Clinical Policy: Diclofenac (Cambia, Flector, Licart, Pennsaid, Zipsor, Zorvolex)

Reference Number: CP.PCH.28
Effective Date: 09.01.20
Last Review Date: 11.25
Line of Business: Commercial, HIM

Revision Log

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

Description
The following are nonsteroidal anti-inflammatory drugs (NSAIDs) requiring prior authorization: diclofenac epolamine topical system (Flector®, Licart®), diclofenac potassium (Cambia®, Zipsor®), diclofenac sodium (Pennsaid®), and diclofenac (Zorvolex®).

FDA Approved Indication(s)
- Cambia is indicated for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older.
- Flector is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions in adults and pediatric patients 6 years and older.
- Licart is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.
- Pennsaid is indicated for the treatment of the pain of osteoarthritis (OA) of the knee(s).
- Diclofenac 3% gel is indicated for the topical treatment of actinic keratoses.
- Zipsor is indicated for relief of mild to moderate acute pain in adults and pediatric patients 12 years of age and older.
- Zorvolex is indicated for management of mild to moderate acute pain and for OA pain.

Limitation(s) of use:
- Cambia is not indicated for the prophylactic therapy of migraine.
- Safety and effectiveness of Cambia is not established for cluster headache, which is present in an older, predominantly male population.

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 health plans affiliated with Centene Corporation® that Cambia, Flector, Licart, Pennsaid, diclofenac 3% gel, Zipsor, and Zorvolex are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Mild to Moderate Acute Pain (must meet all)**:**
1. Diagnosis of acute pain;
2. Request is for Flector, Licart, Zipsor or Zovolex;

3. One of the following (a, b, or c):
   a. Flector: Age ≥ 6 years;
   b. Zipsor: Age ≥ 12 years;
   c. Licart, Zorvolex: Age ≥ 18 years;
4. For Flector or Licart requests, member meets both of the following (a and b):
   a. Failure of both of the following (i and ii), unless clinically significant adverse effects are experienced or all are contraindicated:*
      ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
      i. Two formulary oral generic NSAIDs (*see Appendix B*) at up to maximally indicated doses;
      ii. diclofenac 1% topical gel (generic Voltaren®) within the past 90 days;
   b. Member must use generic diclofenac 1.3% topical system, unless contraindicated or clinically adverse effects are experienced;
5. For Zipsor or Zorvolex requests, member meets both of the following (a and b):*
   ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of both of the following (i and ii), unless clinically significant adverse effects are experienced or all are contraindicated:
      i. Oral generic diclofenac tablet;
      ii. One other preferred oral NSAID *(see Appendix B)* at up to maximally indicated doses;
   b. If request is for brand Zipsor, member must use generic diclofenac capsule; unless contraindicated or clinically adverse effects are experienced;
6. Dose does not exceed any of the following (a, b, c, or d):
   a. Flector: 2 topical systems per day;
   b. Licart: 1 topical system per day;
   c. Zipsor: 100 mg (4 capsules) per day;
   d. Zorvolex: 105 mg (3 capsules) per day.

Approval duration: 12 months

B. Osteoarthritis Pain (must meet all)**:**
1. Diagnosis of OA;
2. Request is for Pennsaid or Zorvolex;
3. Age ≥ 18 years;
4. For Pennsaid requests, member meets both of the following (a and b):
   a. Failure of both of the following (i and ii), unless clinically significant adverse effects are experienced or all are contraindicated:*
      ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
      i. One oral generic NSAID *(see Appendix B);*
      ii. Either diclofenac 1.5% topical solution or diclofenac 1% topical gel;
   b. Member must use generic diclofenac 2% topical solution, unless contraindicated or clinically adverse effects are experienced;
5. For Zorvolex requests, failure of both of the following (a and b), unless clinically significant adverse effects are experienced or all are contraindicated:*
   ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*

a. Oral generic diclofenac;
b. One other preferred NSAID *(see Appendix B)* at up to maximally indicated doses;

6. Dose does not exceed any of the following (a or b):
   a. Pennsaid: 80 mg (4 pumps) per knee per day;
   b. Zorvolex: 105 mg (3 capsules) per day.

Approval duration: 12 months

C. Migraines (must meet all)**:**

1. Diagnosis of migraine attacks;
2. Request is for Cambia;
3. Age ≥ 18 years;
4. Failure of rizatriptan orally disintegrating tablets at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;*
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
5. Documentation supports inability to use oral generic diclofenac;*
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
6. Member must use generic diclofenac packets, unless contraindicated or clinically adverse effects are experienced;
7. Dose does not exceed 50 mg (1 packet) per day.

Approval duration: 12 months

D. Actinic Keratosis (must meet all)**:**

1. Diagnosis of actinic keratosis;
2. Request is for diclofenac 3% gel;
3. Age ≥ 18 years;
4. Failure of 5-fluorouracil and imiquimod cream, unless clinically significant adverse effects are experienced or both are contraindicated;*
   ** For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
5. Prescribed quantity does not exceed 1 tube per 30 days.

Approval duration: 90 days

E. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. For Flector or Licart requests, member must use generic diclofenac 1.3% topical system, unless contraindicated or clinically adverse effects are experienced;
4. For Zipsor requests, member must use generic diclofenac capsule, unless contraindicated or clinically adverse effects are experienced;
5. For Pennsaid requests, member must use generic diclofenac 2% topical solution, unless contraindicated or clinically adverse effects are experienced;
6. For Cambia requests, member must use generic diclofenac packets, unless contraindicated or clinically adverse effects are experienced;
7. For diclofenac 3% gel requests, one of the following (a or b):
   a. Request is for additional treatment of a new lesion;
   b. Request is to complete initial treatment of the same lesion and member has not received more than 90 days of treatment;
8. If request is for a dose increase, new dose does not exceed any of the following (a-g):
   a. Cambia: 50 mg per day (1 packet per day);
   b. Flector: 2 topical systems per day;
   c. Licart: 1 topical system per day;
   d. Pennsaid: 80 mg (4 pumps) per knee per day;
   e. Diclofenac 3% gel: 1 tube per 30 days;
   f. Zipsor: 100 mg (4 capsules) per day;
   g. Zorvolex: 105 mg (3 capsules) per day.

Approval duration: 12 months (up to 90 days for diclofenac 3% gel)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

III. 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.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CABG: coronary artery bypass graft
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug
OA: osteoarthritis

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
Oral NSAIDs		
diclofenac (Voltaren®)	50 mg PO TID	150 mg/day
etodolac (Lodine®)	400 – 500 mg PO BID	1,200 mg/day
fenoprofen (Nalfon®)	400 – 600 mg PO TID to QID	3,200 mg/day
ibuprofen (Motrin®)	400 – 800 mg PO TID to QID	3,200 mg/day
indomethacin (Indocin®)	25 – 50 mg PO BID to TID	200 mg/day
indomethacin SR (Indocin SR®)	75 mg PO QD to BID	150 mg/day
ketoprofen (Orudis®)	50 mg PO QID or 75 mg PO TID	300 mg/day
meloxicam (Mobic®)	7.5 mg – 15 mg PO QD	15 mg/day
naproxen (Naprosyn®)	250 – 500 mg PO BID	1,500 mg/day for up to 6 months
naproxen sodium (Anaprox®, Anaprox DS®)	275 – 550 mg PO BID	1,650 mg/day for up to 6 months
oxaprozin (Daypro®)	600 – 1,200 mg PO QD	1,800 mg/day
piroxicam (Feldene®)	10 – 20 mg PO QD	20 mg/day
salsalate (Disalcid®)	500 – 750 mg PO TID, titrated up to 1,000 mg TID or 1500 mg BID	3,000 mg/day
sulindac (Clinoril®)	150 mg – 200 mg PO BID	400 mg/day
tolmetin DS (Tolectin®)	400 mg PO TID maintenance 200-600 mg TID	1,800 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Topical NSAIDs		
diclofenac 1.5% solution	40 drops QID on each painful knee	160 drops/knee/day
diclofenac 1% gel (Voltaren® Gel)	2 – 4 g applied to affected area QID	32 g/day
Anti-Migraine Agents		
rizatriptan orally disintegrating tablet (Maxalt® MLT)	5 or 10 mg PO QD	30 mg/day
Actinic Keratoses Treatments		
5-fluorouracil (Efudex®, Carac®) 0.5% or 5% topical cream	Apply topically to affected areas QD or BID	Twice daily for 4 weeks
imiquimod 5% topical cream	Apply topically twice weekly at bedtime	Twice weekly for 16 weeks

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) known hypersensitivity to diclofenac or any components of the drug product; history of asthma, urticaria or allergic-type reactions after taking aspirin or other NSAIDS; in the setting of coronary artery bypass graft (CABG) surgery
  - Flector, Licart: use on non-intact or damaged skin
  - Zipsor: contains gelatin and should not be given to patients with known hypersensitivity to bovine protein
- Boxed warning(s): cardiovascular thrombotic events; use in the setting of CABG; gastrointestinal bleeding, ulceration, and perforation

Appendix D: General Information

- Different dose strengths and formulations of oral diclofenac are not interchangeable. This difference should be taken into consideration when changing strengths or formulations.
- For actinic keratosis, complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Diclofenac potassium (Cambia)	Migraine	One packet (50 mg) PO QD	50 mg/day
Diclofenac epolamine (Flector)	Acute pain due to minor strains, sprains, and contusions	1 topical system BID	2 topical systems /day
Diclofenac epolamine (Licart)	Acute pain due to minor strains,	1 topical system QD	1 topical system /day

Drug Name	Indication	Dosing Regimen	Maximum Dose
	sprains, and contusions		
Diclofenac sodium (Pennsaid)	Pain of OA of the knee(s)	40 mg (2 pump actuations) topically BID per knee	80 mg/knee/day (4 pumps/knee/ day)
Diclofenac sodium 3% topical gel	Actinic keratoses	Apply to lesion areas BID. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site.	BID for 60-90 days
Diclofenac potassium (Zipsor)	Mild to moderate acute pain	25 mg PO QID	100 mg/day
Diclofenac (Zorvolex)	Mild to moderate acute pain or OA	18 or 35 mg PO TID	105 mg/day

VI. Product Availability

Drug Name	Availability
Diclofenac potassium (Cambia)	Packets: 50 mg in a soluble powder
Diclofenac epolamine (Flector)	Topical system: 1.3%
Diclofenac epolamine (Licart)	Topical system: 1.3%
Diclofenac sodium (Pennsaid)	Topical solution: 2%
Diclofenac sodium	Topical gel: 3% in tubes of 100 g
Diclofenac potassium (Zipsor)	Capsule: 25 mg
Diclofenac (Zorvolex)	Capsules: 18 mg, 35 mg

VII. References

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12. Kolasinski SL, Neogi T, Hochberg, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis & Rheumatology. 2020;72(2):220-233.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	08.19.21	11.21
4Q 2022 annual review: no significant changes; redirections separated onto two lines for clarity; added must use generic formulation language for brand Flector, Licart and Zipsor; for mild to moderate acute pain, clarified failure of "oral" NSAID and generic diclofenac "tablet" for Zipsor or Zorvolex; contraindications updated per PIs; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.28.22	11.22
4Q 2023 annual review: for brand Pennsaid added requirement to use generic formulation; references reviewed and updated.	06.28.23	11.23
4Q 2024 annual review: removed references to brand Solaraze due to product discontinuation; references reviewed and updated.	07.15.24	11.24
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; added must use generic formulation language for brand Flector, Licart, Zipsor and Pennsaid in continued therapy; added must use generic formulation language for Cambia requests; references reviewed and updated.	07.15.25	11.25

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.

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