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

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.
**Clinical Policy**

**Topical Diclofenac**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltaren® (diclofenac 1% gel)</td>
<td>For topical treatment of pain 2-4 g topically to the affected area QID</td>
<td>32 g/day</td>
</tr>
<tr>
<td>Formulary NSAIDs: diclofenac, etodolac, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmetin</td>
<td>For topical treatment of pain Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>5-fluorouracil (Efudex®, Carac®) 0.5% or 5% topical cream</td>
<td>For AK Apply topically to affected areas QD or BID</td>
<td>Twice daily for 4 weeks</td>
</tr>
<tr>
<td>Imiquimod (Aldara®) topical cream</td>
<td>For AK Apply topically twice weekly at bedtime</td>
<td>Twice weekly for 16 weeks</td>
</tr>
</tbody>
</table>

*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**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac epolamine (Flector)</td>
<td>Acute pain due to minor strains, sprains, and contusions</td>
<td>1 topical system BID</td>
<td>2 topical systems /day</td>
</tr>
<tr>
<td>Diclofenac sodium (Solaraze)</td>
<td>Actinic keratoses</td>
<td>Apply topically to lesions BID</td>
<td>BID for 60-90 days</td>
</tr>
</tbody>
</table>
VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac epolamine</td>
<td>Topical system: 1.3%</td>
</tr>
<tr>
<td>(Flector)</td>
<td></td>
</tr>
<tr>
<td>Diclofenac sodium</td>
<td>Topical gel: 3% in tubes of 100 g</td>
</tr>
<tr>
<td>(Solaraze)</td>
<td></td>
</tr>
</tbody>
</table>

VII. References

Reviews, Revisions, and Approvals

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

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.
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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.

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