

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Nuzyra (omadacycline)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 fill per 30 days

Medications	Quantity Limit
Nuzyra (omadacycline) tablets	30 tablets per fill

APPROVAL CRITERIA

Requests for Nuzyra (omadacycline) may be approved if the following criteria are met:

- I. Individual has been diagnosed with community-acquired bacterial pneumonia (CABP) confirmed by chest radiograph findings (FDA, 2008); **AND**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one alternative antibiotic that the microorganism is susceptible to [examples of alternative antibiotics include but are not limited to: moxifloxacin; levofloxacin; beta-lactam (amoxicillin-clavulanate, cefuroxime, ceftriaxone, cefotaxime, ertapenem) plus a macrolide (azithromycin, clarithromycin); beta-lactam plus doxycycline] (IDSA, 2007);

OR

- III. Individual has been diagnosed with an acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013):
 - A. Cellulitis/erysipelas; **OR**
 - B. Wound infection; **OR**
 - C. Major cutaneous abscess;**AND**
- IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one alternative antibiotic that the microorganism is susceptible to (examples of alternative antibiotics may include but are not limited to: TMP/SMX, doxycycline, vancomycin, daptomycin, telavancin, clindamycin) (IDSA, 2014);

OR

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New Program Date 05/23/2019

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0391-19

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Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

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- V. Individual started treatment with antibiotic(s) in the hospital and requires continued outpatient therapy for a microorganism susceptible to Nuzyra (omadacycline).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 9, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America (IDSA)/American Thoracic Society (ATS) Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. *Clin Infect Dis*. 2007 Mar;44(2):S27-S72.
6. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the infectious Diseases Society of America. *Clin Infect Dis*. 2014 Jul 15;59(2):e10-52. doi: 10.1093/cid/ciu296.
7. US Food and Drug Administration. FDA Briefing Document. Meeting of the Antimicrobial Drugs Advisory Committee. August 8, 2018. Available at <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM615848.pdf>. Accessed: January 10, 2019.
8. US Food and Drug Administration. Guidance for Industry. Acute bacterial skin and skin structure infections: developing drugs for treatment. October 2013. Available at <http://www.fda.gov/downloads/Drugs/.../Guidances/ucm071185.pdf>. Accessed: January 10, 2019.

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