RXADVANCE
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Clinical Policy Title:	delafloxacin
Policy Number:	RxA.356
Drug(s) Applied:	Baxdela®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Delafloxacin (Baxdela®) is a fluoroquinolone antibiotic. It is indicated in adults for the treatment of: acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP)

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

Baxdela is indicated in adults for the treatment of ABSSSI caused by the following susceptible microorganisms:

- Gram-positive 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*, and *Enterococcus faecalis*.
- Gram-negative organisms:
  Escherichia coli, *Enterobacter cloacae*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*,

Baxdela is indicated in adults for the treatment of CABP caused by the following susceptible microorganisms:

- Gram-positive organisms:
  Streptococcus pneumoniae, *Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only)*.
- Gram-negative organisms:
  Escherichia coli, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa, Haemophilus influenzae, and Haemophilus arainfluenzae*
- Other organisms:
  Chlamydia pneumoniae, Legionella pneumophila, and Mycoplasma pneumoniae

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose

Delafloxacin (Baxdela®)	ABSSSI or CABP	450 mg PO every 12 hours OR 300 mg IV every 12 hours over 60 min infusion OR 300 mg IV every 12 hours over 60 min infusion, then switch to 450 mg PO every 12 hours at the discretion of physician	PO: 900 mg per day IV: 600 mg per day

Dosage Forms

- Tablets: 450 mg
- Lyophilized powder in a single dose vial for injection: 300 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Acute Bacterial Skin and Skin Structure Infection or Community-Acquired Bacterial Pneumonia (must meet all)**:**

1. Diagnosis of ABSSSI & CABP;
2. Age 18 years of age or older;
3. Member meets one of the following (a or b):
   a. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
   b. Both of the following (i and ii):
      i. Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is a gram-positive or gram-negative organism susceptible to delafloxacin, unless provider submits documentation that obtaining a C&S report is not feasible;
      ii. Member meets one of the following (a or b):
         a) Failure of one formulary fluoroquinolone, unless all are contraindicated or clinically significant adverse effects are experienced;
         b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis;
4. Dose does not exceed one of the following (a or b):
   a. IV: 600 mg (2 vials) per day;
   b. PO: 900 mg (2 tablets) per day.

Approval duration:
Commercial: 5 to 14 days (ABSSSI); 5 to 10 days (CABP)
Medicaid: 5 to 14 days (ABSSSI); 5 to 10 days (CABP)

II. Continued Therapy Approval

A. Acute Bacterial Skin and Skin Structure Infection (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy ;
   b. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
2. Member is responding positively to therapy;
3. Member has not received ≥ 14 days of therapy for current infection;
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. IV: 600 mg (2 vials) per day;
   b. PO: 900 mg (2 tablets) per day.

Approval duration:
Commercial: 14 days (ABSSI); 10 days (CABP)
Medicaid: 14 days (ABSSI); 10 days (CABP)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

ABSSSI: acute bacterial skin and skin structure infection
C&S: culture & sensitivity
FDA: Food and Drug Administration
MRSA: methicillin-resistant *Staphylococcus aureus*
MSSA: methicillin-susceptible *Staphylococcus aureus*
CABP: community-acquired bacterial pneumonia

APPENDIX B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Therapeutic alternatives include formulary antibiotics that are indicated for member's diagnosis and have sufficient activity against the offending pathogen at the site of the infection.		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to Baxdela or other fluoroquinolones
- Boxed warning(s):
  - Serious adverse reactions including tendinitis, tendon rupture, peripheral neuropathy, central nervous system effects, and exacerbation of myasthenia gravis

References

1. Baxdela Prescribing Information. Lincolnshire, IL. Melinta Therapeutics, Inc.; October 2019. Available at: www.baxdela.com. Accessed July 3,2020.

2. Infectious Diseases Society of America. Available at: http://www.idsociety.org/Organ_System/. Accessed July 3,2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Policy description table was updated 2) Background updated to include new indication and susceptible organisms per latest package insert 3) Dosing information updated per latest package insert 4) Initial therapy approval criteria updated to include new indication 5) Initial therapy and continued therapy criteria approval duration updated for both diagnoses 6) Continued therapy criteria II.A.1a. was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…" 7) Appendix A was updated to include CABP 8) References were updated	07/03/2020	09/14/2020