Clinical Policy: Diclofenac Epolamine Patch (Flector)
Reference Number: ERX.NPA.38
Effective Date: 12.01.15
Last Review Date: 08.17

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

Description
Diclofenac epolamine patch (Flector®) is a topical non-steroidal anti-inflammatory drug (NSAID).

FDA approved indication
Flector is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

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

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Flector is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Pain (must meet all):
      1. Prescribed for the treatment of pain;
      2. Age ≥ 18 years;
      3. Failure of 2 PDL oral generic NSAIDs, unless all are contraindicated or clinically significant adverse effects are experienced;
      4. Failure of topical Capsaicin within the past 6 months, unless contraindicated or clinically significant adverse effects are experienced;
      5. Failure of diclofenac gel 1% (Voltaren) or diclofenac topical solution 1.5% (Pennsaid) within the past 90 days, unless contraindicated or clinically significant adverse effects are experienced;
      6. Dose does not exceed 2 patches/day.
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Pain (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 patches/day.
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
         Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSAID: non-steroidal anti-inflammatory drug
PDL: preferred drug list

Appendix B: Therapeutic Alternatives

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltaren® (diclofenac 1% gel)</td>
<td>2-4 gms topically to the affected area 4 times daily</td>
<td>32 g/day</td>
</tr>
<tr>
<td>Pennsaid® (diclofenac 1.5% topical solution)</td>
<td>40 drops topically to each affected knee 4 times daily</td>
<td>160 drops/knee/day</td>
</tr>
<tr>
<td>Topical capsaicin (over-the-counter)</td>
<td>Apply topically TID-QID</td>
<td>Varies</td>
</tr>
<tr>
<td>PDL NSAIDs*: diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tolmelin, celecoxib</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

*May not be all-inclusive

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute pain due to minor strains, sprains and contusions</td>
<td>1 patch topically BID</td>
<td>2 patches/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Patch: 1.3%

VII. References


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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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