UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Topical NSAIDs

Program	Prior Authorization
Medication	Flector Patch (diclofenac epolamine topical patch 1.3%), Voltaren Gel (diclofenac sodium topical gel), Pennsaid (diclofenac sodium topical solution 1.5%, 2%)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	6/2010
Pharmacy and Theraeputics Approval Date	2/2018
Effective Date	4/2018

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. <u>Flector Patch</u>

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. <u>Pennsaid and Voltaren Gel</u>

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.

-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:

1. Flector Patch [package insert]. Bristol, TN: King Pharmaceuticals Inc.; February 2011.
2. Voltaren Gel [package insert]. Parsippany, NJ: Novartis Consumer Health, Inc.; October 2009.
3. Pennsaid [package insert]. Varennes, Quebec: Nuvo Research Inc.; January 2010.
4. American Academy of Orthopaedic Surgeons Clinical Practice Guideline on the Treatment of Osteoarthritis of the knee (Non-Arthroplasty). Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2008.
5. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 Expert Consensus Document on Reducing the Gastrointestinal Risks of Antiplatelet Therapy and NSAID Use. A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *Circulation*. 2008: 118: 000-000.
6. Mason L, Moore RA, Edwards JE, et al. Topical NSAIDs for acute pain: a meta-analysis. BMC Family Practice. 2004; 5: 10: 1-9.
7. Kidd BL, Langford RM, Wodehouse T. Current approaches in the treatment of arthritic pain. Arthritis Research & Therapy. 2007; 9(13): 214-220.
8. Bookman AA, Williams KS, Shainhouse JZ. Effect of a topical diclofenac solution for relieving symptoms of primary osteoarthritis of the knee: a randomized controlled trial. *CMAJ*. 2004; 171(4): 333-8.

9. Roth SH, Shainhouse JZ. Efficacy and Safety of a Topical Diclofenac Solution (Pennsaid) in the Treatment of Primary Osteoathritis of the Knee. Arch Int Med. 2004; 164: 2017-23.

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