



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELAFLORACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELAFLORACIN	BAXDELA		43532	GPI-14 (05000025100320)	

GUIDELINES FOR USE

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

If yes, approve as follows:

- **Acute bacterial skin or skin structure infection (ABSSSI):** approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.
- **Community-acquired bacterial pneumonia (CABP):** approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.
- **Other indications:** approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.

If no, continue to #2.

2. Does the patient have a diagnosis of acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following?

- The patient is 18 years of age or older
- Infection is suspected to be caused by **ONE** of the following organisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, or *Pseudomonas aeruginosa*

If yes, continue to #3.

If no, continue to #6.

3. Does the patient have a diagnosis of animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitus ulcer formation, myonecrosis or ecthyma gangrenosum?

If yes, do not approve.

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

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. 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 **ONE** standard of care agent for acute bacterial skin or skin structure infection (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to delafloxacin

If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**

If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
- Antimicrobial susceptibility results are unavailable
 - The patient has had a trial of or contraindication to **ONE** of the following agents:
 - Gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, Bactrim, vancomycin)
 - Penicillin antibiotic (e.g., amoxicillin)
 - Fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin)
 - Cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #28 tablets per 14 days.**

If no, do not approve.

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

6. 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 [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila* or *Mycoplasma pneumoniae*

If yes, continue to #7.

If no, do not approve

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

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GUIDELINES FOR USE (CONTINUED)

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 community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to delafloxacin

If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 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 community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)

If yes, **approve 450mg tablets for one fill by GPID or GPI-14 with a quantity limit of #20 tablets per 10 days.**

If no, do not approve.

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 **DELAFLORACIN (Baxdela)** requires the following rule(s) be met for approval:

A. You meet **ONE** of the following:

1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist or
2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI); **OR** community-acquired bacterial pneumonia (CABP: type of lung infection)

B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**

- i. You are at least 18 years of age
- ii. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, and *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*

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GUIDELINES FOR USE (CONTINUED)

- iii. You do not have a diagnosis of animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitus ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
 - iv. You meet **ONE** of the following criteria:
 - i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **ONE** standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), **AND** b) delafloxacin will work against the bacteria
 - ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) **ONE** of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)
- C. **If you have community-acquired bacterial pneumonia (CABP: type of lung infection), 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 [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila* or *Mycoplasma pneumoniae*
 - 3. You meet **ONE** of the following criteria:
 - i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) **AND** b) delafloxacin will work against the bacteria
 - ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

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.

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DELAFLOXACIN

RATIONALE

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

REFERENCES

- Baxdela [Prescribing Information]. Lincolnshire, Illinois USA: Melinta Therapeutics, Inc.; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

Created: 10/17

Client Approval: 02/20

P&T Approval: 01/20