



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMADACYCLINE	NUZYRA		45478	GPI-14 (04200050200320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae*

If yes, continue to #2.
If no, continue to #5.
2. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
If no, continue to #3.
3. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
 - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
If no, continue to #4.
4. Does the patient meet **ALL** of the following criteria?
 - Antimicrobial susceptibility results are unavailable
 - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #26 tablets per 13 days.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus grp.* (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, or *Klebsiella pneumoniae*

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**

If no, continue to #7.

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
- The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**

If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
- Antimicrobial susceptibility results are unavailable
 - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)

If yes, **approve Nuzyra 150mg tablet for one fill by GPID or GPI-14 with a quantity limit of #30 tablets per 14 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
 - 2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)
- B. **If you have community-acquired bacterial pneumonia, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumoniae*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae*
 - 3. You meet ONE of the following criteria:
 - a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
 - c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

(Denial text continued on next page)

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:

1. You are 18 years of age or older
2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (Includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, or *Klebsiella pneumoniae*
3. You meet ONE of the following criteria:
 - a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, ceftazolin), AND 2) Nuzyra will work against the bacteria
 - c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, ceftazolin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

- Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/20

Created: 03/19

Client Approval: 04/20

P&T Approval: 01/19