Pharmacy Policy Bulletin: J-0495 Diclofenac Containing Products – Commercial and Healthcare Reform	
Number: J-0495	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Pennsaid, Zipsor & Zorvolex:** **Quantity Limits (1., 2., or 3.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **3.** Rx Mgmt Performance = MRxC =Yes **Diclofenac potassium 25 mg tab & Lofena:** **Quantity Limits (1., 2., or 3.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **3.** Quantity Limits = QPC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0495-012	**Original Date:** 09/07/2016
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Diclofenac potassium tablet 25 mg • Lofena (diclofenac potassium) • Pennsaid (diclofenac sodium) topical solution 2% • Zorvolex (diclofenac) capsule • Zipsor (diclofenac potassium) capsule

FDA-Approved Indication(s):	• Diclofenac potassium tablet 25 mg and Lofena 25 mg
	  ○ Primary dysmenorrhea
	  ○ Mild to moderate pain
	  ○ Osteoarthritis
	  ○ Rheumatoid arthritis
	• Pennsaid (diclofenac sodium) topical solution
	  ○ Osteoarthritis (OA) knee pain
	• Zorvolex (diclofenac) capsule
	  ○ Mild to moderate acute pain
	  ○ Osteoarthritis pain
	• Zipsor (diclofenac potassium) capsule
	  ○ Mild to moderate pain in adult and pediatric patients 12 years of age and older

Background:	• Diclofenac is a nonsteroidal anti-inflammatory (NSAID) of the phenylacetic acid class and is used to reduce pain and inflammation. It works by blocking the effect of chemicals called cyclooxygenase 1 and 2 (COX-1 and COX-2) which results in reduction of prostaglandin formation.
	• Utilization management is applied to diclofenac containing products to ensure safety, appropriate utilization, and use of cost-effective therapeutic treatments.
	• All NSAIDs have black box warnings for the following:
	  ○ Increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
	  ○ NSAIDs are contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
	  ○ NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Approval Criteria

I. Initial Authorization

A. <u>Pennsaid topical solution</u>

When a benefit, coverage of Pennsaid may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of osteoarthritis knee pain. (ICD-10: M17.9)
3. The member has experienced therapeutic failure, contraindication, or intolerance to three (3) plan-preferred formulary, oral generic NSAIDs, one (1) of which must be oral diclofenac.
4. The prescriber provides documentation that the member has experienced therapeutic failure to one (1) of the following plan-preferred products **(a. or b.)**:
  a. Generic diclofenac sodium 1.5% topical solution (drops)
  b. Prescription, generic diclofenac sodium 1% gel

B. <u>Zorvolex capsules</u>

When a benefit, coverage of Zorvolex may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 18 years of age or older.
2. The member has one (1) of the following diagnoses **(a. or b.)**:
  a. Mild to moderate acute pain (ICD-10: R52)

b. Osteoarthritis (ICD-10: M15, M16, M17, M18, M19)

3. The prescriber provides documentation that the member has experienced therapeutic failure, contraindication, or intolerance to three (3) plan-preferred formulary, oral generic NSAIDs, one (1) of which must be oral diclofenac.

C. <u>Zipsor capsules</u>

When a benefit, coverage of Zipsor (diclofenac potassium) may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 12 years of age or older.

2. The member has a diagnosis of mild to moderate pain (ICD-10: R52).

3. The prescriber provides documentation that the member has experienced therapeutic failure, contraindication, or intolerance to three (3) plan-preferred formulary, oral generic NSAIDs, one (1) of which must be oral diclofenac.

D. <u>Diclofenac potassium 25 mg tablets and Lofena 25 mg tablets</u>

When a benefit, coverage of diclofenac potassium 25 mg tablets may be approved when all of the following criteria are met: **(1., 2., and 3.):**

1. The member is 18 years of age or older.

2. The member has one (1) of the following diagnoses **(a. through d.):**

a. Primary dysmenorrhea (ICD-10: N94.4)

b. Mild to moderate pain (ICD-10: R52)

c. Osteoarthritis (ICD-10: M15, M16, M17, M18, M19)

d. Rheumatoid arthritis (ICD-10: M05, M06)

3. The prescriber provides documentation that the member has experienced therapeutic failure, contraindication, or intolerance to three (3) plan-preferred formulary, oral generic NSAIDs, one (1) of which must be oral diclofenac (e.g., diclofenac sodium oral tablet, delayed release or extended release).

II. Reauthorization

When a benefit, reauthorization of a diclofenac-containing product may be approved when the following criteria is met **(A. and B.):**

A. The member continues to use the medication for an FDA approved indication.

B. The prescriber attests that the member has experienced positive clinical response to therapy.

III. <u>Quantity Limitation:</u>

When prior authorization is approved, products may be authorized in quantities as follows:

Brand Name	Generic Name	Limit
Pennsaid 2% Topical Solution	diclofenac sodium topical solution	112 grams/28 days
Zorvolex Capsule	diclofenac capsule	3 capsules/day
Zipsor (diclofenac potassium) Capsule	diclofenac potassium capsule	4 capsules/day
diclofenac potassium 25 mg tablet	diclofenac potassium 25 mg tablet	3 tablets/day
Lofena 25 mg tablet	diclofenac potassium 25 mg tablet	3 tablets/day

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Pennsaid [package insert]. Deerfield, IL: Horizon Medicines LLC; January 2022.
2. Zorvolex [package insert]. Wayne, PA: Zyla Life Science US Inc.; April 2021.
3. Zipsor [package insert]. Lake Forest, IL: Assertio Therapeutics, Inc.; May 2021.
4. Diclofenac potassium [package insert]. Pennington, NJ: Zydus Pharmaceutical (USA) Inc.; July 2024.
5. Lofena [package insert]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC; July 2021