Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
IV Antibiotics/Hydration Administration (IV)/External Infusion Pumps	MP-IV-FP-01-23	☒ MMM MA ☐ MMM Multihealth

Service Category

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other IV Antibiotics/Hydration Administration (IV)/External Infusion Pumps

Service Description

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. The components needed to perform home infusion include the drug (for example, antivirals, immune globulin), equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. Nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

Antibiotics are medicines that fight infections caused by bacteria in humans and animals by either killing the bacteria or making it difficult for the bacteria to grow and multiply. Bacteria are germs, they live in the environment and all over the inside and outside of our bodies. Most bacteria are harmless and even helpful to people, but some can cause infections.

Antibiotics are important to treat infections and have saved countless lives. However, anytime antibiotics are used, they can cause side effects and contribute to antibiotic resistance, one of the most urgent threats to the public's health.

When antibiotics are needed, the benefits usually outweigh the risks of side effects or antibiotic resistance. However, too many antibiotics are prescribed unnecessarily and misused, which threatens the usefulness of these important drugs.

This is why it's important that we all use antibiotics ONLY when we need them to protect us from harms caused by unnecessary antibiotic use and to combat antibiotic resistance.

Enclosed document contains but is not limited to the following information: classification of antibiotics, a brief service description, limitations and restrictions, the most common antibiotics within each class and references utilized.

Please note that all services described in this policy require prior authorization.

- Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.
- Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.
- Providers must submit all required and requested documentation for case evaluation and determination including but not limited to the following: Medical Order with all required documentation, History of previous and or failed treatment, History of allergies, General information related to diagnosis which include but is not limited to the following: CBS, Urinalysis, Urine Culture, Blood Culture, Studies that confirm diagnosis Ex: MRI, Bone Scan, Infectology and or Surgery Consults.
- The plan may request additional documentation and information not received and or provided initially related to condition and diagnosis for case evaluation and determination.

- Any additional documentation submitted specifying medical necessity criteria and considered important for case evaluation and determination will be reviewed by Clinical Team utilizing guidelines and regulation criteria.
- **Sanford Guidelines are utilized for review of antibiotics criteria and recommended therapy. Guideline utilized for case determination will be furnished upon request**.
- LCD and articles are utilized to determine hydrations, supplies and equipment as per standard regulation.

Medical Necessity Guidelines

Service Description	Medical Necessity Guidelines	Limits or Restrictions	Most Common Antibiotics
1. Penicillins	Penicillin is one of the most commonly used antibiotics globally; it has a wide range of clinical indications. It is also considered one of the strongest. Interrupts proliferation of the bacteria. Penicillin is effective against many different infections involving gram-positive cocci, gram-positive rods (e.g., Listeria), most anaerobes, and gram-negative cocci (e.g., Neisseria). Importantly, certain bacterial species have obtained penicillin resistance, including enterococci. Enterococci infections now receive treatment with a combination of penicillin and streptomycin or gentamicin. Certain gram-negative rods are also resistant to penicillin due to penicillin's poor ability to penetrate the porin channel. However, later generations of broad-spectrum penicillins are effective against gram-negative rods. Second-generation penicillins (ampicillin and amoxicillin) can also penetrate the porin channel, making these drugs effective against Proteus mirabilis, Shigella, H. influenzae, Salmonella, and E. coli. Third-generation penicillin such as carbenicillin is also able	It's important to note that penicillins may interfere with the effectiveness of birth control pills. Some individuals exhibit a severe allergic reaction to penicillin known as anaphylaxis. Anaphylaxis is a potentially life-threatening condition that causes dysfunction in several body systems. Penicillins and other beta-lactams do not penetrate well into phagocytes, thus limiting their ability to kill intracellular pathogens. In addition, penicillins only exert their bactericidal effect on bacteria that are actively replicating.	Penicillin G Pennicillin VK Nafcillin Oxacillin Cloxacillin Flucoxacillin Dicloxacillin Ampicillin Amoxicillin Amox-Clav Amp-Sulb Pip-Tazo

	to penetrate gram-negative bacterial porin channels. Fourth-generation penicillins such as piperacillin are effective against the same bacterial strains as third-generation penicillins and Klebsiella, enterococci, Pseudomonas aeruginosa, and Bacteroides fragilis. **Penicillins are commonly used for the following conditions:** Pneumonia, Tonsillitis, Dental Abscess, Strep Throat, Urinary Tract.		
2. Cephalosporins	These types of antibiotics are usually grouped into categories that are called generations. There are five generations of cephalosporins. The first generation of these antibiotics is usually used for infections that are easier to treat. The latter generations are for more serious bacterial infections. Cephalosporins are often used for strep throat, meningitis, pneumonia, urinary tract infections and ear infections. The fifth generation of cephalosporins is called Ceftaroline and is used for antibiotic resistant infections such as MRSA. The cephalosporins that are primarily prescribed include cephalexin, cefaclor and ceftriaxone (as an injection). Cefazolin, cefuroxime and cefoxitin are not used as often and normally prescribed for individuals with cystic fibrosis or those undergoing dialysis.	Side effects are similar to those experienced with penicillin. These include nausea, diarrhea, rash and thrush. If someone is allergic to penicillins it is likely they will be allergic to cephalosporins since they are similar in molecular structure. Depending on how severe the allergy is, some individuals may be able to still take third, fourth or fifth generation cephalosporins. Cephalosporins have the following limitations: Lack of activity against enterococci. Enterococcus faecalis and E. faecium cause a variety of infections, including endocarditis, urinary tract infections.	Cefazolin Cefotetan Cefoxitin Cefuroxime Cefotaxime Ceftizoxime Cefuroxime Cefoperazone Ceftriaxone Ceftazidime Cefepime Ceftaz-Avibac Ceftaroline Ceftobiprole Ceftobiprole Cefto-Tazo Cefuderocol
3. Carbapenems	They are a class of antibiotics also known as beta lactam.	Adverse effects include increased resistance to one	Doripenem Ertapenem

		They work by inhibiting synthesis of the bacterial cell wall. Carbapenems are often used for serious urinary infections, abdominal infections, blood infections and pneumonia. Carbapenems possess the broadest spectrum of activity and greatest potency against Gram-positive and Gram-negative bacteria. As a result, they are often used as "last-line agents" or "antibiotics of last resort" when patients with infections become gravely ill or are suspected of harboring resistant bacteria. The carbapenem antibiotics and their role in our antimicrobial armamentarium. Among the β-lactams currently available, carbapenems are unique because they are relatively resistant to hydrolysis by most β-lactamases, in some cases act as "slow substrates" or inhibitors of β-lactamases, and still target penicillin binding proteins. This "value-added feature" of inhibiting β-lactamases serves as a major rationale for expansion of this class of β-lactams. Interferes with membrane proteins. The most common are: Mero-Meropenem, IMP-cila -rele, Imp-cilastatin, Ertapenem, Doripenem Doripenem, ertapenem, imipenem, and meropenem are each drugs in the Carbapenem class that are usually	of the drugs used in the combination, as well as a lack of synergy or additivity and strain dependence. Carbapenems have low oral bioavailability and thus do not cross gastrointestinal membranes readily and must be administered intravenously. Are eliminated predominately by renal excretion. Carbapenems exhibit unique pharmacological properties and are typically used to treat complicated bacterial infections. A carbapenem is often combined with an antibiotic that targets Gram-positive bacteria when used for the empirical treatment of patients with serious nosocomial infections of unidentified origin. Safety and tolerability. Nephrotoxicity, neurotoxicity, and immunomodulation have been reported with the use of carbapenems, and thus predisposing factors should be considered when administering any carbapenem, they alter the intestinal microflora and select for carbapenem-resistant isolates.	Imp-cilastatin Imp-cila-rele Meropenem Mero-Vabor Aztreonam

	administered intravenously or injected into a muscle. These drugs are often prescribed for infections that aren't easily treated with other antibiotics. Carbapenems are similar to penicillins. These types of antibiotics, however, so far seem unaffected by the increasing problem of antibiotic resistance.		
4. Fluoroquinolone	The fluoroquinolones are a family of broad spectrum, systemic antibacterial agents that have been used widely as therapy of respiratory and urinary tract infections. Interferes with bacteria DNA replication and transcription. Fluoroquinolones are active against a wide range of aerobic gram-positive and gram-negative organisms. • Gram-positive coverage includes penicillinase- and non-penicillinase producing Staphylococci, Streptococcus pneumoniae and viridans, Enterococcus faecalis, Listeria monocytogenes, and Nocardia species. • Gram negative coverage includes Neisseria meningitides and gonorrhoeae, Haemophilus influenzae, and most clinically important Enterobacteriaceae species, Pseudomonas aeruginosa and Vibrio species.	It is generally recommended to use these antibiotics only after other courses of treatment have failed. Fluroquinolones have also been linked in recent years to mental health problems, disturbances with blood sugar and specifically aortic aneurysms. Within the last year the FDA has required labeling changes to strengthen the warnings. There may be some cases, however, such as when treating bacterial pneumonia, that the potential benefits outweigh the risks. Serious cases of pneumonia and abdominal infections may require the use of fluoroquinolones.	Ciprofloxacin Delafloxacin Gemifloxacin Ofloxacin Levofloxacin Moxifloxacin Norfloxacin Prulifloxacin Gemifloxacin Gatifloxacin
Aminoglycosides	The aminoglycosides are natural products and	The aminoglycosides all have serious toxicities	Gentamicin Tobramycin

		semisynthetic derivatives from a variety of actinomycetes and have potent activity against many gram negative bacteria. The first aminoglycoside used in clinical practice was streptomycin which was derived from Streptomyces griseus and was the first effective agent against mycobacterium tuberculosis. The aminoglycosides are believed to act by binding to ribosomes of bacteria and blocking protein synthesis. The aminoglycosides are poorly absorbed orally and typically are given parenterally, either by intravenous or intramuscular injection. Gentamicin, tobramycin and amikacin are given parenterally and are used for severe gram negative bacterial infections usually in combination with penicillins or cephalosporins. Streptomycin is now rarely used and largely as adjunctive therapy of multi-drug resistant tuberculosis. Plazomicin is a recently introduced agent and is given intravenously as monotherapy for complicated urinary tract infections or acute pyelonephritis. Plazomicin is a semi-synthetic aminoglycoside which has been modified to evade conventional forms of aminoglycoside resistance. Neomycin is used orally to treat hepatic encephalopathy. Because it is poorly absorbed orally, neomycin causes a decrease in intestinal bacteria, thereby decreasing ammonia production and absorption from the colon.	which often limit their applicability and the dose and duration of therapy. The common serious adverse effects of the aminoglycosides are ototoxicity, neuropathy and nephrotoxicity. Liver injury from the aminoglycosides is rare, perhaps because the other side effects of aminoglycosides limit the amount that can be given. Isolated case reports of idiosyncratic hepatotoxicity have been published for most, but not all of the aminoglycosides.	Amikacin Plazomicin

		Aminoglycosides are broad-spectrum bactericidal antibiotics used mainly to treat aerobic Gram-negative bacteria and selected Gram-positive bacteria often in combination with other antibiotics. Aminoglycosides entered widespread clinical use to combat infections caused by members of the Enterobacterales order of Gram-negatives including Escherichia coli and Klebsiella pneumonia (Krause et al. 2016), and they have also been used effectively against Pseudomonas aeruginosa (Karlowsky et al. 2003) and Staphylococcus aureus (Lee and Lee 2016).		
	6. Macrolides	They are usually given as oral medication. Macrolides are often used to treat very basic bacterial infections. Inhibits synthesis of proteins by bacteria, occasionally leading to cell death. These antibiotics are often used for specific types of pneumonia, chlamydia and urethritis. Macrolides are sometimes prescribed to prevent a bacterial infection. If an individual has had their spleen removed or suffers from sickle-cell disease the person may need to use one of these antibiotics on a regular basis to prevent an infection. Specific drugs in this class include roxithromycin, clarithromycin, azithromycin and erythromycin.	Minor side effects can include nausea, diarrhea and ringing in the ears. Macrolides are often a good alternative for individuals that are allergic to penicillins or cephalosporins. However, potential complications regarding these antibiotics are that they do have some drug interaction concerns that could lead to serious heart complications.	Eriythromycin Azithromycin Clarithromycin Telithromycin

	7. Tetracyclines	Tetracyclines (tetracycline, doxycycline, minocycline, tigecycline) are a class of medication used to manage and treat various bacterial infections. Tetracyclines classify as protein synthesis inhibitor antibiotics and are considered to be broad-spectrum. Tetracyclines activity against a wide range of microorganisms including gram-positive and gram-negative bacteria, chlamydiae, mycoplasmas, rickettsiae, and protozoan parasites. Tetracycline resistance now occurs in an increasing number of pathogenic, opportunistic, and commensal bacteria. The presence of tetracycline-resistant pathogens limits the use of these agents in treatment of disease. Tetracycline resistance is often due to the acquisition of new genes, which code for energy-dependent efflux of tetracyclines or for a protein that protects bacterial ribosomes from the action of tetracyclines. Many of these genes are associated with mobile plasmids or transposons and can be distinguished from each other using molecular methods including DNA-DNA hybridization with oligonucleotide probes and DNA sequencing. A limited number of bacteria acquire resistance by mutations, which alter the permeability of the outer	The most common side effects may include nausea, diarrhea, swollen tongue, troubling swallowing and soreness or swelling in the genital area. A rare but potential serious side effect is possible blindness due to intracranial hypertension. Tetracycline should be taken on an empty stomach, at least 1 hour before or 2 hours after meals or snacks. Drink a full glass of water with each dose of tetracycline. Do not take tetracycline with food, especially dairy products such as milk, yogurt, cheese, and ice cream. Tetracyclines are contraindicated in pregnancy because of the risk of hepatotoxicity in the mother, the potential for permanent discoloration of teeth in the fetus (yellow or brown in appearance), as well as impairment of fetal long bone growth. Tetracycline usage is also associated with teeth discoloration in children under the age of eight. Thus it should be avoided in pediatric patients under that age. Clinicians should also avoid tetracyclines in patients with renal failure due to the excretion of the drug being primarily by the kidneys. If tetracyclines must be used in this group	Doxycicline Eravacycline Minocycline Omadacycline Tetracycline Tigecycline

	membrane porins and/or lipopolysaccharides in the outer membrane, change the regulation of innate efflux systems, or alter the 16S rRNA. These drugs can treat rickettsial infections, ehrlichiosis, anaplasmosis, leptospirosis, amebiasis, actinomycosis, nocardiosis, brucellosis, melioidosis, tularemia, chlamydial infections, pelvic inflammatory disease, syphilis, traveler's diarrhea, early Lyme disease, acne, legionnaire's disease, and Whipple disease. They cover Borrelia recurrentis, Mycobacterium marinum, Mycoplasma pneumoniae, Staphylococcus aureus (including methicillin-resistant S. aureus [MRSA]), Vibrio vulnificus, and vancomycin-resistant enterococcus (VRE) (susceptible strains). Meningococcal prophylaxis is also achievable. Other indications of tetracyclines include rosacea, bullous dermatoses, sarcoidosis, Kaposi sarcoma, pyoderma gangrenosum, hidradenitis suppurativa, Sweet syndrome, a1-antitrypsin deficiency, panniculitis, pityriasis lichenoides chronica, rheumatoid arthritis, scleroderma, cancer, and cardiovascular diseases (abdominal aortic aneurysm and acute myocardial infarction).	of patients, either reduce the dosage and/or increase the interval between doses should be prolonged.	
8. Glico-Lipo	The term glycopeptide refers to a group of antimicrobial agents that includes vancomycin and		Daptomycin Vancomycin Teicoplanin

		teicoplanin. Since the first two VISA isolates in the United States were also resistant to teicoplanin, the term glycopeptide-intermediate S. aureus (GISA) was used to indicate this broader resistance profile. While GISA may be a more specific term for strains intermediate to both vancomycin and teicoplanin, not all VISA strains are intermediate to teicoplanin; therefore, VISA is a more accurate and widely used term.		Telavancin Oritavancin Dalbavancin
	9. Ox-Lid (Oxazolidinones)	Oxazolidinones are a new class of antibiotics used to treat serious skin and bacterial infections, often after other antibiotics have been ineffective. Target protein synthesis in a wide spectrum of gram-positive and anaerobic bacteria. Inhibits synthesis of proteins by bacteria, preventing growth. Oxazolidinones are a recent class of synthetic antibiotics with a chemical structure characterized by a basic nucleus of 2-oxazolidone active against a wide spectrum of multidrug-resistant Gram-positive bacteria (GPB), namely vancomycin-resistant Enterococcus (VRE), MRSA and Mycobacterium tuberculosis (Mtb). Oxazolidinones bind to the 50S ribosomal subunit, inhibiting the biosynthesis of bacterial proteins. The first oxazolidinone clinically available was Linezolid (LNZ),		Linezolide Tedizoline

		discovered in 1996 and approved in 2000 for clinical use by the FDA (U.S. Food and Drug Administration). LNZ is widely employed for GPB infections and it is considered an efficient drug for surgical infections and in the treatment of drug-resistant pulmonary infections and MDR-TB infections. Among oxazolidinones, only LNZ and Tedizolid are clinically approved for MDR-TB infections. Tedizolid (TZD) belongs to the second generation of oxazolidinones and is also indicated for the treatment of skin infections. Radezolid (RZD), belonging to the biaryl oxazolidinone family, is effective against resistant LNZ strains. Although clinical trials into community-acquired pneumonia and into skin and soft tissue infections have concluded, studies on its acceptability are not yet finished. In the field of treating MDR-TB infections, many efforts have been made to discover the next generation of oxazolidinones having better antibacterial efficacy and fewer adverse effects. Recently, several oxazolidinone analogs have been developed at well-known pharmaceutical companies, some of which have been found to be suitable for treating MDR-TB.		
	10. Poly	Polymyxins comprise a class of antibiotics targeting gram-negative bacterial infections.	Hypersensitivity to polymyxin B, colistin methanesulfonate, colistin, or any formulation component.	Polymyxin B Colistin Lefamulin

		Polymyxin B and Polymyxin E (colistin) are the two drugs within this antibiotic class used primarily in clinical practice. They are FDA approved for serious infections with multidrug-resistant gram-negative bacteria, especially those caused by Enterobacteriaceae, Pseudomonas aeruginosa and Acinetobacter baumannii. Polymyxins are often the only effective antibiotic agent against multidrug-resistant organisms, particularly carbapenem-resistant Enterobacteriaceae. They have become the last line of treatment for infections that are resistant to other antibiotics. They are useful in treating infections of the urinary tract, meninges, and bloodstream by susceptible strains of pseudomonas aeruginosa, Enterobacteriaceae, and Acinetobacter baumannii. Drugs act on the outer membrane of gram-negative bacteria by destabilizing the phospholipids and lipopolysaccharides (LPS) present. There is an electrostatic interaction between the positively charged polymyxin and the phosphate groups of the negatively charged lipid A membrane, which causes displacement of divalent cations such as calcium and magnesium from the phosphate groups within these membrane lipids. This activity leads to increased permeability, a disrupted outer cell membrane, and	Renal function requires close monitored during the administration of intravenous polymyxins as a result of the high frequency of nephrotoxicity and potential severity. Therapeutic drug monitoring of polymyxins is also a recommendation due to a narrow therapeutic window for efficacy and toxicity. However, therapeutic drug monitoring for the polymyxins is not universally available. Decreasing urine output, increasing BUN, and creatinine may require discontinuation of systemic therapy with polymyxins. The recommended target serum concentration level is 2 mg/mL for susceptible strains.		

	intracellular contents begin to leak out, resulting in cellular bacterial death.		
11. Anti fungals	Fungi are unicellular or multi-cellular eukaryotic organisms that exist in all environments worldwide. While most fungi do not play a significant role in human disease, there are several hundred fungi that do, resulting in fungal infection or disease. Fungal infections (mycoses) range from common benign infections like 'jock itch' to serious, life-threatening infections such as cryptococcal meningitis. Antifungal antimicrobials are one drug class that can combat these mycoses. Clinically, fungal infections are best categorized first according to the site and extent of the infection, then the route of acquisition, and finally, the virulence of the causative organism. These classifications are essential when determining the most effective treatment regimen for a particular mycosis. Mycoses classify as local (superficial, cutaneous, subcutaneous) or systemic (deep, bloodborne). The acquisition of the fungal infection is either an exogenous (airborne/inhalation, cutaneous exposure, percutaneous inoculation) or an endogenous process (normal flora or reactivated infection). The virulence of the organism is classified as either a primary infection (disease arising in a healthy host) or opportunistic infection (disease arising in human hosts that have a compromised	All formulations of amphotericin B (AMB-d, L-AMB, ABLC, ABCD) are contraindicated in patients with a known or likely hypersensitivity to amphotericin B or any components of the L-AMB, ABLC, or ABCD formulations. Nystatin is contraindicated in patients with hypersensitivity to the drug or any additional components in the dosage formulation. All azoles should be avoided in patients with hypersensitivities to azole drugs or dosage form components and used with caution in patients with renal impairment/failure and or hepatic impairment/failure. Fluconazole requires cautious administration in patients with electrolyte abnormalities, torsades de pointes, and or medical history, family history, and or current QTc prolongation. Itraconazole has an FDA boxed warning against the use in treating onychomycosis in patients with CHF. Itraconazole is contraindicated in pregnancy, left ventricular dysfunction, and current or active congestive heart failure. This drug should be	Amphotericin B Micafungin Casposfungin Anidulafungin Isavuconazonium Sulfate Posaconazole Voriconazole Itraconazole Fluconazole

		immune system or other defenses). Aspergillosis - Aspergillus fumigatus, A. flavus Blastomycosis - Blastomyces dermatitidis Candidiasis - Candida albicans, C. glabrata, C. krusei, C. parasilosis, C. tropicalis Chromoblastomycosis (Chromomycosis) - Cladosporium carrionii, Phialophora verrucosa, Fonsecaea pedrosoi Coccidioidomycosis - Coccidioides imitis, C. posadasii Cryptococcosis - Cryptococcus neoformans, C. gattii Dermatophytosis (Tinea) - Microsporum spp., Epidermophytum spp., Trichophyton spp. Fusariosis - Fusarium oxysporum, F. proliferatum, F. verticillioides Histoplasmosis - Histoplasma capsulatum Mucormycosis (Zygomycosis) - Mucor spp., Rhizopus spp. Paracoccidioidomycosis - Paracoccidioides brasiliensis Pneumocystis pneumonia - Pneumocystis jirovecii (formerly called P. carinii)* *While this is an essential and prevalent fungal disease, it is not treated with typical antifungal agents. Sporotrichosis - Sporothrix schenckii Tinea (Pityriasis) Versicolor - Malassezia furfur (also called Pityrosporum orbiculare), M. globosa	used cautiously in patients with cystic fibrosis, cardiovascular disease, pulmonary disease, and the elderly. Ketoconazole carries several FDA boxed warnings: • This agent should be used only when another effective antifungal, including azoles, cannot be tolerated or is not available • This agent carries a significant risk of hepatotoxicity, even in patients without predisposing factors, and thus any treatment with ketoconazole should include close liver function monitoring. • Ketoconazole has several contraindicated drug interactions that may cause QTc prolongation by increasing concentrations of cisapride, disopyramide, dofetilide, dronedarone, methadone, quinidine, or ranolazine. Ketoconazole is a cytochrome P450 inhibitor. Voriconazole is contraindicated in galactose malabsorption/intolerance, Lapp lactase deficiency, glucose malabsorption, uncorrected electrolyte		

			abnormalities, and pregnancy. Clinicians should use this agent with caution in patients with a medical or family history of QTc prolongation, history of torsades de pointes, and or hematologic malignancy. Isavuconazole is contraindicated in patients with familial short QTc syndrome and should be used with caution in patients with hematologic malignancies. Posaconazole is contraindicated in pregnancy. Caution is advisable in patients with electrolyte abnormalities, renal insufficiency, cardiomyopathy, torsades de pointes, or medical history/family history/congenital prolonged QTc interval. Terbinafine should be utilized with caution or avoided in patients with hypersensitivity reactions, depression, gastrointestinal issues, liver failure, and immune suppression secondary to hematologic effects. All echinocandins are contraindicated in patients with hypersensitivities to any of the echinocandin drugs or dosage form components. Caspofungin should be used with caution in hepatic impairment. Treatment with griseofulvin should include considerations for	

			potential adverse events in susceptible patients and those with existing disease states; particularly patients with a hypersensitivity to griseofulvin, a hypersensitivity to penicillins (there is a possible cross-reaction between penicillins and griseofulvin), hepatic failure, patients with known porphyrias, and patients that are pregnant or nursing. Flucytosine carries an FDA boxed warning that this agent should be used with extreme caution in renal impairment and that hematologic, hepatic, and renal function should have close monitoring. This agent is contraindicated in patients with hypersensitivity to this drug or its components, first trimester pregnancies, and breastfeeding women. Caution is advisable with this agent in patients with renal impairment, hepatic impairment, bone marrow depression, and pregnant patients in their second or third trimester. The quinolines iodoquinol and clioquinol are contraindicated in patients with hypersensitivities to the drugs or their components. Antifungals, which are utilized only as topical agents, including ciclopirox, potassium iodide, and zinc pyrithione, should be avoided in patients with		

		hypersensitivities to these agents.	
12. Hydration Administration	Billing and Coding: Hydration Services A5273 **96360**: Intravenous Infusion, hydration; initial, 31 minutes to 1 hour **96361**: Intravenous Infusion, hydration; each additional hour (list separately in addition to code for primary procedure). These codes are intended to report a hydration IV infusion consisting of pre-packaged fluid with or without electrolytes (e.g. normal saline, D5-1/2 normal saline+30mEq KCl/liter) and are not used to report infusion of drugs or other substances. Hydration Defined: The hydration codes 96360 and 96361 were developed to report specific therapeutic interventions undertaken when a patient presents with dehydration and volume loss requiring clinically necessary intravenous fluid. The necessity for hydration should be supported in the medical record. Documentation would include but is not limited to: A. Clinical assessment, typically on the same date of service, of the patient's anticipated fluid needs. This can be demonstrated from the patient's history, clinical	J. Non-payable scenarios: The following infusion circumstances do not represent hydration and should not be reported using any of these CPT codes: If the sole purpose of the intravenous fluid is to maintain patency (i.e. keep open) of an IV line prior to, during, or subsequent to a chemotherapeutic or therapeutic infusion, or transfusion. If used as "maintenance" IV therapy replacing normal sensible and insensible fluid losses, not losses associated with a pathological condition. When the purpose of the infusion is to accommodate a therapeutic IV piggyback through the same IV access to safely infuse the agent (e.g. IV fluids infused simultaneously with drug administration). If the fluid is used as the diluent to mix the drug (i.e. the fluid is the vehicle in which the drug is administered). Hydration that is integral to the performance of a surgical procedure to establish an initial and underlying IV flow for a diagnostic or therapeutic infusion is not separately	**Isotonic Solutions:** 9% NaCl (Normal Saline Solution, NSS) Dextrose 5% in Water (D5W) Lactated Ringer's 5% Dextrose in Water (D5LRS) Ringer's Solution **Hypotonic Solutions:** 45% Sodium Chloride (0.45% NaCl) 5% Dextrose in Water (D2.5W)

		examination, and pertinent laboratory testing to support the need for IV hydration therapy as reasonable and necessary for the patient's treatment or diagnosis. Documentation of the assessment should describe symptoms warranting hydration, such as those associated with dehydration, the inability to ingest fluids or clear clinical contraindication to oral intake, abnormal fluid losses, abnormal vital signs, and/or abnormal laboratory studies, such as an elevated BUN, creatinine, glucose or lactic acid. Nausea itself does not necessarily indicate fluid volume depletion nor support necessity of fluid repletion. B. These codes are not intended to be reported/billed by the physician or other qualified healthcare professional in the facility setting, as these codes most likely represent facility charges with applicable reimbursement through the respective fee schedule. However, in the physician office setting (example, Place of Service 11), the physician may report these codes when the physician's clinical staff or the physician administers the fluids. C. For facility reporting, an initial infusion is predicated on using a hierarchy. D. When administering multiple infusions (e.g. IV fluids and subsequent IV chemotherapy infusion on	billable (e.g. IV fluids administered preoperatively, intraoperatively, and/or postoperatively). Routine administration of IV fluids, pre/post operatively while the patient is NPO for example, without documentation supporting signs and/or symptoms including those of dehydration or fluid loss is not supported as medically necessary. Infusion of IV fluids with electrolytes for the purpose of treating an electrolyte deficiency (e.g. hypokalemic patient being treated specifically for low potassium level for which 20 mEq of KCL is added to an IV fluid).		

		same date of service), only one primary infusion code should be reported for a given date, unless protocol requires that two separate IV sites must be used. E. Hydration cannot be reported concurrently with any other infusion or drug administration service. F. The definition of infusion time is inherent and presented in the guidelines for these codes. In other words, a minimum time duration of 31 minutes of hydration infusion is required to report the service. G. Consequently, infusion time is calculated from the time the administration commences (i.e. the infusion starts dripping) to when it ends (i.e. the infusion stops dripping). H. In accordance with Medicare Reasonable and Necessary Criteria, (Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.2), the benefit must meet but does not exceed the beneficiary's medical need, and as such, IV fluids should be avoided if not deemed clinically necessary. For example, although some conditions may warrant intravenous rehydration, if documentation supports the same benefit could be achieved by oral hydration, IV hydration would not be considered reasonable and necessary. However, it is understood that there are clinical scenarios in			

		which the patient's need for hydration cannot wait for oral trials, even if an option. The intent should be understood within the body of documentation. I. Examples of Additional Payable Scenarios: If therapeutic fluid administration is medically necessary: for the correction of dehydration or prevention of nephrotoxicity immediately before or after transfusion, chemotherapy, or administration of potentially nephrotoxic medications. immediately before or after IV contrast infusion for a diagnostic procedure in a patient with renal insufficiency.		
	13. External Infusion Pumps	LCD 33794 Coverage Indications, Limitations, and/or Medical Necessity For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Administration of other drugs if either of the following sets of criteria (1) or (2) are met: Criteria set 1: Parenteral administration of the drug in the home is reasonable and necessary An infusion pump is necessary to safely administer the drug	When an infusion pump is covered, the drug necessitating the use of the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, the beneficiary, or the rental cap has been reached, the drug necessitating the use of the pump and supplies are covered as long as the coverage criteria for the pump are met. An external infusion pump and related drugs and supplies will be denied as not reasonable and necessary in the home setting for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion.	N/A

	The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy The therapeutic regimen is proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours Criteria set 2: Parenteral administration of the drug in the home is reasonable and necessary An infusion pump is necessary to safely administer the drug The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the beneficiary to return to the practitioner's office prior to the beginning of each infusion Systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information		

Reference Information

Links:

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https://www.idsociety.org/practice-guideline/amr-guidance/#null

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https://www.hopkinsguides.com/hopkins/index/Johns_Hopkins_ABX_Guide/Antibiotics_(_FDA)

A5273
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Policy History

Date	Version	Comments
12/07/2023	Draft	New Medical Policy
12/15/2023	Final	Approved by Medical Policy Committee