Clinical Policy: Topical Diclofenac (Solaraze, Flector)

Reference Number: HIM.PA.123
Effective Date: 12.01.17
Last Review Date: 08.19
Line of Business: HIM

Revision Log

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

Description

Diclofenac sodium topical gel (Solaraze®) and diclofenac epolamine topical system (Flector®) are topical non-steroid anti-inflammatory drugs (NSAIDs).

FDA Approved Indication(s)

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.

Solaraze gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

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.

I. Initial Approval Criteria

A. Pain (must meet all)**:**

1. Prescribed for the treatment of pain;
2. Request is for diclofenac epolamine topical system (Flector);
3. Age ≥ 6 years;
4. Failure of TWO formulary oral generic NSAIDs *(see Appendix B)* at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of diclofenac gel 1% (Voltaren®) within the past 90 days, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 2 topical systems per day.

Approval duration: 12 months

B. Actinic Keratosis (must meet all):

1. Diagnosis of AK;
2. Request is for diclofenac 3% gel (Solaraze);
3. Age ≥ 18 years;
4. Failure of 5-fluorouracil and imiquimod cream, unless both are contraindicated or clinically significant adverse effects are experienced;
5. Prescribed quantity does not exceed 1 tube per 30 days.

Approval duration: 90 days

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Pain (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2 topical systems per day.

Approval duration: 12 months

B. Actinic Keratosis (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Additional treatment is for a new lesion or to complete initial treatment (up to 90 days);
3. Prescribed quantity does not exceed 1 tube per 30 days.

Approval duration: Up to 90 days

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 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 – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AK: actinic keratosis
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug

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
Voltaren® (diclofenac 1% gel)	For topical treatment of pain 2-4 g topically to the affected area QID	32 g/day
Formulary NSAIDs: diclofenac, etodolac, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin	For topical treatment of pain Varies	Varies
5-fluorouracil (Efudex®, Carac®) 0.5% or 5% topical cream	For AK Apply topically to affected areas QD or BID	Twice daily for 4 weeks
imiquimod (Aldara®) topical cream	For AK 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

- Contraindication(s):
  - Flector and Solaraze: hypersensitivity; in the setting of coronary artery bypass graft (CABG) surgery;
  - Flector: history of asthma, urticarial, or other allergic-type reactions after taking aspirin or other NSAIDs; for use on non-intact or damaged skin
- Boxed warning(s): Flextor: risk of serious cardiovascular and gastrointestinal events

Appendix D: General Information

- 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 epolamine (Flector)	Acute pain due to minor strains, sprains, and contusions	1 topical system BID	2 topical systems /day
Diclofenac sodium (Solaraze)	Actinic keratoses	Apply topically to lesions BID	BID for 60-90 days

VI. Product Availability

Drug Name	Availability
Diclofenac epolamine (Flector)	Topical system: 1.3%
Diclofenac sodium (Solaraze)	Topical gel: 3% in tubes of 100 g

VII. References

1. Flector Prescribing Information. New York, NY: Pfizer Inc; March 2019. Available at: www.flectorpatch.com. Accessed May 3, 2019.
2. Solaraze Prescribing Information. Melville, NY: Fougera Pharmaceuticals, Inc.; May 2016. Available at: https://www.accessdata.fda.gov. Accessed May 3, 2019.
3. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 3, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.01.17	11.17
Coverage criteria added for diclofenac 3% cream (Solaraze) for actinic keratosis	12.06.17	02.18
3Q18 annual review: Coverage criteria for Voltaren topical gel (no longer requires prior authorization on the HIM formulary) was replaced with coverage criteria for Flector topical patch (now requires prior authorization on the HIM formulary); References reviewed and updated.	05.29.18	08.18
No significant changes; updated FDA approved indications to include pediatric patients 6 years and older; updated criteria requirement from ≥ 18 to ≥ 6; changed nomenclature from patch to topical systems to align with change in labeling; references reviewed and updates;	03.14.19	
3Q 2019 annual review: No significant changes; reference reviewed and updated.	04.03.19	08.19

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 Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.