Clinical Policy Title:	delafloxacin
Policy Number:	RxA.356
Drug(s) Applied:	Baxdela®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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*, *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, Haemophilus arainfluenzae*
- Other organisms:
  Chlamydia pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
delafloxacin (Baxdela®)	ABSSSI or CABP	450 mg orally every 12 hours OR 300 mg intravenously every 12 hours over 60 min infusion OR	Oral: 900 mg per day Intravenous: 600 mg per day 5 – 14 days for ABSSSI 5 – 10 days for CABP

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
		300 mg intravenouslyevery 12 hours over 60 min infusion, then switch to 450 mg orally every 12 hours at the discretion of physician. Renal dose adjustment (eGFR 15-20 mL/min/1.73 m^2): 200 mg every 12 hours Or 200 mg every 12 hours, then switch to a 450 mg BAXDELA tablet orally every 12 hours at the discretion of the physician	

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of ABSSSI or 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. Intravenous: 600 mg per day;
   b. Oral: 900 mg per day.

Approval duration:

Commercial: 14 days (ABSSSI); 10 days (CABP)

Medicaid: 14 days (ABSSSI); 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 member has previously 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. Intravenous: 600 mg per day;
   b. Oral: 900 mg 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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	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 generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

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.

APPENDIX D: General Information

- Delafloxacin belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature. The antibacterial activity of delafloxacin is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial DNA replication, transcription, repair, and recombination. Delafloxacin exhibits a concentration-dependent bactericidal activity against gram-positive and gram-negative bacteria in vitro.

References

1. Baxdela® Prescribing Information. Lincolnshire, IL. Melinta Therapeutics, Inc.; February 2021. Available at: https://baxdela.com/docs/baxdela-prescribing-information.pdf. Accessed May 29, 2021.
2. Infectious Diseases Society of America. Available at: http://www.idsociety.org/Organ_System/. Accessed May 29, 2021.

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
Policy was reviewed: 1. Dosing Information dosing regimen was updated to include renal dosing, "Renal dose adjustment (eGFR 15-20 mL/min/1.73 m^2): 200 mg every 12 hours Or 200 mg every 12 hours…". 2. Dosing Information maximum dose was updated to include "5 – 14 days for ABSSSI" and "5 – 10 days for CABP". 3. Statement about provider sample ''The provision of provider samples does not	05/29/2021	09/14/2021

guarantee coverage…" was added to Clinical Policy. 4. Initial Approval criteria I.A.1 was updated from "Diagnosis of ABSSSI & CABP" to "Diagnosis of ABSSSI or CABP". 5. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 7. Appendix B: Therapeutic Alternatives was updated to include drug name "fluoroquinolone antibiotics"; its dosing regimen and maximum dose was updated to include "varies". 8. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 9. Appendix D was updated to include "Delafloxacin belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature…". 10. References were reviewed and updated.		