Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Diclofenac 3% Gel, Diclofenac 1.5% and 2% Topical Solution

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

Clinical Information Included in this Document

Diclofenac 3% Topical Gel

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section

Diclofenac 1.5% and 2% Topical Solution

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Revision Notes

Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table

Diclofenac 3% Gel

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
DICLOFENAC SODIUM 3% GEL	86831
SOLARAZE 3% GEL	86831

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Diclofenac 3% Gel

Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a **diagnosis of actinic keratosis** in the last 730 days?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

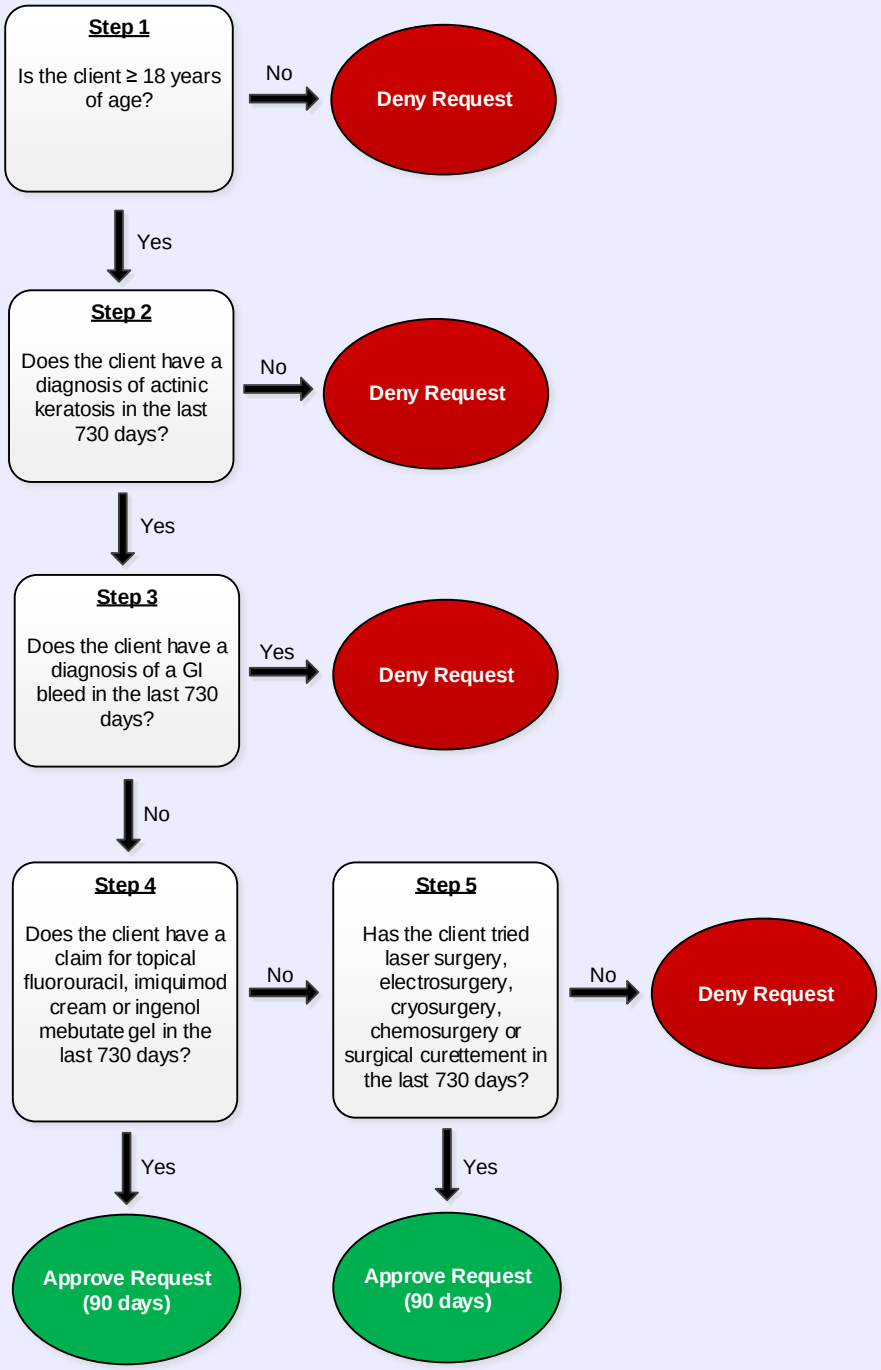
3. Does the client have a history of a **GI bleed** in the last 730 days?
   [ ] Yes (Deny)
   [ ] No (Go to #4)

4. Does the client have a claim for **topical fluorouracil, imiquimod cream or ingenol mebutate gel** in the last 730 days?
   [ ] Yes (Approve – 90 days)
   [ ] No (Go to #5)

5. Has the client tried laser **surgery, electrosurgery, cryosurgery, chemosurgery or surgical curettement** in the last 730 days?
   [ ] Yes (Approve – 90 days)
   [ ] No (Deny)

Diclofenac 3% Gel

Clinical Criteria Logic Diagram



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Diclofenac 3% Gel

Clinical Criteria Supporting Tables

Step 2 (diagnosis of actinic keratosis) Required diagnosis: *1* Look back timeframe: *730 days*	
ICD-10 code	**Description**
L570	ACTINIC KERATOSIS

Step 3 (diagnosis of GI bleed) Required diagnosis: *1* Look back timeframe: *730 days*	
ICD-10 code	**Description**
K250	ACUTE GASTRIC ULCER WITH HEMORRHAGE
K251	ACUTE GASTRIC ULCER WITH PERFORATION
K252	ACUTE GASTRIC ULCER WITH BOTH HEMORRHAGE AND PERFORATION
K253	ACUTE GASTRIC ULCER WITHOUT HEMORRHAGE OR PERFORATION
K254	CHRONIC OR UNSPECIFIED GASTRIC ULCER WITH HEMORRHAGE
K255	CHRONIC OR UNSPECIFIED GASTRIC ULCER WITH PERFORATION
K256	CHRONIC OR UNSPECIFIED GASTRIC ULCER WITH BOTH HEMORRHAGE AND PERFORATION
K257	CHRONIC GASTRIC ULCER WITHOUT HEMORRHAGE OR PERFORATION
K259	GASTRIC ULCER, UNSPECIFIED AS ACUTE OR CHRONIC, WITHOUT HEMORRHAGE OR PERFORATION
K260	ACUTE DUODENAL ULCER WITH HEMORRHAGE
K261	ACUTE DUODENAL ULCER WITH PERFORATION
K262	ACUTE DUODENAL ULCER WITH BOTH HEMORRHAGE AND PERFORATION
K263	ACUTE DUODENAL ULCER WITHOUT HEMORRHAGE OR PERFORATION
K264	CHRONIC OR UNSPECIFIED DUODENAL ULCER WITH HEMORRHAGE
K265	CHRONIC OR UNSPECIFIED DUODENAL ULCER WITH PERFORATION
K266	CHRONIC OR UNSPECIFIED DUODENAL ULCER WITH BOTH HEMORRHAGE AND PERFORATION
K267	CHRONIC DUODENAL ULCER WITHOUT HEMORRHAGE OR PERFORATION
K269	DUODENAL ULCER, UNSPECIFIED AS ACUTE OR CHRONIC, WITHOUT HEMORRHAGE OR PERFORATION

Step 3 (diagnosis of GI bleed) **Required diagnosis:** *1* **Look back timeframe:** *730 days*	
K270	ACUTE PEPTIC ULCER, SITE UNSPECIFIED, WITH HEMORRHAGE
K271	ACUTE PEPTIC ULCER, SITE UNSPECIFIED, WITH PERFORATION
K272	ACUTE PEPTIC ULCER, SITE UNSPECIFIED, WITH BOTH HEMORRHAGE AND PERFORATION
K273	ACUTE PEPTIC ULCER, SITE UNSPECIFIED, WITHOUT HEMORRHAGE OR PERFORATION
K274	CHRONIC OR UNSPECIFIED PEPTIC ULCER, SITE UNSPECIFIED, WITH HEMORRHAGE
K275	CHRONIC OR UNSPECIFIED PEPTIC ULCER, SITE UNSPECIFIED, WITH PERFORATION
K276	CHRONIC OR UNSPECIFIED PEPTIC ULCER, SITE UNSPECIFIED, WITH BOTH HEMORRHAGE AND PERFORATION
K277	CHRONIC PEPTIC ULCER, SITE UNSPECIFIED, WITHOUT HEMORRHAGE OR PERFORATION
K279	PEPTIC ULCER, SITE UNSPECIFIED, UNSPECIFIED AS ACUTE OR CHRONIC, WITHOUT HEMORRHAGE OR PERFORATION

Step 4 (claim for a topical fluorouracil, imiquimod cream or ingenol mebutate gel) **Required claims:** *1* **Look back timeframe:** *730 days*	
Label Name	**GCN**
EFUDEX 5% CREAM	30781
FLUOROURACIL 0.5% CREAM	12514
FLUOROURACIL 2% TOPICAL SOLN	30791
FLUOROURACIL 5% CREAM	30781
FLUOROURACIL 5% TOP SOLUTION	30792
IMIQUIMOD 5% CREAM PACKET	54201
PICATO 0.015% GEL	31302
PICATO 0.05% GEL	31303
TOLAK 4% CREAM	39576
ZYCLARA 3.75% CREAM	28216

Step 5 (CPT code for laser surgery, electrosurgery, cryosurgery, chemosurgery or surgical curettement) **Required CPT code:** *1* **Look back timeframe:** *730 days*	
CPT Code	**Description**
17000	DESTRUCTION (E.G., LASER SURGERY, ELECTROSURGERY, CRYOSURGERY, CHEMOSURGERY, SURGICAL CURETTEMENT), PREMALIGNANT LESIONS (E.G., ACTINIC KERATOSES); FIRST LESION
17003	DESTRUCTION (E.G., LASER SURGERY, ELECTROSURGERY, CRYOSURGERY, CHEMOSURGERY, SURGICAL CURETTEMENT), PREMALIGNANT LESIONS (E.G., ACTINIC KERATOSES); 2 THROUGH 14 LESIONS
17004	DESTRUCTION (E.G., LASER SURGERY, ELECTROSURGERY, CRYOSURGERY, CHEMOSURGERY, SURGICAL CURETTEMENT), PREMALIGNANT LESIONS (E.G., ACTINIC KERATOSES); 15 OR MORE LESIONS

Diclofenac 1.5% and 2% Solution

Drugs Requiring Prior Authorization

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Drugs Requiring Prior Authorization	
Label Name	**GCN**
DICLOFENAC 1.5% TOPICAL SOLUTION	19454
PENNSAID 2% PUMP	35936

Diclofenac 1.5% and 2% Solution

Clinical Criteria Logic

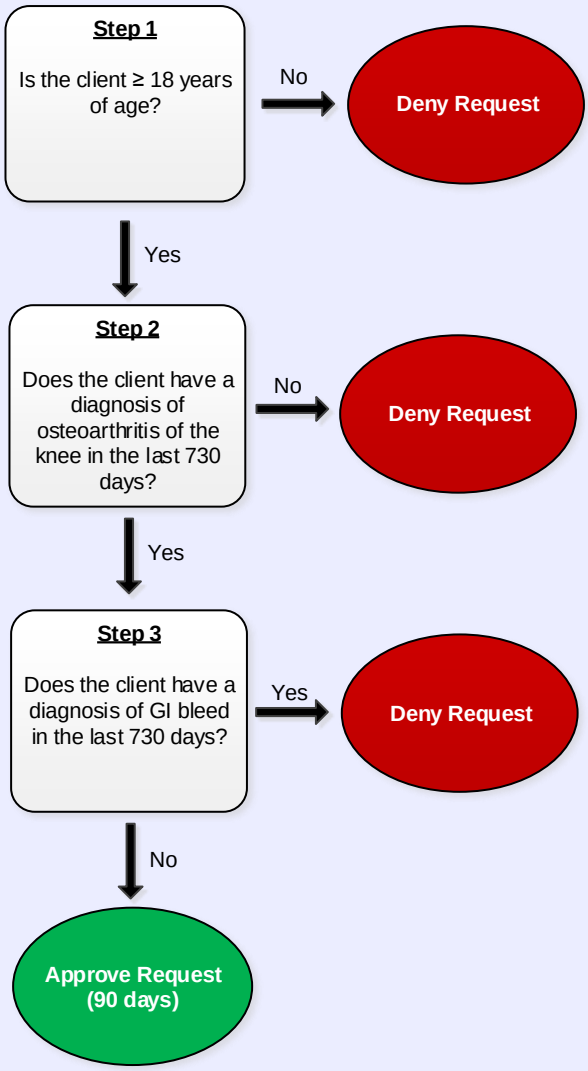
1. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a **diagnosis of osteoarthritis of the knee** in the last 730 days?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Does the client have a history of a **GI bleed** in the last 730 days?
   [ ] Yes (Deny)
   [ ] No (Approve – 90 days)

Diclofenac 1.5% and 2% Solution

Clinical Criteria Logic Diagram



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Clinical Criteria Supporting Tables

Step 2 (diagnosis of osteoarthritis of the knee) **Required diagnosis:** *1* **Look back timeframe:** *730 days*	
ICD-10 code	**Description**
M170	BILATERAL PRIMARY OSTEOARTHRITIS OF KNEE
M1710	UNILATERAL PRIMARY OSTEOARTHRITIS, UNSPECIFIED KNEE
M1711	UNILATERAL PRIMARY OSTEOARTHRITIS, RIGHT KNEE
M1712	UNILATERAL PRIMARY OSTEOARTHRITIS, LEFT KNEE
M172	BILATERAL POST-TRAUMATIC OSTEOARTHRITIS OF KNEE
M1730	UNILATERAL POST-TRAUMATIC OSTEOARTHRITIS, UNSPECIFIED KNEE
M1731	UNILATERAL POST-TRAUMATIC OSTEOARTHRITIS, RIGHT KNEE
M1732	UNILATERAL POST-TRAUMATIC OSTEOARTHRITIS, LEFT KNEE
M174	OTHER BILATERAL SECONDARY OSTEOARTHRITIS OF KNEE
M175	OTHER UNILATERAL SECONDARY OSTEOARTHRITIS OF KNEE
M179	OSTEOARTHRITIS OF KNEE, UNSPECIFIED

Step 3 (diagnosis of GI bleed) **Required diagnosis:** *1* **Look back timeframe:** *730 days*

For the list of diagnoses that pertain to this step, see the **GI Bleed Diagnoses** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

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Clinical Criteria References

1. 2015 ICD-9-CM Diagnosis Codes. 2015. Available at **www.icd9data.com**. Accessed on July 28, 2017.
2. 2017 ICD-10-CM Diagnosis Codes. 2017. Available at **www.icd10data.com**. Accessed on July 28, 2017.
3. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2017. Available at **www.clinicalpharmacology.com**. Accessed on July 28, 2017.
4. Micromedex [online database]. 2017. Available at **www.micromedexsolutions.com**. Accessed on July 28, 2017.
5. Solaraze Prescribing Information. Melville, NY. PharmaDerm. May 2016.
6. Pennsaid Prescribing Information. Lake Forest, IL. Horizon Pharma USA Inc. May 2016.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
07/28/2017	Initial publication and presentation to the DUR Board
08/03/2017	Updated with DUR Board Recommendations • Changed all lookback periods to 730 days, page 4 • Added question 3, history of GI bleed, page 4 • Updated logic diagram, page 5 • Added table 3, page 6-7 • Added question 3, history of GI bleed, page 10 • Updated logic diagram, page 11 • Added table 3, page 12
03/27/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table

