Clinical Pharmacy Program Guidelines for Topical NSAIDs

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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</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>
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<tr>
<td>P&amp;T Approval Date</td>
<td>11/2016</td>
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<tr>
<td>Effective Date</td>
<td>1/2017</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 the hands or knees.

   -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

-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>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>March 2013</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>December 2015</td>
<td>Annual review, no change</td>
</tr>
<tr>
<td>November</td>
<td>Update policy template, add new Pennsaid strength, add step</td>
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<tr>
<td></td>
<td>through generic Voltaren gel for Pennsaid and brand Voltaren gel</td>
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