizziness. • Liver enzyme elevation.	**Limitations of Use:** • Not effective for MRSA. • Reserve for patients without alternative treatments.	[44]
🟢 **Erythromycin lactobionate-Erythrocin Lactobionate-I**	**Warnings / Precautions:** • Hepatotoxicity (including cholestatic hepatitis). • QT prolongation; torsades risk. • CDAD.	**Adverse Reactions:** • Nausea, vomiting, abdominal pain, diarrhea. • Elevated liver enzymes, cholestasis. • Rash.	**Limitations of Use:** • Use only when oral therapy is not appropriate. • Use only in proven/suspected susceptible infections.	[45]
🟢 **Azithromycin (IV) - Zithromax**	**Warnings / Precautions:** • Known hypersensitivity to azithromycin, erythromycin, or macrolides/ketolides. • QT prolongation risk (from label — inferred). • CDAD risk (common class warning).	**Adverse Reactions:** • Diarrhea, nausea, injection-site reactions (from class-typical profile).	**Limitations of Use:** • Use only for susceptible infections requiring IV therapy.	[46]
🟢 **Daptomycin-CUBICIN®**	**Warnings / Precautions:** • Myopathy; CPK elevation → requires weekly CPK. • Eosinophilic pneumonia (may occur after 2–4 weeks). • Peripheral neuropathy. • CDAD. • Hypersensitivity reactions. • Interference with PT/INR assays.	**Adverse Reactions:** • Constipation, nausea, headache. • Injection-site reactions. • Elevated CPK, rash, insomnia.	**Limitations of Use:** • **Not indicated for pneumonia** (inactivated by lung surfactant). • Use only for susceptible infections; not for CNS empiric	[47]

			therapy.	
🟢 **Linezolid - Zyvox®**	**Warnings and Precautions:** • Myelosuppression (anemia, leukopenia, thrombocytopenia). • Peripheral and optic neuropathy with prolonged use. • Risk of serotonin syndrome with serotonergic agents. • CDAD risk. • Lactic acidosis, seizures, hypoglycemia, hyponatremia/SIADH.	**Adverse Reactions:** • Diarrhea, nausea, vomiting. • Headache, insomnia. • Cytopenia's tigeincluding thrombocytopenia.	**Limitations of Use:** • Active only against Gram-positive bacteria; not effective for Gram-negative infections. • Use only when infection with susceptible organisms is proven or strongly suspected.	[48]
🟢 **Metronidazole - Metronidazole Injection, USP**	**Warnings / Precautions:** • Possible carcinogenicity (animal data). • Peripheral neuropathy; seizures. •CDAD. • Disulfiram-like reaction with alcohol.	**Adverse Reactions:** • Nausea, metallic taste, vomiting, diarrhea. •Headache, rash. •Reversible leukopenia.	**Limitations of Use:** •Use only in confirmed or strongly suspected anaerobic infections.	[49]
🟢 **Sulfamethoxazole and trimethoprim - BACTRIM® Injection.**	**Warnings/Precautions:** • Severe dermatologic reactions (SJS/TEN). • Fulminant hepatic necrosis. • Serious hematologic disorders (agranulocytosis, aplastic anemia). • CDAD. • Hypoglycemia, hyperkalemia, hyponatremia. • Aseptic meningitis.	**Adverse Reactions:** • Nausea, vomiting, anorexia. • Rash, urticaria, photosensitivity. • Elevated liver enzymes, hepatitis. • Leukopenia, thrombocytopenia, anemia. • Local IV reactions: pain, irritation, rare thrombophlebitis.	**Limitations of Use:** • Use only in susceptible infections. • Not appropriate for Group A Streptococcus pharyngitis (does not eradicate the organism).	[49]
🟡 **Aztreonam 100 mg - Azactam**	**Warnings / Precautions** • Risk of **hypersensitivity reactions**, including anaphylaxis. • **Monitor liver and renal function**, especially if using aminoglycosides. • **Superinfection** may occur with prolonged use (Gram-positive organisms and fungi). • Risk of **C. difficile–associated diarrhea**.	**Adverse Reactions** • Diarrhea, nausea, rash, elevated liver enzymes, injection-site reactions.	**Limitations of Use** • Use **only for susceptible Gram-negative infections**. • **No activity** against Gram-positive or anaerobes. • May need additional	[51]

			coverage in mixed infections.	
Clindamycin-CLEOCIN PHOSPHATE (Another Presentation)	Main warning: Clostridioides difficileassociated diarrhea (CDAD) has been reported with almost all antibacterials, including clindamycin. It should be considered before selecting clindamycin. • It does not diffuse properly into the cerebrospinal fluid; therefore, it should not be used for meningitis. • Warns about the potential for overgrowth of non-susceptible organisms (especially fungi) during use.	Diarrhea, pseudomembranous colitis (related to C. difficile), and other gastrointestinal reactions.	• No debe usarse para meningitis (por pobre difusión al líquido cefalorraquídeo). • "Clindamycin Phosphate in Sodium Chloride Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria."	[52]
Tigecycline - TYGACIL® and other formulations of tigecycline for injection.	**Warnings and Precautions:** • Increased mortality compared to other antibiotics; reserve for cases without suitable alternatives. • Hypersensitivity reactions, including anaphylaxis; caution in tetracycline allergy. • Hepatotoxicity (elevated bilirubin, transaminases, PT). • Pancreatitis. • CDAD risk. • Class effects: tooth discoloration, possible bone growth inhibition, photosensitivity.	**Adverse Reactions:** • Nausea, vomiting, diarrhea. • Abdominal pain. • Elevated liver enzymes. • Infusion-site reactions.	**Limitations of Use:** • Should be reserved when alternative antibiotics are not appropriate due to increased mortality risk. • Not indicated for hospital-acquired or ventilator-associated pneumonia.	[54]

Policy Name:	Policy Number:	Scope:	Origination Date:	Frequently Revision:
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Codes Information:

ICD-10 Diagnostic Codes:

Codes	Description
A41.9	Sepsis, unspecified organism
R78.81	Bacteremia
R78.2	Fungemia
B37.7	Candidemia
M86.00–M86.9	Osteomyelitis (acute, chronic, unspecified)
L03.90–L03.91	Cellulitis
L03.115	Cellulitis of leg
L08.9	Local skin infection
M72.6	Necrotizing fasciitis
J18.9	Pneumonia, unspecified
J18.9	Pneumonia, unspecified
J15.6	Pneumoniadueto*Pseudomonas*
J15.9	Bacterial pneumonia, unspecified
J15.212	MRSA pneumonia
J85.1	Abscess of lung
J86.0–J86.9	Empyema
N10	Acute pyelonephritis
N39.0	UTI, unspecified
K65.0	Acute peritonitis
K61.2	Intra-abdominal abscess
B37.7	Candidemia
L97.401–L97.529	Non-pressure chronic ulcers with infection

HCPCS Codes:

Codes	Description
N/A	N/A

CPT Codes:

Codes	Description
99601	Home infusion/specialty drug administration, first hour
99602	Home infusion/specialty drug administration, each additional hour
J0696	Injection, ceftriaxone sodium, per 250 mg
J3370	Injection, vancomycin hydrochloride, per 500 mg
J0290	Injection, ampicillin, up to 500 mg
J1200	Injection, diphenhydramine hydrochloride, up to 50 mg (when medically necessary for premedication)
J0278	Amikacin Sulfate Injection
J0290	Ampicillin 500 Mg Injection
J0295	Ampicillin Sodium Per 1.5 Gm

J0348	Anidulafungin Injection
J0456	Azithromycin
J0457	Injection Aztreonam 100 Mg
J0561	Penicillin G Benzathine Injection
J0690	Cefazolin Sodium Injection
J0692	Cefepime Hcl For Injection
J0694	Cefoxitin Sodium Injection
J0695	Injection Ceftolozane 50 Mg & Taz 25 Mg
J0696	Ceftriaxone Sodium Injection
J0697	Sterile Cefuroxime Injection
J0698	Cefotaxime Sodium Injection
J0712	Injection Ceftaroline Fosamil 10 Mg
J0713	Injection Ceftazidime Per 500 Mg
J0714	Injection Ceftazidime & Avibactam 0.5 G/0.125 G
J0736	Injection Clindamycin Phosphate 300 Mg
J0737	Injection Clindamycin Phosphate Not Thr Eq J0736 300 Mg
J0744	Ciprofloxacin IV
J0878	Daptomycin Injection
J1267	Doripenem Injection
J1335	Ertapenem Injection
J1364	Erythromycin Lactobionate /500 Mg
J1450	Fluconazole
J1580	Garamycin Gentamicin Injection
J1836	Injection Metronidazole 10 Mg
J1956	Levofloxacin Injection
J2020	Linezolid Injection
J2185	Meropenem
J2280	Injection Moxifloxacin 100 Mg
J2290	Injection Nafcillin Sodium 20 Mg
J2540	Penicillin G Potassium Injection
J2543	Piperacillin/Tazobactam
J2865	Injection Sulfamethoxazole/Trimethoprim 5 mg/1 mg
J3243	Tigecycline Injection
J3260	Tobramycin Sulfate Injection

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Superseded	This policy, titled *"Antibiotic and Antifungal – Parenteral Therapy in the Home Setting - MP-OTHER-FP-01-25"*, supersedes in its entirety the prior policy identified as *"IV Antibiotics- MP-IV-FP-01-24"*. The update includes a full replacement of the previous text. The revision encompassed a comprehensive overhaul of clinical content, a complete redefinition of the list of preauthorized parenteral antibiotics and antifungals; restructuring of criteria for clinical necessity, documentation, monitoring, home infusion standards and drug-specific requirements; and alignment with current regulatory standards. As of this version, all prior versions are deprecated and archived, and the present document official the medical polices for these services.	**No apply**	**12/12/2025**