Clinical Pharmacy Program Guidelines for Topical NSAIDs

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Flector Patch (diclofenac epolamine topical patch 1.3%), Voltaren Gel (diclofenac sodium topical gel), Pennsaid (diclofenac sodium topical solution 1.5%, 2%)</td>
</tr>
<tr>
<td>Markets in Scope</td>
<td>Arizona, California, Florida-CHEP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island</td>
</tr>
<tr>
<td>Issue Date</td>
<td>6/2010</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>2/2018</td>
</tr>
<tr>
<td>Effective Date</td>
<td>4/2018</td>
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1. **Background:**

The intent of the criteria is to ensure the appropriate utilization of Flector Patch, Voltaren Gel, and Pennsaid within their labeled indications and consistent with current evidence in the literature.

**FDA Approved Indications**

1. **Acute pain**

   *Flector Patch* is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

2. **Osteoarthritis Pain**

   *Voltaren Gel* is indicated for the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

   *Pennsaid* is indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

2. **Coverage Criteria:**

   **A. Flector Patch**

   1. **Flector Patch** will be approved based on the following criteria:

      a. Diagnosis of acute pain due to minor strains, sprains, or contusions

      -AND-
b. One of the following:

(1) The patient did not receive adequate pain relief when treated with at least three formulary non-steroidal anti-inflammatory drugs (NSAIDs) in the previous three months. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy.

-OR-

(2) The patient has one of the following risk factors:

(a) The patient is 60 years of age or greater
(b) The patient has a previous clinical history of gastroduodenal ulcer, gastrointestinal bleeding, or gastroduodenal perforation
(c) Concomitant use of chronic systemic corticosteroids, anticoagulants, or anti-platelet agents

Authorization will be issued for 2 weeks.

B. Pennsaid and Voltaren Gel

1. Pennsaid or Voltaren Gel will be approved based on the following criteria:

a. One of the following:

(1) The requested medication is Pennsaid and the patient has a diagnosis of osteoarthritis of the knee(s)

-OR-

(2) The requested medication is Voltaren Gel and the patient has a diagnosis of osteoarthritis of joints amenable to topical treatment, including but not limited to the hands, knees, ankles, elbows, feet, and wrists.

-AND-

b. One of the following:

(1) The patient did not receive adequate pain relief when treated with at least three formulary non-steroidal anti-inflammatory drugs (NSAIDs) in the previous three months. An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy.
resolved after 14 days of therapy.

- OR -

(2) The patient has one of the following risk factors:

(a) The patient is 60 years of age or greater
(b) The patient has a previous clinical history of gastroduodenal ulcer, gastrointestinal bleeding, or gastroduodenal perforation
(c) Concomitant use of chronic systemic corticosteroids, anticoagulants, or anti-platelet agents

- AND -

c. If the request is for brand or generic Pennsaid or brand Voltaren Gel, patient has a history of failure, intolerance, or contraindication to generic Voltaren Gel (diclofenac sodium topical gel)

Authorization will be issued for 12 months.

3. References:


<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization –Topical NSAIDs</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>6/2010</td>
<td>New drug policy</td>
</tr>
<tr>
<td>3/2011</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>3/2012</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>3/2013</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>12/2015</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>11/2016</td>
<td>Update policy template, add new Pennsaid strength, add step through generic Voltaren gel for Pennsaid and brand Voltaren gel</td>
</tr>
<tr>
<td>11/2017</td>
<td>Annual review, no changes</td>
</tr>
<tr>
<td>1/2018</td>
<td>Updated approvable osteoarthritis conditions for Voltaren gel to match language in package insert.</td>
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