Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Imiquimod

Clinical Criteria Information Included in this Document

Imiquimod 5% Cream

- **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

Zyclara 3.75% Cream

- **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.

Revision Notes

- Removed GCN for Aldara (54201)

Imiquimod
Aldara 5% Cream
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**
IMIQUIMOD 5% CREAM PACKET	54201

Imiquimod
Aldara 5% Cream

Clinical Criteria Logic

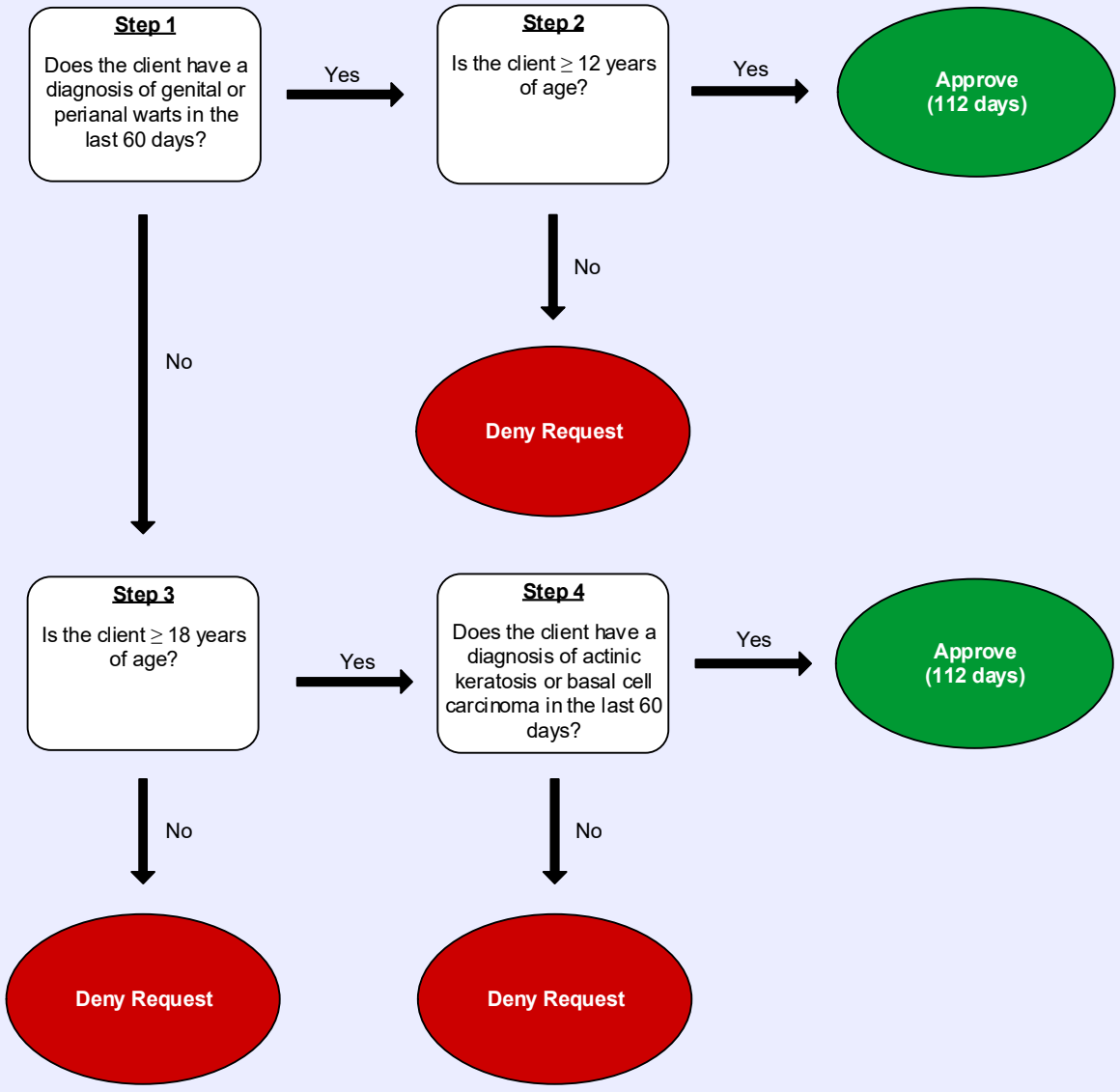
1. Does the client have a diagnosis of **genital or perianal warts** in the last 60 days?
   [ ] Yes (Go to #2)
   [ ] No (Go to #3)

2. Is the client greater than or equal to (≥) 12 years of age?
   [ ] Yes (Approve – 112 days)
   [ ] No (Deny)

3. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Does the client have a diagnosis of **actinic keratosis or basal cell carcinoma** in the last 60 days?
   [ ] Yes (Approve - 112 days)
   [ ] No (Deny)

Imiquimod
Aldara 5% Cream
Clinical Criteria Logic Diagram



RxPERT PAxpress™

Imiquimod
Aldara 5% Cream
Clinical Criteria Supporting Tables

Step 1 (diagnosis of genital or perianal warts) **Required diagnosis:** *1* **Look back timeframe:** *60 days*	
ICD-10 Code	**Description**
A630	ANOGENITAL (VENEREAL) WARTS

Step 4 (diagnosis of actinic keratosis or basal cell carcinoma) **Required diagnosis:** *1* **Look back timeframe:** *60 days*	
ICD-10	**Description**
BASAL CELL CARCINOMA	
C4400	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF LIP
C4401	BASAL CELL CARCINOMA OF SKIN OF LIP
C4409	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF LIP
C44101	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED EYELID, INCLUDING CANTHUS
C44111	BASAL CELL CARCINOMA OF SKIN OF UNSPECIFIED EYELID, INCLUDING CANTHUS
C44191	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED EYELID, INCLUDING CANTHUS
C44201	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED EAR AND EXTERNAL AURICULAR CANAL
C44211	BASAL CELL CARCINOMA OF SKIN OF UNSPECIFIED EAR AND EXTERNAL AURICULAR CANAL
C44291	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED EAR AND EXTERNAL AURICULAR CANAL
C44300	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED PART OF FACE
C44301	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF NOSE
C44309	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF OTHER PARTS OF FACE
C44310	BASAL CELL CARCINOMA OF SKIN OF UNSPECIFIED PARTS OF FACE
C44311	BASAL CELL CARCINOMA OF SKIN OF NOSE
C44319	BASAL CELL CARCINOMA OF SKIN OF OTHER PARTS OF FACE
C44390	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED PART OF FACE
C44391	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF NOSE

Step 4 (diagnosis of actinic keratosis or basal cell carcinoma) **Required diagnosis:** *1* **Look back timeframe:** *60 days*	
C44399	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF OTHER PARTS OF FACE
C4440	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF SCALP AND NECK
C4441	BASAL CELL CARCINOMA OF KIN OF SCALP AND NECK
C4449	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF SCALP AND NECK
C44500	UNSPECIFIED MALIGNANT NEOPLASM OF ANAL SKIN
C44501	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF BREAST
C44509	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF OTHER PART OF TRUNK
C44510	BASAL CELL CARCINOMA OF ANAL SKIN
C44511	BASAL CELL CARCINOMA OF SKIN OF BREAST
C44519	BASAL CELL CARCINOMA OF SKIN OF OTHER PART OF TRUNK
C44590	OTHER SPECIFIED MALIGNANT NEOPLASM OF ANAL SKIN
C44591	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF BREAST
C44599	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF OTHER PART OF TRUNK
C44601	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED UPPER LIMB, INCLUDING SHOULDER
C44611	BASAL CELL CARCINOMA OF SKIN OF UNSPECIFIED UPPER LIMB, INCLUDING SHOULDER
C44691	OTHER SPECIFIED MALIGNANT NEOPLASM OF UNSPECIFIED UPPER LIMB, INCLUDING SHOULDER
C44701	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED LOWER LIMB, INCLUDING HIP
C44711	BASAL CELL CARCINOMA OF SKIN OF UNSPECIFIED LOWER LIMB, INCLUDING HIP
C44791	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN OF UNSPECIFIED LOWER LIMB, INCLUDING HIP
C4480	UNSPECIFIED MALIGNANT NEOPLASM OF OVERLAPPING SITES OF SKIN
C4481	BASAL CELL CARCINOMA OF OVERLAPPING SITES OF SKIN
C4489	OTHER SPECIFIED MALIGNANT NEOPLASM OF OVERLAPPING SITES OF SKIN
C4490	UNSPECIFIED MALIGNANT NEOPLASM OF SKIN, UNSPECIFIED
C4491	BASAL CELL CARCINOMA OF SKIN, UNSPECIFIED
C4499	OTHER SPECIFIED MALIGNANT NEOPLASM OF SKIN, UNSPECIFIED
ACTINIC KERATOSIS	
L570	ACTINIC KERATOSIS

Imiquimod
Zyclara 3.75% Cream
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**
ZYCLARA 3.75% CREAM	28216
IMIQUIMOD CREAM 3.75% PUMP	31436

RxPERT® PAXPRESS™

Imiquimod
Zyclara 3.75% Cream
Clinical Criteria Logic

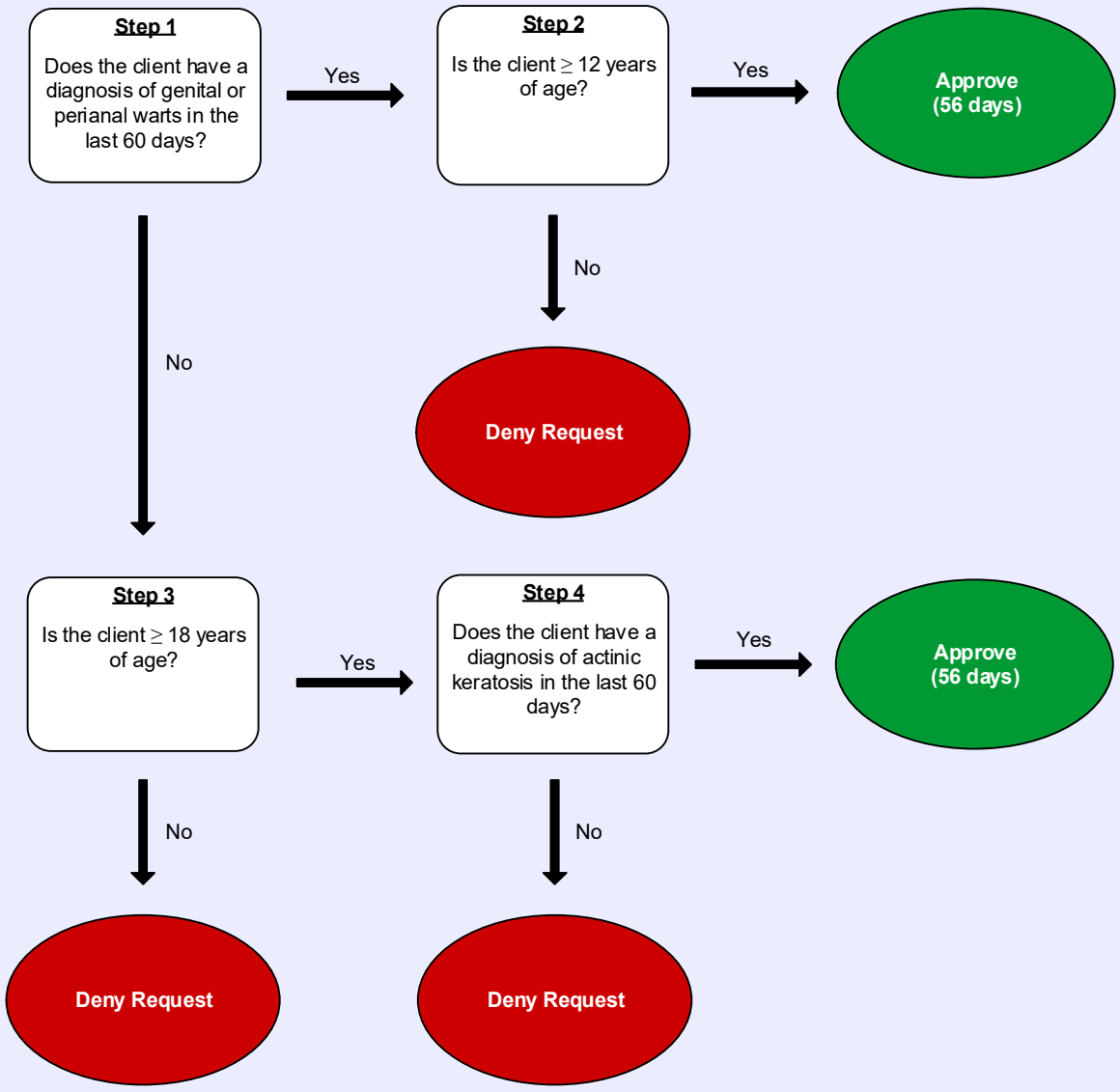
1. Does the client have a diagnosis of **genital or perianal warts** in the last 60 days?
   [ ] Yes (Go to #2)
   [ ] No (Go to #3)

2. Is the client greater than or equal to (≥) 12 years of age?
   [ ] Yes (Approve - 56 days)
   [ ] No (Deny)

3. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #4)
   [ ] No (Deny)

4. Does the client have a diagnosis of **actinic keratosis** in the last 60 days?
   [ ] Yes (Approve – 56 days)
   [ ] No (Deny)

Imiquimod
Zyclara 3.75% Cream
Clinical Criteria Logic Diagram



Imiquimod
Zyclara 3.75% Cream
Clinical Criteria Supporting Table

Step 2 (diagnosis of actinic keratosis)
Required diagnosis: *1*
Look back timeframe: *60 days*

For the list of actinic keratosis diagnoses that pertain to this step, see the **Actinic Keratosis** diagnosis table in this "Supporting Tables" section.

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

RxPERT PAxpress

Imiquimod

Clinical Criteria References

1. Aldara Prescribing Information. Bridgewater, NJ. Valeant Pharmaceuticals North America, LLC. April 2018.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2022. Available at www.clinicalpharmacology.com. Accessed on July 13, 2022.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on July 13, 2022.
4. 2015 ICD-9-CM Diagnosis Codes. 2015. Available at www.icd9data.com. Accessed on April 3, 2015.
5. 2015 ICD-10-CM Diagnosis Codes. 2015. Available at www.icd10data.com. Accessed on April 3, 2015.
6. American Medical Association data files. 2015 ICD-9-CM Diagnosis Codes. Available at **www.commerce.ama-assn.org**.
7. American Medical Association data files. 2015 ICD-10-CM Diagnosis Codes. Available at **www.commerce.ama-assn.org**.
8. Zyclara Prescribing Information. Bridgewater, NJ. Bausch Health US, LLC. June 2020.

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
04/11/2012	Initial publication and posting to website
4/3/2015	Updated to include ICD-10s
05/08/2017	Annual review by staff Updated criteria logic to show approval duration of 112 days Updated logic diagram Removed ICD-9 codes from Table 1 and 4 Updated criteria logic to show approval duration of 56 days and updated age requirements Updated logic diagram Removed ICD-9 codes from Table 2 Updated references
05/18/2018	Updated Table 1
12/10/2018	Added GCN for imiquimod cream 3.75% pump to Drugs Requiring PA
03/29/2019	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
10/19/2022	Annual review by staff Updated references
12/13/2023	Removed GCN for Aldara (54201)

