Diclofenac topical
Policy Number: C4962-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
6/1/2013	1/1/2019	1/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
	Pending Q2 Review	Q4

PRODUCTS AFFECTED:
CapsFenac Pak THPK 1.5 & 0.025%, DermacinRx Analgesic ComboPak KIT 75MG, DermacinRx, Lexitral PharmaPak THPK 1.5 & 0.025%, DFS DR/MS/Menth/Cap Pak KIT 75MG, DFS/MS/Menth/Cap Pak KIT 1.5%, Diclofex DC THPK 1.5 & 0.025%, Diclopak THPK 1.5 & 0.025%, Diclosaicin THPK 1.5 & 0.025%, Flexipak THPK 75 & 0.025MG-%, Inflammacin THPK 75 & 0.025MG-%, Inflamma-K KIT 1.5 & 3.1-6-10%, Inflammation Reduction Pack THPK 75-150-2.5-2.5MG-MG-%-%, NuDiclo SoluPak THPK 1.5 & 0.025%, NuDiclo TabPak THPK 75 & 0.025MG-% NuDroxiPAK DSDR-50 KIT 50MG, NuDroxipak DSDR-75 KIT 75MG, Ormeca KIT 3 & 46-0.4-1.1%-MG, PrevidolRx Plus Analgesic THPK 75 & 0.025MG-%, Sure Result DSS Premium Pack THPK 1.5 & 0.025%, Trixylitral THPK 1.5-3.88%, Xelitral THPK 1.5 & 0.025%, Xenaflamm THPK 75 & 0.025MG-%, Diclo Gel KIT 1%, Diclo Gel with Xrylix Sheets THPK 1%. Diclofenac Sodium GEL 1% Diclofenac Sodium GEL 3%, Diclofenac Sodium SOLN 1.5%, Diclofenac Sodium SOLN 1.5% Diclofenac Sodium SOLN 1.5%, Diclofono GEL 1.6%, Diclofono GEL 1.6%, DicloPR KIT 1 & 10-30%, Diclozor THPK 1%, DiThol THPK 1.5-10%, EnovaRX-Diclofenac Sodium CREA 2.5%, Flector PTCH 1.3%, Klofensaid II SOLN 1.5%, Lexixryl THPK 1.5%, Pennsaid SOLN 2%, Rexaphenac CREA 1%, Voltaren GEL 1%, Xrylix THPK 1.5%

DRUG CLASS:
Anti-inflammatory Agent

ROUTE OF ADMINISTRATION:
Topical

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
CapsFenac Pak THPK 1.5 & 0.025%, DermacinRx Analgesic ComboPak KIT 75MG, DermacinRx, Lexitral PharmaPak THPK 1.5 & 0.025%, DFS DR/MS/Menth/Cap Pak KIT 75MG, DFS/MS/Menth/Cap Pak KIT 1.5%, Diclofex DC THPK 1.5 & 0.025%, Diclopak THPK 1.5 & 0.025%, Diclosaicin THPK 1.5 & 0.025%, Flexipak THPK 75 & 0.025MG-%, Inflammacin THPK 75 & 0.025MG-%, Inflamma-K KIT 1.5 & 3.1-6-10%, Inflammation Reduction Pack THPK 75-150-2.5-2.5MG-MG-%-%, NuDiclo SoluPak THPK 1.5 & 0.025%, NuDiclo TabPak THPK 75 & 0.025MG-% NuDroxiPAK DSDR-50 KIT 50MG, NuDroxipak DSDR-75 KIT 75MG, Ormeca KIT 3 & 46-0.4-1.1%-MG, PrevidolRx Plus Analgesic THPK 75 & 0.025MG-%, Sure Result DSS Premium Pack THPK 1.5 & 0.025%, Trixylitral THPK 1.5-3.88%, Xelitral THPK 1.5 & 0.025%, Xenaflamm THPK 75 & 0.025MG-%, Diclo Gel KIT 1%, Diclo Gel with Xrylix Sheets THPK 1%. Diclofenac Sodium GEL 1% Diclofenac Sodium GEL 3%, Diclofenac Sodium SOLN 1.5%, Diclofenac Sodium SOLN 1.5% Diclofenac Sodium SOLN 1.5%, Diclofono GEL 1.6%, Diclofono GEL 1.6%, DicloPR KIT 1 & 10-30%, Diclozor THPK 1%, DiThol THPK 1.5-10%, EnovaRX-Diclofenac Sodium CREA 2.5%, Flector PTCH 1.3%, Klofensaid II SOLN 1.5%, Lexixryl THPK 1.5%, Pennsaid SOLN 2%, Rexaphenac CREA 1%, Voltaren GEL 1%, Xrylix THPK 1.5%

FDA-APPROVED USES:
Diclofenac sodium 3% gel is a topical nonsteroidal anti-inflammatory drug (NSAID) indicated for the topical treatment of actinic keratoses (AK)

Voltaren Gel (diclofenac sodium gel 1%) 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 (diclofenac solution) indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

Flector patches (diclofenac epolamine patch) 1.3% indicated for topical treatment of acute mild pain or moderate pain due to minor strains, sprains, and contusions

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: actinic keratoses (AK) or osteoarthritis

REQUIRED MEDICAL INFORMATION:
A. ACTINIC KERATOSIS (3% GEL ONLY):
1. Confirmed diagnosis of actinic keratosis (AK) within the last 365 days
   AND
2. Member has failure, contraindication or intolerance to BOTH Tolak 4% (fluorouracil) cream and imiquimod 5% cream
   AND
3. Member has tried or is not a suitable candidate for laser surgery, electrosurgery, cryosurgery, chemosurgery or surgical curettement in the last 365 days
   AND
4. FOR COMBINATION PRODUCTS REQUESTS: combination products are not covered; Notify prescriber that separate topical products are formulary and are covered when valid prescriptions are presented to the pharmacy.

B. OSTEOARTHRITIS/ACUTE MILD TO MODERATE PAIN:
1. Member has a diagnosis osteoarthritis pain susceptible to topical treatment (e.g. knees, hands, feet, elbows, etc)
   AND
2. Documentation of prior adequate trial and failure of 4 formulary NSAIDs (meloxicam, etodolac, nabumetone, ibuprofen, naproxen) or GI intolerance to 2 formulary NSAIDs USED WITH PPI
   AND
3. FOR COMBINATION PRODUCTS REQUESTS: combination products are not covered; Notify prescriber that separate topical products are formulary and are covered when valid prescriptions are presented to the pharmacy.

DURATION OF APPROVAL: ACTINIC KERATOSIS (3% GEL ONLY): Initial authorization: 3 months, Continuation of therapy: 2 months OSTEOARTHRITIS/ACUTE MILD TO MODERATE PAIN: Initial authorization: 3 months, Continuation of therapy: 6 months

QUANTITY: DICLOFENAC 3%: Up to one 100 gm tube/30 days for UP TO 90 days

PRESCRIBER REQUIREMENTS: 3% GEL ONLY: Prescribed by or in consultation with a dermatologist. Consultation notes must be submitted.

AGE RESTRICTIONS: 18 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. ACTINIC KERATOSIS (3% GEL ONLY):
   1. Member's condition has not worsened while on therapy defined as: Actinic keratosis lesions are larger
      AND
   2. Member has been adherent with the medication for 90 days
      AND
   3. Member has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use: Hematuria, Dyspnea, Pneumonia, Arthralgia

B. OSTEOARTHRITIS:
   1. Documentation that topical diclofenacl has provided improvement in the member's condition

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of topical diclofenac are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:
Diclofenac sodium 3% gel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for **Osteoarthritis (OA).** There has been one small, randomized, placebo-controlled study assessing the efficacy of a topical diclofenac 3%/sodium hyaluronate 2.5% gel (Canadian formulation) applied as 2 grams four times daily (QID) to one joint for 2 weeks in patients (n = 119) with uncontrolled OA pain despite chronic (≥ 1 month) oral NSAID use. The effect of topical diclofenac 3%/sodium hyaluronate 2.5% gel in patients who continued their chronic oral NSAID therapy demonstrated only marginally significantly greater analgesic effect than placebo gel: the mean change from baseline in overall pain from OA (using a 5-point scale) was -0.7 vs. -0.4 for topical diclofenac and placebo, respectively (P = 0.0568). Additional data are needed to define the place in therapy of diclofenac sodium 3% gel for the treatment of OA. Other topical agents are indicated for this use.

APPENDIX: None

REFRENCES:

1. Solaraze® gel [prescribing information]. Melville, NY: PharmaDerm® , a division of Fougera Pharmaceuticals, Inc.; April 2016.
2. Stockfleth E, Ferrandiz C, Grob JJ, et al for the European Skin Academy. Development of a treatment algorithm for actinic keratoses: a European Consensus. Eur J Dermatol. 2008;18(6):651-659.
3. Voltaren® Gel [prescribing information]. Princeton, NJ: Sandoz; April 2016.
4. Flector Patch [package insert]. Bristol, TN: King Pharmaceuticals Inc.; February
5. 2011.
6. Marks S, Varma R, Cantrell W, et al. Diclofenac sodium 3% gel as a potential treatment for disseminated superficial actinic porokeratosis. J Eur Acad Dermatol Venereol. 2009;23(1):42-45.
7. Vlachou C, Kanellease AI, Martin-Clavijo A, Berth-Jones J. Treatment of disseminated superficial actinic porokeratosis with topical diclofenac gel: a case series. J Eur Acad Dermatol Venereol. 2008;22(11):1343-1345.
8. American Osteopathic College of Dermatology. Disseminated superficial actinic porokeratosis. Available at: http://www.aocd.org/skin/dermatologic_diseases/dsap.html.
9. Roth SH. A controlled clinical investigation of 3% diclofenac/2.5% sodium hyaluronate topical gel in the treatment of uncontrolled pain in chronic oral NSAID users with osteoarthritis. Int J Tissue React. 1995;17(4):129-132.