

Medical Policy:

Baxdela™ (delafloxacin) for injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.53	April 2, 2024	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

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Definitions

The fluoroquinolone Baxdela (delafloxacin) is approved for use in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP) caused by designated susceptible bacteria. In order to reduce the development of drug-resistant bacteria and maintain the effectiveness of Baxdela, it should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- ABSSSI: 600 billable units every day for 14 days
- CABP: 600 billable units every day for 10 days

Guideline

Baxdela (delafloxacin) is considered medically necessary when the following criteria are met:

1. Patient is 18 years of age or older; **AND**

2. Patient has a diagnosis of acute bacterial skin and skin structure infection (ABSSSI); **OR**
3. Patient has a diagnosis of community-acquired bacterial pneumonia (CABP)
4. Current culture and sensitivity (C&S) report 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 possible.

Limitations/Exclusions

1. Approval will be granted for 10 days for CABP and 14 days for ABSSSI.
2. Subsequent approvals will require a new authorization

Applicable Procedure Codes

Code	Description
C9462	Injection, delafloxacin, 1 mg
J3490	Unclassified drugs

Applicable NDCs

Code	Description
70842-0102-03	Baxdela 300mg Solution Reconstituted C9462 Injection, delafloxacin, 1 mg

ICD-10 Diagnoses

Code	Description
A46	Erysipelas
A48.1	Legionnaires' disease
A49.01	Methicillin susceptible Staphylococcus aureus infection, unspecified site
A49.02	Methicillin resistant Staphylococcus aureus infection, unspecified site
A49.1	Streptococcal infection, unspecified site
H00.031	Abscess of right upper eyelid
H00.032	Abscess of right lower eyelid
H00.033	Abscess of eyelid right eye, unspecified eyelid
H00.034	Abscess of left upper eyelid
H00.035	Abscess of left lower eyelid
H00.036	Abscess of eyelid left eye, unspecified eyelid
H00.039	Abscess of eyelid unspecified eye, unspecified eyelid
H05.011	Cellulitis of right orbit
H05.012	Cellulitis of left orbit
H05.013	Cellulitis of bilateral orbits
H05.019	Cellulitis of unspecified orbits
H60.00	Abscess of external ear, unspecified ear
H60.01	Abscess or right external ear
H60.02	Abscess of left external ear
H60.03	Abscess of external ear, bilateral
H60.10	Cellulitis of external ear, unspecified ear
H60.11	Cellulitis of right external ear

H60.12	Cellulitis of left external ear
H60.13	Cellulitis of external ear, bilateral
J12.2	Parainfluenza virus pneumonia
J13	Pneumonia due to Streptococcus pneumoniae
J14	Pneumonia due to Hemophilus influenzae
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomona
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.5	Pneumonia due to Escherichia coli
J15.7	Pneumonia due to Mycoplasma pneumoniae
J16.0	Chlamydial pneumonia
J34.0	Abscess, furuncle and carbuncle of nose
K12.2	Cellulitis and abscess of mouth
K61.0	Anal abscess
K61.1	Rectal abscess
K61.2	Anorectal abscess
K61.3	Ischiorectal abscess
K61.4	Intrasphincteric abscess
L00	Staphylococcal scalded skin syndrome
L01.00	Impetigo, unspecified
L01.01	Non-bullous impetigo
L01.02	Bockhart's impetigo
L01.03	Bullous impetigo
L01.09	Other impetigo
L01.1	Impetiginization of other dermatoses
L02.01	Cutaneous abscess of face
L02.02	Furuncle of face
L02.03	Carbuncle of face
L02.11	Cutaneous abscess of neck
L02.12	Furuncle of neck
L02.13	Carbuncle of neck
L02.211	Cutaneous abscess of abdominal wall
L02.212	Cutaneous abscess of back [any part, except buttock]
L02.213	Cutaneous abscess of chest wall
L02.214	Cutaneous abscess of groin
L02.215	Cutaneous abscess of perineum
L02.216	Cutaneous abscess of umbilicus
L02.219	Cutaneous abscess of trunk, unspecified
L02.221	Furuncle of abdominal wall
L02.222	Furuncle of back [any part, except buttock]
L02.223	Furuncle of chest wall
L02.224	Furuncle of groin
L02.225	Furuncle of perineum
L02.226	Furuncle of umbilicus
L02.229	Furuncle of trunk, unspecified
L02.231	Carbuncle of abdominal wall

L02.232	Carbuncle of back [any part, except buttock]
L02.233	Carbuncle of chest wall
L02.234	Carbuncle of groin
L02.235	Carbuncle of perineum
L02.236	Carbuncle of umbilicus
L02.239	Carbuncle of trunk, unspecified
L02.31	Cutaneous abscess of buttock
L02.32	Furuncle of buttock
L02.33	Carbuncle of buttock
L02.411	Cutaneous abscess of right axilla
L02.412	Cutaneous abscess of left axilla
L02.413	Cutaneous abscess of right upper limb
L02.414	Cutaneous abscess of left upper limb
L02.415	Cutaneous abscess of right lower limb
L02.416	Cutaneous abscess of left lower limb
L02.419	Cutaneous abscess of limb, unspecified
L02.421	Furuncle of right axilla
L02.422	Furuncle of left axilla
L02.423	Furuncle of right upper limb
L02.424	Furuncle of left upper limb
L02.425	Furuncle of right lower limb
L02.426	Furuncle of left lower limb
L02.429	Furuncle of limb, unspecified
L02.431	Carbuncle of right axilla
L02.432	Carbuncle of left axilla
L02.433	Carbuncle of right upper limb
L02.434	Carbuncle of left upper limb
L02.435	Carbuncle of right lower limb
L02.436	Carbuncle of left lower limb
L02.439	Carbuncle of limb, unspecified
L02.511	Cutaneous abscess of right hand
L02.512	Cutaneous abscess of left hand
L02.519	Cutaneous abscess of unspecified hand
L02.521	Furuncle of right hand
L02.522	Furuncle of left hand
L02.529	Furuncle of unspecified hand
L02.531	Carbuncle of right hand
L02.532	Carbuncle of left hand
L02.539	Carbuncle of unspecified hand
L02.611	Cutaneous abscess of right foot
L02.612	Cutaneous abscess of left foot
L02.619	Cutaneous abscess of unspecified foot
L02.621	Furuncle of right foot
L02.622	Furuncle of left foot
L02.629	Furuncle of unspecified foot
L02.631	Carbuncle of right foot

L02.632	Carbuncle of left foot
L02.639	Carbuncle of unspecified foot
L02.811	Cutaneous abscess of head [any part except face]
L02.818	Cutaneous abscess of other sites
L02.821	Furuncle of head [any part except face]
L02.828	Furuncle of other sites
L02.831	Carbuncle of head [any part except face]
L02.838	Carbuncle of other sites
L02.91	Cutaneous abscess, unspecified
L02.92	Furuncle, unspecified
L02.93	Carbuncle, unspecified
L03.011	Cellulitis of right finger
L03.012	Cellulitis of left finger
L03.019	Cellulitis of unspecified finger
L03.021	Acute lymphangitis of right finger
L03.022	Acute lymphangitis of left finger
L03.029	Acute lymphangitis of unspecified finger
L03.031	Cellulitis of right toe
L03.032	Cellulitis of left toe
L03.039	Cellulitis of unspecified toe
L03.041	Acute lymphangitis of right toe
L03.042	Acute lymphangitis of left toe
L03.049	Acute lymphangitis of unspecified toe
L03.111	Cellulitis of right axilla
L03.112	Cellulitis of left axilla
L03.113	Cellulitis of right upper limb
L03.114	Cellulitis of left upper limb
L03.115	Cellulitis of right lower limb
L03.116	Cellulitis of left lower limb
L03.119	Cellulitis of unspecified part of limb
L03.121	Acute lymphangitis of right axilla
L03.122	Acute lymphangitis of left axilla
L03.123	Acute lymphangitis of right upper limb
L03.124	Acute lymphangitis of left upper limb
L03.125	Acute lymphangitis of right lower limb
L03.126	Acute lymphangitis of left lower limb
L03.129	Acute lymphangitis of unspecified part of limb
L03.211	Cellulitis of face
L03.212	Acute lymphangitis of face
L03.213	Periorbital cellulitis
L03.221	Cellulitis of neck
L03.222	Acute lymphangitis of neck
L03.311	Cellulitis of abdominal wall
L03.312	Cellulitis of back [any part except buttock]
L03.313	Cellulitis of chest wall
L03.314	Cellulitis of groin

L03.315	Cellulitis of perineum
L03.316	Cellulitis of umbilicus
L03.317	Cellulitis of buttock
L03.319	Cellulitis of trunk, unspecified
L03.321	Acute lymphangitis of abdominal wall
L03.322	Acute lymphangitis of back [any part except buttock]
L03.323	Acute lymphangitis of chest wall
L03.324	Acute lymphangitis of groin
L03.325	Acute lymphangitis of perineum
L03.326	Acute lymphangitis of umbilicus
L03.327	Acute lymphangitis of buttock
L03.329	Acute lymphangitis of trunk, unspecified
L03.811	Cellulitis of head [any part, except face]
L03.818	Cellulitis of other sites
L03.891	Acute lymphangitis of head [any part, except face]
L03.898	Acute lymphangitis of other sites
L03.90	Cellulitis, unspecified
L03.91	Acute lymphangitis, unspecified
L04.0	Acute lymphadenitis face, head and neck
L04.1	Acute lymphadenitis of trunk
L04.2	Acute lymphadenitis of upper limb
L04.3	Acute lymphadenitis of lower limb
L04.8	Acute lymphadenitis of other sites
L04.9	Acute lymphadenitis, unspecified
L05.01	Pilonidal cyst with abscess
L05.02	Pilonidal sinus with abscess
L05.91	Pilonidal cyst without abscess
L05.92	Pilonidal sinus without abscess
L08.0	Pyoderma
L08.1	Erythrasma
L08.81	Pyoderma vegetans
L08.82	Omphalitis not of newborn
L08.89	Other specified local infection of the skin and subcutaneous tissue
L08.9	Local infection of the skin and subcutaneous tissue, unspecified
N48.21	Abscess of corpus cavernosum and penis
N48.22	Cellulitis of corpus cavernosum and penis
N61.0	Mastitis without abscess
N61.1	Abscess of the breast and nipple
N76.4	Abscess of vulva

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/2/2024	Annual Review: No Criteria Changes

EmblemHealth & ConnectiCare	7/27/2023	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	3/31/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	12/30/2020	Update to include new indication of community acquired bacterial pneumonia (CABP)
EmblemHealth & ConnectiCare	10/08/2019	No updates made during annual review

References

1. Baxdela (delafloxacin) tablets [prescribing information]. Lincolnshire, IL: Melinta Therapeutics, Inc; October 2020.