Clinical Policy: Ophthalmic Agents: Antibiotic and Antibiotic-Steroid Combination Drops and Ointments

Reference Number: OH.PHAR.PPA.74
Effective Date: 01/01/2020 Revision Log
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

OPHTHALMIC AGENTS: ANTIBACTERIAL - QUINOLONES

NO PA REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
CILOXAN® ointment (ciprofloxacin) CIPROFLOXACIN drops (generic of Ciloxan®) MOXIFLOXACIN (generic for Vigamox®) OFLOXACIN drops (generic of Ocuflox®)	BESIVANCE® drops (besifloxacin) GATIFLOXACIN drops (generic of Zymaxid®) LEVOFLOXACIN drops (generic of Quixin®) MOXEZA® drops (moxifloxacin)

OPHTHALMIC AGENTS: ANTIBACTERIAL – NON-QUINOLONE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BACITRACIN-POLYMYXIN ointment ERYTHROMYCIN ointment (generic of Ilotycin®) GENTAMICIN drops NEOMYCIN/POLYMYXIN/ BACITRACIN ointment (generic of Neosporin®) NEOMYCIN/POLYMYXIN/ GRAMICIDIN drops (generic of Neosporin®) POLYMYXIN/TRIMETHOPRIM drops (generic of Polytrim®) SULFACETAMIDE drops TOBRAMYCIN drops (generic of Tobrex®) TOBREX® ointment (tobramycin)	AZASITE® drops (azithromycin) BACITRACIN ointment GENTAMICIN ointment SULFACETAMIDE ointment

OPHTHALMIC AGENTS: ANTIBACTERIAL – STEROID COMBINATIONS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NEOMYCIN/POLYMYXIN/ DEXAMETHASONE drops (generic of Maxitrol®) NEOMYCIN/POLYMYXIN/ DEXAMETHASONE ointment (generic of Maxitrol®) SULFACETAMIDE/ PREDNISOLONE drops (generic of Vasocidin®) TOBRADEX® drops, ointment (dexamethasone/tobramycin)	BLEPHAMIDE® drops, ointment (prednisolone/sulfacetamide) NEOMYCIN/POLYMYXIN/ HYDROCORTISONE drops (generic of Cortisporin®) NEOMYCIN/POLYMYXIN/ BACITRACIN/ HYDROCORTISONE ointment PRED-G® drops, ointment (prednisolone/ gentamicin) TOBRADEX ST® (dexamethasone/ tobramycin) TOBRAMYCIN/ DEXAMETHASONE drops (generic of TobraDex®) ZYLET® drops (tobramycin/ loteprednol)

FDA approved indication(s)
Ciprofloxacin is indicted for:

- Treatment of bacterial infections, including bacterial conjunctivitis and corneal ulcer

Moxifloxacin is indicated for:

- Treatment of bacterial conjunctivitis (including chlamydial conjunctivitis) due to susceptible organisms
- For ophthalmic surgical prophylaxis

Ofloxacin is indicated for:

- Treatment of ophthalmic bacterial infections, including bacterial conjunctivitis and corneal ulcer

Besivance, gatifloxacin, and levofloxacin are indicated for:

- Treatment of bacterial conjunctivitis due to susceptible organisms

Bacitracin-Polymyxin, Neosporin, and Bacitracin are indicated for:

- Treatment of superficial ophthalmic infection caused by susceptible bacteria (e.g., bacterial conjunctivitis, keratitis, keratoconjunctivitis, blepharitis, and blepharoconjunctivitis)

Erythromycin is indicated for:

- Prevention of ophthalmia neonatorum (i.e., ophthalmia neonatorum prophylaxis) due to *Neisseria gonorrhoeae* or *Chlamydia trachomatis* in neonates
- Treatment of superficial ophthalmic infection involving the conjunctiva and/or cornea

Gentamicin and Tobramycin are indicated for:

- Treatment of blepharitis, blepharoconjunctivitis, bacterial conjunctivitis, corneal ulcer, dacryocystitis, keratitis, keratoconjunctivitis, and acute meibomianitis

Polymyxin/trimethoprim is indicated for:

- Treatment of ocular infections, including bacterial conjunctivitis and blepharoconjunctivitis, caused by susceptible strains of bacteria

Sulfacetamide is indicated for:

- Treatment of conjunctivitis, corneal ulcer and other superficial ophthalmic infections caused by susceptible organisms, and as adjunctive treatment in systemic sulfonamide therapy of chlamydial conjunctivitis including trachoma and inclusion conjunctivitis

Azasite is indicated for:

- Treatment of bacterial conjunctivitis caused by susceptible strains of *CDC coryneform group G, H. influenzae, S. aureus, S. mitis group,* and *S. pneumoniae*

Neomycin/polymyxin/dexamethasone, sulfacetamide/prednisolone, Tobradex, neomycin/polymyxin/hydrocortisone, neomycin/polymyxin/bacitracin/hydrocortisone, and Pred-G are indicated for:

- Treatment of corticosteroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ophthalmic infection or a risk of bacterial infection exists, including bacterial conjunctivitis, chronic anterior uveitis, and corneal injury (corneal abrasion) from chemical, radiation or thermal burns, or penetration of foreign bodies

Zylet is indicated for:

- Treatment of corticosteroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where a superficial bacterial ophthalmic infection or a risk of bacterial infection exists, including bacterial conjunctivitis, allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster ocular infection (keratitis), iritis, cyclitis, and chronic anterior uveitis or corneal injury resulting from chemical, radiation, or thermal ocular burns or from the penetration of foreign bodies

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

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Ophthalmic Agents: Antibiotic and Antibiotic-Steroid Combination Drops and Ointments are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Failure of at least two preferred medications, each used for ≥ 3 days, unless member meets one of the following (a, b, c, or d):
   a. Allergy to medications not requiring prior approval;
   b. Contraindication to or drug interaction with medications not requiring prior approval;
   c. History of unacceptable/toxic side effects to medications not requiring prior approval;
   d. Culture and Sensitivity (C&S) report for the current infection shows resistance of the organism to preferred medications, unless provider submits documentation that obtaining a C&S report is not feasible.

Approval Duration: 14 days

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation Key
C&S: culture and sensitivity report
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

- Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource.

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Please refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.