Original Effective Date: 08/01/2018
Current Effective Date: 03/24/2023
Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
Policy Number: C14555-A

Tygacil (tigecycline)

PRODUCTS AFFECTED

Tygacil (tigecycline), tigecycline

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Complicated Skin and Skin Structure Infections, Complicated Intra-abdominal Infections, Community-Acquired Bacterial Pneumonia

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. FOR ALL INDICATIONS:
1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported.
   AND
2. (a) Documentation of inadequate treatment response, serious side effects, contraindication

or non-susceptibility to a first-line antibiotic treatment:

- Community-acquired bacterial pneumonia (e.g., PO azithromycin, PO or IV moxifloxacin or levofloxacin, PO or IV doxycycline, IV ceftriaxone, IV ertapenem, IV vancomycin, IV Linezolid)
- Complicated intra-abdominal infections (e.g., PO amoxicillin-clavulanate, IV ertapenem or meropenem, IV ciprofloxacin/levofloxacin plus metronidazole OR moxifloxacin, ceftriaxone or cefepime plus metronidazole, or IV piperacillin/tazobactam)
- Complicated skin and skin structure infections (e.g., PO amoxicillin- clavulanate, PO cephalexin, PO trimethoprim-sulfamethoxazole or doxycycline, IV ceftriaxone, IV vancomycin, IV nafcillin continuous infusion, IV cefazolin, IV Linezolid)

OR

(b) Request is for continuation of therapy that was started at an inpatient setting (within the last 14 days) and member is at time of request transitioning to an outpatient site of care [DISCHARGE DOCUMENTATION REQUIRED WHICH INCLUDES INFECTIOUS DISEASE PRESCRIBER, DURATION OF THERAPY; START AND END DATE]

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: 14 days, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age or older

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous Infusion

DRUG CLASS:
Glycylcyclines

FDA-APPROVED USES:
TYGACIL is indicated in patients 18 years of age and older for:

- Complicated skin and skin structure infections
- Complicated intra-abdominal infections
- Community-acquired bacterial pneumonia

Limitations of Use: TYGACIL is not indicated for treatment of diabetic foot infection or hospital-acquired

pneumonia, including ventilator-associated pneumonia.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of TYGACIL and other antibacterial drugs, TYGACIL should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

Tygacil is indicated in patients 18 years of age and older for the treatment of complicated skin and skin structure infections caused by susceptible isolates of Escherichia coli, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and - resistant isolates), Streptococcus agalactiae, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae, and Bacteroides fragilis.
Tygacil is indicated in patients 18 years of age and older for the treatment of complicated intra-abdominal infections caused by susceptible isolates of Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis (vancomycin-susceptible isolates), Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros.
Tygacil is indicated in patients 18 years of age and older for the treatment of community acquired bacterial pneumonia caused by susceptible isolates of Streptococcus pneumoniae (penicillin-susceptible isolates), including cases with concurrent bacteremia, Haemophilus influenzae, and Legionella pneumophila.

COMPENDIAL APPROVED OFF-LABELED USES:
Pseudomembranous colitis due to C. difficile infection

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of tigecycline are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Tygacil (tigecycline) include: a known hypersensitivity to tigecycline.

OTHER SPECIAL CONSIDERATIONS:
Tygacil (tigecycline) has a black box warning for all-cause mortality. All-cause mortality was higher in patients treated with Tygacil than comparators in a meta-analysis of clinical trials. The cause of this mortality risk difference of 0.6% (95% CI 0.1, 1.2) has not been established. Tygacil should be reserved for use in situations when alternative treatments are not suitable.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3243	Injection, tigecycline, 1mg
J3244	Injection, tigecycline (accord) not therapeutically equivalent to J3243, 1 mg

AVAILABLE DOSAGE FORMS:
Tigecycline SOLR 50MG single dose vial
Tygacil SOLR 50MG single dose vial

REFERENCES

1. Tygacil (tigecycline) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals LLC, a subsidiary of Pfizer Inc; May 2021.
2. Bergallo C, Jasovich A, Teglia O, et al, "Safety and Efficacy of Intravenous Tigecycline in Treatment of Community-Acquired Pneumonia: Results From a Double-Blind Randomized Phase3 Comparison Study With Levofloxacin," Diagn Microbiol Infect Dis, 2009, 63(1):52-61
3. Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. Clin Infect Dis.2012;54(12):e132-e173.
4. Metlay JP, Waterer GW, Long AC, et al. Diagnosis and treatment of adults with community-acquired pneumonia. An official clinical practice guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med. 2019;200(7):e45-e67. doi:10.1164/rccm.201908-1581ST
   Solomkin JS, Mazuski JE, Bradley JS, et al. Diagnosis and management of complicated intra-abdominal infections in adults and children: guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. Clin Infect Dis. 2010;50(2):133-164.
5. Stevens DL et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases.2014 Jul 15;56(2):e10-e52.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Duration of Approval Prescriber Requirements FDA-Approved Uses Compendial Off Labeled Uses Contraindications/Exclusions/Discontinuation Other Special Considerations HCPCS Code and Description Available Dosage Forms	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file