Topical Actinic Keratosis, Basal Cell Carcinoma, Genital Warts Agents Prior Authorization with Quantity Limit Program Summary

This prior authorization with quantity limit program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace and KeyRx formularies.

The quantity limit only program applies to FocusRx.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
05-01-2024	02-01-2017

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Aldara® (imiquimod) 5% cream*	Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults Topical treatment of biopsy-confirmed primary superficial basal cell carcinoma (sBCC) in immunocompetent adults, with a maximum tumor diameter of 2.0 cm, located on the trunk (excluding anogenital skin), neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured Treatment of external genital and perianal warts (condyloma acuminata) in patients 12 years or older	* generic available	6
Carac® (fluorouracil) 0.5% cream*	Topical treatment of multiple actinic or solar keratoses of the face and anterior scalp	* generic available	2
diclofenac 3% gel	Topical treatment of actinic keratosis (AK)		1
Efudex® (fluorouracil) 5% cream*	Topical treatment of multiple actinic or solar keratoses Treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites	* generic available	4
Fluoroplex® (fluorouracil) 1% cream	Topical treatment of multiple actinic (solar) keratoses		3

Agent(s)	FDA Indication(s)	Notes	Ref#
Klisyri® (tirbanibulin) 1% ointment	Topical treatment of actinic keratosis on the face or scalp		8
Tolak® (fluorouracil) 4% cream	Topical treatment of actinic keratosis lesions of the face, ears, and/or scalp		5
Zyclara® (imiquimod) 3.75% cream*	Topical treatment of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults Treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older	* generic available	7
Zyclara® (imiquimod) 2.5% cream	Topical treatment of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults		7

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Actinic Keratosis (AK)	Actinic keratoses (AK or solar keratoses) are keratotic or scaling macules, papules, or plaques resulting from the intraepidermal proliferation of atypical keratinocytes in response to prolonged exposure to ultraviolet radiation.(9) Although most AKs do not progress to squamous cell carcinoma (SCC), AKs are a concern because the majority of cutaneous SCCs arise from pre-existing AKs and AKs that will progress to SCC cannot be distinguished from AKs that will spontaneously resolve or persist.(9,10) According to NCCN guidelines, topical first-line therapies for AK include 5-fluorouracil (5-FU), imiquimod, and tirbanibulin. Topical diclofenac is considered 2B (based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate) due to varying efficacy results across large randomized trials.(10) UpToDate indicates 5-FU and imiquimod as first-line topical therapies, and diclofenac and tirbanibulin as second-line.
Superficial Basal Cell Carcinoma (BCC)	Basal cell carcinoma (BCC) is a common skin cancer that arises from the basal layer of epidermis and its appendages.(11) First-line therapy is surgical excision, however for some patients with low-risk superficial BCC, where surgery is contraindicated or impractical, topical therapies such as 5-fluorouracil (5-FU) or imiquimod may be considered, even though the cure rate may be lower.(11,12)
Genital Warts	Condylomomata acuminata, also known as anogenital warts or external genital / perianal warts (EGW), are a manifestation of anogenital human papillomavirus (HPV) infection. The treatment of genital warts should be guided by the extent of disease (e.g., wart size, number, and anatomic site), patient preference, cost and availability of treatment, and the experience of the health care provider. Patient-applied therapies include imiquimod 3.75% and 5%, and podophyllotoxin.(13,14) The majority of genital warts respond within 3 months of therapy.(14)

REFERENCES

Number	Reference
1	Diclofenac 3% gel prescribing information. Glenmark Pharmaceuticals Inc. June 2016.

Number	Reference
2	Carac 0.5% cream prescribing information. Bausch Health US, LLC. May 2021.
3	Fluoroplex prescribing information. Almirall, LLC. March 2022.
4	Efudex prescribing information. Bausch Health Companies Inc. October 2021.
5	Tolak prescribing information. Hill Dermaceuticals, Inc. March 2020.
6	Aldara prescribing information. Valeant Pharmaceuticals International, Inc. June 2022.
7	Zyclara prescribing information. Bausch Health US, LLC. June 2020.
8	Klisyri prescribing information. Almirall, LLC. August 2021.
9	Berman B, et al. Treatment of Actinic Keratosis. UpToDate. Last updated February 2023. Literature review current through June 2023.
10	National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer. Version 1.2023.
11	Aasi SZ, et al. Treatment and Prognosis of Basal Cell Carcinoma at Low Risk of Recurrence. UpToDate. Last updated December 2022. Literature review current through June 2023.
12	National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer. Version 1.2023.
13	Rosen T, et al. Condylomata Acuminata (Anogenital Warts): Management of External Condylomata Acuminata in Adult Males. UpToDate. Last updated February 2023. Literature review current through June 2023.
14	Workowski KA, Bachmann LH, Chan PA, et al. Centers for Disease Control and Prevention (CDC) Treatment Guidelines on Sexually Transmitted Diseases. MMWR. 2021;70(4):1-187.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
	diclofenac sodium (actinic keratoses) gel	3 %	M ; N ; O ; Y	Y		
Carac	Fluorouracil Cream 0.5%	0.5 %	M ; N ; O ; Y	M		
	Fluorouracil Cream 1%		M ; N ; O ; Y			
Tolak	Fluorouracil Cream 4%	4 %	M ; N ; O ; Y	N		
Efudex	Fluorouracil Cream 5%	5 %	M ; N ; O ; Y	O ; Y		
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	M ; N ; O ; Y	N		
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	M ; N ; O ; Y	O ; Y		
Aldara	Imiquimod Cream 5%	5 %	M ; N ; O ; Y	O ; Y		
Klisyri	Tirbanibulin Ointment	1 %	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Quantity Limit									

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	300	Grams	90	DAYS			
	Fluorouracil Cream 1%		60	Grams	42	DAYS			
Aldara	Imiquimod Cream 5%	5 %	48	Packets	112	DAYS			
Carac	Fluorouracil Cream 0.5%	0.5 %	30	Grams	28	DAYS			
Efudex	Fluorouracil Cream 5%	5 %	240	Grams	84	DAYS			
Klisyri	Tirbanibulin Ointment	1 %	5	Packets	90	DAYS			
Tolak	Fluorouracil Cream 4%	4 %	40	Grams	28	DAYS			
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	56	Grams	56	DAYS			
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	2	Bottles	42	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
Prior Authorization with Quantity Limit							
90374035304020		Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	Actinic keratoses: one 100 gram tube per month for up to 90 days			
90372030003710		Fluorouracil Cream 1%		Multiple actinic or solar keratoses: one 30 gram tube per month for up to 6 weeks			
90773040003720	Aldara	Imiquimod Cream 5%	5 %	Actinic keratoses: three boxes (36 packets) for up to 16 weeks External genital and perianal warts (EGW) (condyloma acuminata): 12 packets per month for up to 16 weeks Superficial basal cell carcinoma: three boxes (36 packets) for up to 6 weeks			
90372030003705	Carac	Fluorouracil Cream 0.5%	0.5 %	Multiple actinic or solar keratoses: one 30 gram tube per month for up to 4 weeks			
90372030003730	Efudex	Fluorouracil Cream 5%	5 %	Multiple actinic or solar keratoses: one 40 gram tube per month for up to 4 weeks Superficial basal cell carcinomas: two 40 gram tubes per month for up to 12 weeks			
90374580004220	Klisyri	Tirbanibulin Ointment	1 %	Actinic keratoses (face or scalp): 5 packets for up to 90 days			
90372030003725	Tolak	Fluorouracil Cream 4%	4 %	Actinic keratoses: one 40 gram tube per month for up to 4 weeks			
90773040003715	Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	Actinic keratoses: two boxes (56 packets) for up to 6 weeks two 7.5 gm pump bottles for up to 6 weeks External genital or perianal warts (EGW) (condyloma acuminata): two boxes (56 packets) for up to 8 weeks two 7.5 gm pump bottles for up to 8 weeks			
90773040003710	Zyclara pump	Imiquimod Cream 2.5%	2.5 %	Actinic keratoses: two 7.5 gm pump bottles for up to 6 weeks			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
			FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	diclofenac sodium (actinic keratoses) gel	3 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Fluorouracil Cream 1%		FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aldara	Imiquimod Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Carac	Fluorouracil Cream 0.5%	0.5 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Efudex	Fluorouracil Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Klisyri	Tirbanibulin Ointment	1 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tolak	Fluorouracil Cream 4%	4 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Diclofenac Sodium (Actinic Keratoses) Gel 3%	3 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Fluorouracil Cream 1%		FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Fluorouracil Cream 1%		FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aldara	Imiquimod Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Aldara	Imiquimod Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Carac	Fluorouracil Cream 0.5%	0.5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Carac	Fluorouracil Cream 0.5%	0.5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Efudex	Fluorouracil Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Efudex	Fluorouracil Cream 5%	5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Klisyri	Tirbanibulin Ointment	1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Klisyri	Tirbanibulin Ointment	1 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tolak	Fluorouracil Cream 4%	4 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Tolak	Fluorouracil Cream 4%	4 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara ; Zyclara pump	Imiquimod Cream 3.75%	3.75 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Zyclara pump	Imiquimod Cream 2.5%	2.5 %	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Prior Authorization with Quantity Limit	**Evaluation** **Effective 5/1/24 for:** **Those who were approved after 5/1/24** **Those who have started a new plan year since last authorization** **Target Agent(s)** will be approved when ALL of the following are met: 1. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR** B. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND** 2. The requested agent is diclofenac 3% gel, Efudex (Fluorouracil) 5% cream, OR Fluoroplex **OR**

Module	Clinical Criteria for Approval
	C. BOTH of the following: 1. The patient has a diagnosis of superficial basal cell carcinoma **AND** 2. The requested agent is Aldara OR Efudex (Fluorouracil) 5% cream **OR** D. BOTH of the following: 1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND** 2. The requested agent is Aldara OR Zyclara (Imiquimod) 3.75% cream **AND** 3. ONE of the following: A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic imiquimod 5% cream AND fluorouracil solution cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. For a diagnosis of external genital warts, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR** 2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic imiquimod 5% cream cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

Module	Clinical Criteria for Approval
	Effective until 4/30/25 for: **Those with an original PA date 5/1/24-4/30/25 seeking reauthorization AND that have not started a new plan year.** **Target Agent(s)** will be approved when ALL of the following are met: 1. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, OR Zyclara 2.5% cream **OR** B. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the face and/or scalp: **AND** 2. The requested agent is diclofenac 3% gel, Carac (Fluorouracil) 0.5% cream, Efudex (Fluorouracil) 5% cream, Fluoroplex, Tolak, Aldara, Zyclara (Imiquimod) 3.75% cream, Zyclara 2.5% cream, OR Klisyri **OR** C. BOTH of the following: 1. The patient has a diagnosis of actinic (solar) keratoses of the trunk and/or extremities: **AND** 2. The requested agent is diclofenac 3% gel, Efudex (Fluorouracil) 5% cream, OR Fluoroplex **OR** D. BOTH of the following: 1. The patient has a diagnosis of superficial basal cell carcinoma **AND** 2. The requested agent is Aldara OR Efudex (Fluorouracil) 5% cream **OR** E. BOTH of the following: 1. The patient has a diagnosis of external genital and/or perianal warts (EGW) / condyloma acuminata **AND** 2. The requested agent is Aldara OR Zyclara (Imiquimod) 3.75% cream **AND** 3. ONE of the following: A. For a diagnosis of actinic keratoses or superficial basal cell carcinoma, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream or fluorouracil solution **OR** 2. The patient has an intolerance or hypersensitivity to therapy with generic imiquimod 5% cream or fluorouracil solution **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream AND fluorouracil solution **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic imiquimod 5% cream AND fluorouracil solution cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

Module	Clinical Criteria for Approval
	B. For a diagnosis of external genital warts, ONE of the following: 1. The patient has tried and had an inadequate response to generic imiquimod 5% cream **OR** 2. The patient has an intolerance of hypersensitivity to therapy with generic imiquimod 5% cream **OR** 3. The patient has an FDA labeled contraindication to generic imiquimod 5% cream **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that generic imiquimod 5% cream cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL Standalone	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) and/or duration does NOT exceed the program quantity limit for the requested indication **OR** 2. Information has been provided to support therapy with the requested quantity (dose) and/or duration of therapy for the requested indication **Length of Approval:** up to 12 months
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) and/or duration does NOT exceed the program quantity limit for the requested indication **OR** 2. Information has been provided to support therapy with the requested quantity (dose) and/or duration of therapy for the requested indication **Length of Approval:** Up to duration in the program quantity limit for the requested indication; or durations above program quantity limit with appropriate supportive information for up to 12 months

