Clinical Policy: Diclofenac sodium topical gel (Solaraze, Voltaren)

Reference Number: HIM.PA.123
Effective Date: 12.01.17
Last Review Date: 02.18 Revision Log
Line of Business: Health Insurance Marketplace

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

Description
Diclofenac sodium topical gel (Solaraze®, Voltaren®) is a topical non-steroid anti-inflammatory drug (NSAID).

FDA Approved Indication
Voltaren gel is indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

Limitation of use: Diclofenac sodium topical gel, 1% was not evaluated for use on joints of the spine, hip, or shoulder.

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

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Osteoarthritis (must meet all)**:**
1. Diagnosis of osteoarthritis;
2. Request is for Voltaren topical gel;
3. Age ≥ 18 years;
4. Failure of one oral NSAID (at up to maximally indicated doses) unless contraindicated or clinically significant adverse effects are experienced;
5. Prescribed quantity does not exceed 2 tubes/30 days.

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/30 days.

Approval duration: 90 days

C. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Osteoarthritis (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. Prescribed quantity does not exceed 2 tubes/30 days.

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/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 HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 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: 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. References

1. Diclofenac sodium 1% Prescribing Information. Pulaski, TN: AvKARE, Inc.; August 2016. Available at: https://dailymed.nlm.nih.gov. Accessed August 31, 2017.
2. Solaraze Prescribing Information. Melville, NY: Fougera Pharmaceuticals, Inc.; May 2016. Available at: https://www.accessdata.fda.gov. Accessed September 28, 2017.

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

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.