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Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C4962-A

Diclofenac Topical

PRODUCTS AFFECTED

diclofenac epolamine topical patch, diclofenac topical gel, diclofenac topical solution, Diclofono (diclofenac) gel, Flector (diclofenac epolamine) topical patch, Licart (diclofenac epolamine) topical patch, Pennsaid (diclofenac sodium) topical solution, Solaraze (diclofenac), Voltaren Gel (diclofenac)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Actinic keratoses (AK), Osteoarthritis, Mild or moderate pain

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACTINIC KERATOSIS (DICLOFENAC 3% GEL ONLY):
   1. Documented diagnosis of actinic keratosis with active lesions

AND

2. Documentation of treatment failure, serious side effects or clinical contraindication to BOTH topical fluorouracil cream and imiquimod cream
   AND
3. Documentation member has tried or is not a suitable candidate for laser surgery, electrosurgery, cryosurgery, chemosurgery or surgical curettement for current lesions
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to diclofenac 3% include: hypersensitivity to diclofenac, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium, in the setting of coronary artery bypass graft (CABG) surgery, avoid in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events, avoid patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure, applying to open wounds or infections or peeling skin, avoid in late pregnancy]

B. OSTEOARTHRITIS (GEL OR SOLUTION ONLY PER FDA LABEL):
   NOTE TO MOLINA REVIEWER: DICLOFENAC 3% IS NOT INDICATED AND HAS NO LITERATURE TO SUPPORT THE USE IN ANY INDICATION OTHER THAN ACTINIC KERATOSIS. ALL REQUESTS FOR THE 3% GEL FOR ANY OTHER INDICATION SHOULD BE REVIEWED USING OFF-LABEL POLICY.
   1. Documented diagnosis of osteoarthritis of an area susceptible to topical treatment per product label (e.g., knees, hands, feet, elbows, etc.)
      AND
   2. Documentation of ANY of the following: (a) prior adequate trial and failure of 3 formulary oral NSAIDs (e.g., meloxicam, etodolac, nabumetone, ibuprofen, naproxen, etc.) OR (b) gastrointestinal intolerance to 2 formulary NSAIDs used concurrently with a proton pump inhibitor OR (c) member has a labeled contraindication to oral NSAIDs
      AND
   3. FOR PRESCRIPTION (NON-FORMULARY) DICLOFENAC GEL/SOLUTION ONLY: Member has a diagnosis of KNEE osteoarthritis AND Documentation of a trial (minimum of 4 weeks) and failure of preferred formulary diclofenac 1% gel OTC (OTC is preferred and does NOT require a PA- quantity limits still apply) AND Requests for NON-PREFERRED diclofenac 1% gel RX requires documented medical justification for need of RX dosage form over the OTC dosage form
      AND
   4. FOR PENNSAID ONLY: Member has a diagnosis of KNEE osteoarthritis AND member has tried (at least 3 months) and failed diclofenac 1% gel OTC (over-the-counter)
      AND
   5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to diclofenac gel and solution include: hypersensitivity to diclofenac or any component of the drug product, history of asthma, urticaria, or allergic-type reaction after taking aspirin or other NSAIDs, in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin, avoid patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure, avoid patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function, avoid in late pregnancy, avoid concurrent use with oral NSAIDs, avoid in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events]

C. ACUTE MILD TO MODERATE PAIN (PATCH ONLY PER FDA LABEL):
   NOTE TO MOLINA REVIEWER: DICLOFENAC 3% IS NOT INDICATED AND HAS NO LITERATURE TO SUPPORT THE USE IN ANY INDICATION OTHER THAN ACTINIC KERATOSIS. ALL REQUESTS FOR THE 3% GEL FOR ANY OTHER INDICATION SHOULD BE REVIEWED USING OFF-LABEL POLICY.
   1. Documented diagnosis of acute pain of an area susceptible to topical treatment per product

label (e.g., knees, hands, feet, elbows, etc.)
AND

2. Documentation of ANY of the following: (a) prior adequate trial and failure of 3 formulary oral NSAIDs (e.g., meloxicam, etodolac, nabumetone, ibuprofen, naproxen, etc.) OR (b) gastrointestinal intolerance to 2 formulary NSAIDs used concurrently with a proton pump inhibitor OR (c) member has a labeled contraindication to oral NSAIDs
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to diclofenac epolamine include: hypersensitivity to diclofenac or any component of the drug product, history of asthma, urticaria, or allergic-type reaction after taking aspirin or other NSAIDs, in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin, avoid patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure, avoid patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function, avoid in late pregnancy, avoid concurrent use with oral NSAIDs, avoid in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events]

CONTINUATION OF THERAPY:

A. ACTINIC KERATOSIS (3% GEL ONLY): N/A

B. OSTEOARTHRITIS:
1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
2. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms

C. ACUTE MILD TO MODERATE PAIN: N/A, REQUEST SHOULD BE REVIEWED AS NEW INITIAL AUTHORIZATION

DURATION OF APPROVAL:

ACTINIC KERATOSIS (3% GEL ONLY): Initial authorization: 3 months, Continuation of therapy: N/A [Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.]
OSTEOARTHRITIS: Initial authorization: 6 months, Continuation of therapy: 12 months
ACUTE MILD TO MODERATE PAIN: Initial authorization: 6 months, Continuation of therapy: NA

PRESCRIBER REQUIREMENTS:

3% GEL ONLY: Prescribed by or in consultation with a dermatologist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:

FLECTOR ONLY: 6 years and older
ALL OTHER PRODUCTS: 18 years of age and older

QUANTITY:

DICLOFENAC GEL 3%: for UP TO 90 days, 0.5g gel is used on each 5 x 5 cm lesion site
DICLOFENAC 1% GEL: Formulary quantity limit 200g/30 days*
Lower extremities: Apply 4 g of 1% gel to affected area 4 times daily (maximum: 16 g per joint/day)
Upper extremities: Apply 2 g of 1% gel to affected area 4 times daily (maximum: 8 g per joint/day)
*Can approve up to maximum FDA label if medical necessity demonstrated for that quantity

DICLOFENAC 2% SOLUTION: 224g/30 days
DICLOFENAC EPOLAMINE (Flector) PATCHES 60 patches/30 days
DICLOFENAC EPOLAMINE (Licart) PATCHES: 30 patches/30 days

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Topical

DRUG CLASS:
Anti-inflammatory Agent

FDA-APPROVED USES:
Diclofenac sodium 3% gel is indicated for the topical treatment of actinic keratoses (AK)

Voltaren Gel (diclofenac sodium gel 1%) RX is indicated for the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Diclofenac sodium topical gel was not evaluated for use on joints of the spine, hip, or shoulder.

Voltaren Gel (diclofenac sodium gel 1%) OTC is indicated for the temporary relief of arthritis pain only in the following areas:
- hand, wrist, elbow (upper body areas)
- foot, ankle, knee (lower body areas)

Pennsaid (diclofenac solution) is indicated for the treatment of the pain of osteoarthritis of the knee(s)

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of topical diclofenac are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to diclofenac 3% include: hypersensitivity to diclofenac, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium, in the setting of coronary artery bypass graft (CABG) surgery, avoid in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events, avoid patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure, spending time in sunlight or artificial light, applying to open wounds or infections or peeling skin, avoid in late pregnancy. Contraindications to diclofenac gel, solution and diclofenac epolamine include: hypersensitivity to diclofenac or any component of the drug product, history of asthma, urticaria, or allergic-type reaction after taking aspirin or other NSAIDs, in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin, avoid patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure, avoid patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function, avoid in late pregnancy, avoid concurrent use with oral NSAIDs, avoid in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events.

OTHER SPECIAL CONSIDERATIONS:
Topical diclofenac has a black box warning for risk of serious cardiovascular and gastrointestinal events. Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an 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. Diclofenac sodium and diclofenac epolamine is 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.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Diclofenac Epolamine PTCH 1.3%
Diclofenac Sodium GEL 1% OTC
Diclofenac Sodium GEL 1% RX
Diclofenac Sodium GEL 3%
Diclofenac Sodium SOLN 1.5%
Diclofenac Sodium SOLN 2%
Diclofono GEL 1.6%
Flector PTCH 1.3%
Licart PT24 1.3%
Pennsaid SOLN 2%
Voltaren Arthritis Pain GEL 1% OTC
Voltaren GEL 1% RX

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3. Voltaren Arthritis Pain (diclofenac sodium) topical gel 1% OTC [drug facts]. Warren, NJ: GlaxoSmithKline Consumer Healthcare Inc; December 2023.
4. Pennsaid 2% (diclofenac sodium) [prescribing information]. Lake Forest, IL: Horizon Medicines LLC; January 2022.
5. Pennsaid 1.5% (diclofenac sodium) [prescribing information]. Hazelwood, MO: Mallinckrodt Brand Pharmaceuticals; May 2016.
6. Licart (diclofenac epolamine) topical system [prescribing information]. Parsippany, NJ: IBSA Pharma Inc; April 2021.
7. Diclofenac sodium solution 1.5% (topical) [prescribing information]. Baton Rouge, LA; SOLA Pharmaceuticals LLC: June 2021.
8. Diclofenac sodium solution (topical) [prescribing information]. Orlando, FL: Ingenus pharmaceuticals, LLC; November 2020.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information FDA-Approved Uses Other Special Considerations Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file