UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Topical NSAIDs

Program	Prior Authorization
Medication	Flector Patch (diclofenac epolamine topical patch 1.3%), diclofenac sodium topical gel 1%, Pennsaid (diclofenac sodium topical solution 1.5%, 2%), Voltaren gel OTC (diclofenac sodium topical gel 1%)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	6/2010
Pharmacy and Theraeputics Approval Date	2/2021
Effective Date	4/2021

1. Background:

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**

   Pennsaid is indicated for the treatment of the pain of osteoarthritis of the knee(s). **Diclofenac sodium topical gel 1% (Rx formulation)** and **Voltaren OTC** are indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.

Black boxed warnings include but may not be limited to risk of serious cardiovascular and gastrointestinal events.

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 preferred non-steroidal anti-inflammatory drugs (NSAIDs). An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy.

      -OR-

      (2) **One** of the following risk factors for NSAID-induced adverse GI events:
      a. Patient is greater than or equal to 65 years of age
      b. Prior history of peptic, gastric, or duodenal ulcer
      c. History of NSAID-related ulcer
      d. History of clinically significant GI bleeding
      e. Untreated or active *H. Pylori* gastritis
      f. Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
      g. Concurrent use of anticoagulants (e.g. warfarin, heparin)
      h. Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Authorization will be issued for 2 weeks.

B. Pennsaid

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

   a. Diagnosis of pain due to osteoarthritis of the knee(s)

   -AND-

   b. **One** of the following:

      (1) The patient did not receive adequate pain relief when treated with at least three preferred non-steroidal anti-inflammatory drugs

(NSAIDs). An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy.

-OR-

(2) **One** of the following risk factors for NSAID-induced adverse GI events:
   a. Patient is greater than or equal to 65 years of age
   b. Prior history of peptic, gastric, or duodenal ulcer
   c. History of NSAID-related ulcer
   d. History of clinically significant GI bleeding
   e. Untreated or active *H. Pylori* gastritis
   f. Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
   g. Concurrent use of anticoagulants (e.g. warfarin, heparin)
   h. Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

-AND-

c. The patient has a history of failure, intolerance, or contraindication to diclofenac topical gel 1% (Rx formulation) or Voltaren OTC.

Authorization will be issued for 12 months.

C. Diclofenac topical gel 1% (Rx formulation) and Voltaren OTC

1. **Diclofenac topical gel 1% (Rx formulation) or Voltaren OTC** will be approved based on the following criteria:

a. Diagnosis of pain due to 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 preferred non-steroidal anti-inflammatory drugs (NSAIDs). An inadequate response to treatment is defined as pain and/or inflammatory symptoms not resolved after 14 days of therapy.

-OR-

(2) **One** of the following risk factors for NSAID-induced adverse GI events:
   a. Patient is greater than or equal to 65 years of age
   b. Prior history of peptic, gastric, or duodenal ulcer
   c. History of NSAID-related ulcer
   d. History of clinically significant GI bleeding
   e. Untreated or active *H. Pylori* gastritis
   f. Concurrent use of oral corticosteroids (e.g. prednisone, prednisolone, dexamethasone)
   g. Concurrent use of anticoagulants (e.g. warfarin, heparin)
   h. Concurrent use of antiplatelets (e.g. aspirin including low-dose, clopidogrel)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Flector [package insert]. New York, NY: Pfizer Inc.; March 2019.
2. Diclofenac gel [package isnert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2019.
3. Pennsaid [package insert]. Lake Forest, IL: Horizon Pharma USA Inc.; March 2020.
4. Lanza FL, Chan FK, Quigley EM, et al. Guidelines for prevention of NSAID-related ulcer complications. *Am J Gastroentero*l. 2009; 104(3):728-38.
5. Voltaren Gel [package insert]. Warren, NJ: GlaxoSmithKline Consumer Healthcare; February 2018.

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.
6/2018	Changed “formulary” to “preferred”
12/2018	Removed “in the previous three months” from the try/fail requirement.
12/2019	Separted Pennsaid and diclofenac topical gel 1% into individual sections. Removed references to brand Voltaren gel since no longer on the market. Updated the risk factors for a GI-induced ulcer to match the Celebrex criteria.
10/2020	Added Voltaren OTC and updated Pennsaid step therapy drugs.
12/2020	Removed Voltaren OTC, not moving forward with 1/1/21 initiative.
2/2021	Added back Voltaren OTC for 4/1/21 go-live. Updated background and references.