Clinical Policy: Ophthalmic Agents: NSAIDs

Reference Number: OH.PHAR.PPA.78
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

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DICLOFENAC (generic of Voltaren®) FLURBIPROFEN (generic of Ocufen®) KETOROLAC (generic of Acular®, Acular LS®)	ACUVAIL® (ketorolac) BROMFENAC (generic of Bromday®, Xibrom®) BROMSITE™ (bromfenac) ILEVRO® (nepafenac) NEVANAC® (nepafenac) PROLENSA® (bromfenac)

FDA approved indication(s)

Acuvail is indicated for:

- Reduction of postoperative ocular inflammation and ocular pain after cataract surgery in adults.

Bromfenac is indicated for:

- Reduction of postoperative ocular inflammation and ocular pain after cataract surgery in adults.

Bromsite is indicated for:

- Reduction of postoperative ocular inflammation and ocular pain after cataract surgery in adults.

Diclofenac is indicated for:

- Treatment of postoperative ocular inflammation following cataract extraction in adults.
- Reduction of photophobia and ocular pain following corneal refractive surgery in adults.

Flurbiprofen is indicated for:

- Intraoperative miosis inhibition in adults.
- Treatment of postoperative ocular inflammation in adults.

Ilevro is indicated for:

- Treatment of ocular pain and postoperative ocular inflammation following cataract surgery in adults and children 10 years of age and older.

Ketorolac is indicated for:

- For the 0.4% ophthalmic solution: reduction of ocular pain and burning/stinging after corneal refractive surgery in adults and children 3 years of age and older.

- For the 0.5% ophthalmic solution: reduction of postoperative ocular inflammation and ocular pain after cataract surgery in adults and children 2 years of age and older.
- For the 0.5% ophthalmic solution: treatment of ocular pruritus due to seasonal allergic conjunctivitis in adults and children 2 years of age and older.

Nevanac is indicated for:

- Treatment of ocular pain and postoperative ocular inflammation following cataract surgery in adults and children 10 years of age and older.

Prolensa is indicated for:

- Treatment of postoperative ocular inflammation and ocular pain following cataract surgery in adults.

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: NSAIDs 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. If request is for Ilevro® or Nevanac®, age ≥ 10 years;
3. If request is for Acuvail®, bromfenac, Bromsite®, or Prolensa®, age ≥ 18 years;
4. Failure of ≥ 3 days of one preferred medication, unless member meets one of the following (a, b, or c):
   a. Allergy to medications not requiring prior approval;
   b. Contraindication to or drug interaction with medications not requiring prior approval;
   c. History or unacceptable/toxic side effects to medications not requiring prior approval.
   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
FDA: Food and Drug Administration

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
Diclofenac	Postoperative ocular inflammation following cataract extraction: 1 drop to affected eye(s) QID, starting 24 hours after cataract surgery and continue for 2 weeks Reduction of photophobia and ocular pain following corneal refractive surgery: 1 to 2 drops to affected eye(s) within 1 hour prior to surgery, then 1 to 2 drops 15 minutes after surgery and then QID beginning 4 to 6 hours after surgery and continue for up to 3 days as needed.	N/A
Flurbiprofen (Ocufen®)	Intraoperative miosis inhibition: 1 drop to affected eye(s) every 30 minutes beginning 2 hours before surgery (4 drops total) Postoperative ocular inflammation: 1 drop to affected eye(s) every 4 hours for 1 to 3 weeks	N/A
Ketorolac (Acular®, Acular LS®)	Reduction of postoperative ocular inflammation and ocular pain after cataract surgery: For 0.5% solution in adults and children 2 years of age and older: 1 drop to affected eye(s) QID beginning 24 hours after cataract surgery and continue through first 2 weeks Reduction of ocular pain and burning/stinging after corneal refractive surgery: For 0.4% solution in adults and children 3 years of age and older: 1 drop to affected eye(s) QID as needed for up to 4 days after surgery Treatment of ocular pruritus due to seasonal allergic conjunctivitis: For 0.5% solution in adults and children 2 years of age and older: 1 drop to affected eye(s) QID	N/A

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

- Contraindications(s): NSAID hypersensitivity
- Boxed warning(s): none reported

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Acuvail	1 drop to affected eye(s) BID beginning 1 day prior to cataract surgery; continue on the day of surgery and through the first 2 weeks after surgery	N/A
Bromfenac	Bromfenac (Bromday®): 1 drop to affected eye(s) QD beginning 24 hours prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period Bromfenac (Xibrom®): 1 drop to affected eye(s) BID beginning 24 hours after cataract surgery, continued through the first 14 days of the postoperative period	1 drop/day per affected eye for Bromday solutions 2 drops/day per affected eye for Xibrom solutions
Bromsite	1 drop to affected eye(s) BID beginning 1 day prior to surgery, continued on the day of surgery, and through the first 14 days of the postoperative period	2 drops/day per affected eye
Ilevro	1 drop to affected eye(s) QD beginning 1 day prior to cataract surgery and continued through the first 2 weeks of the postoperative period. On the day of surgery, 1 drop should be administered as usual with an additional drop administered 30-120 minutes prior to surgery	1 drop/day per affected eye
Nevanac	1 drop to affected eye(s) TID beginning 1 day prior to cataract surgery, continued on the day of surgery, and through the first 2 weeks of the postoperative period	3 drops/day in each eye
Prolensa	1 drop to affected eye(s) QD beginning 24 hours prior to cataract surgery, continued on the day of surgery, and through the first 14 days of the postoperative period	1 drop/day per affected eye

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Acuvail	Ophthalmic solution: 0.45%

Drug	Availability
bromfenac	Ophthalmic solution: 0.09%
Bromsite	Ophthalmic solution: 0.075%
diclofenac	Ophthalmic solution: 0.1%
flurbiprofen	Ophthalmic solution: 0.03%
Ilevro	Ophthalmic suspension: 0.3%
ketorolac	Acular LS ophthalmic solution: 0.4% Acular ophthalmic solution: 0.5%
Nevanac	Ophthalmic suspension: 0.1%
Prolensa	Ophthalmic solution: 0.07%

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.

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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.

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