BlueCross BlueShield of Alabama

Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Prior Authorization with Quantity Limit and Quantity Limit Program Summary

The prior authorization with quantity limit program applies to Commercial, GenPlus, SourceRx, and Health Insurance Marketplace formularies.

The quantity limit program applies to NetResults A series.

Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Prior Authorization with Quantity Limit

OBJECTIVE

The intent of the Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Prior Authorization with Quantity Limit program is to encourage appropriate selection of patients for treatment according to product labeling, clinical studies, and/or guidelines, and to promote the use the cost effective generics. The PA program defines appropriate use as therapy for a Food and Drug Administration (FDA) approved label indication. In addition, the PA program will review for quantities and duration of therapy consistent with FDA labeled recommended dosing, clinical studies, and/or guidelines.

TARGET AGENTS

Diclofenac Gel
- **Solaraze** (diclofenac gel)[b]

Fluorouracil Cream
- **Carac** (fluorouracil cream)
- **Efudex** (fluorouracil cream)[a]
- **Fluorouracil cream**
- **Fluoroplex** (fluorouracil cream)
- **Tolak** (fluorouracil cream)

Imiquimod Cream
- **Aldara** (imiquimod cream)[a]
- **Zyclara** (imiquimod cream)

Ingenol Gel
- **Picato** (ingenol gel)

a – generic available and not included in prior authorization program
b – generic available and included in prior authorization program

PROGRAM PRIOR AUTHORIZATION, QUANTITY AND DURATION LIMIT

Brand (generic)	GPI	Multisource Code for Prior Authorization	Quantity Limit (applies to all MSC Codes)
Diclofenac Gel			
Solaraze (diclofenac gel)[b] 3% gel	90374035304020	M, N, O, Y	Actinic keratosis: one 100 gram tube per month for up to 90 days
Fluorouracil Cream			
Carac (fluorouracil cream), Fluorouracil Cream 0.5% cream	90372030003705	M, N, O, Y	Multiple actinic or solar keratosis: one 30 gram tube per month for up to 4 weeks

Brand (generic)	GPI	Multisource Code for Prior Authorization	Quantity Limit (applies to all MSC Codes)
Efudex (fluorouracil cream)[a], 5% cream	90372030003730	M, N, O	Multiple actinic or solar keratosis: one 40 gram tube per month for up to 4 weeks Superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites: two 40 gram tubes per month for up to 12 weeks
Fluoroplex (fluorouracil cream) 1% cream	90372030003710	M, N, O, Y	Multiple actinic or solar keratosis: one 30 gram tube per month for up to 6 weeks
Tolak (fluorouracil cream) 4%	90372030003725	M, N, O, Y	Actinic Keratosis: one 40 gram tube per month for up to 4 weeks
Imiquimod Cream			
Aldara (imiquimod cream)[a] 5% cream	90773040003720	M, N, O	External genital and perianal warts or Actinic keratosis: 12 packets per month for up to 4 months Superficial basal cell carcinoma: 24 packets per month for up to 2 months
Zyclara (imiquimod cream) 2.5%	90773040003710	M, N, O, Y	Actinic keratosis: 56 packets for up to 6 weeks two 7.5 gm pumps for up to 6 weeks one 15 gm pump for up to 6 weeks
Zyclara (imiquimod cream) 3.75%	90773040003715	M, N, O, Y	Actinic keratosis: 56 packets for up to 6 weeks two 7.5 gm pumps for up to 6 weeks one 15 gm pump for up to 6 weeks External genital or perianal warts (condyloma acuminata): 56 packets for up to 8 weeks two 7.5 gm pumps for up to 8 weeks one 15 gm pump for up to 8 weeks
Ingenol Gel			

Brand (generic)	GPI	Multisource Code for Prior Authorization	Quantity Limit (applies to all MSC Codes)
Picato (ingenol gel) 0.015%	90378035204020	M, N, O, Y	Actinic keratosis (face or scalp): 3 tubes for up to 90 days
Picato (ingenol gel) 0.05%	90378035204040	M, N, O, Y	Actinic keratosis (trunk or extremities): 2 tubes for up to 90 days

a – generic available and not included in prior authorization program
b – generic available and included in prior authorization program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Solaraze, diclofenac gel will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes at least one generic fluorouracil cream or generic imiquimod cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream

    AND
2. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
    a. The quantity prescribed does not exceed one 100 gram tube per month for up to 90 days.
    OR
    b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Carac, Fluorouracil Cream will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic fluorouracil cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream

    AND
2. The patient has diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
    a. The quantity prescribed does not exceed one 30 gram tube over 4 weeks
    OR
    b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Efudex will be approved when ALL of the following is met:

1. ONE of the following:
    a. The patient's medication history includes generic fluorouracil cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream

AND

2. ONE of the following:
    a. The patient has a diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
        i. The quantity prescribed does not exceed one 40 gram tube over 4 weeks
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

    OR

    b. The patient has a diagnosis of superficial basal cell carcinoma **AND** ONE of the following:
        i. The quantity prescribed does not exceed two 40 gram tubes per month over 12 weeks
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Fluoroplex will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic fluorouracil cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream

    AND

2. The patient has a diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
    a. The quantity prescribed does not exceed one 30 gram tube per month over 6 weeks
    OR
    b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Tolak will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic fluorouracil cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream

    AND

2. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
    a. The quantity prescribed does not exceed one 40 gram tube over 4 weeks
    OR
    b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Aldara will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic imiquimod cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream

AND

2. ONE of the following:
    a. The patient has a diagnosis of external genital and/or perianal warts/condyloma acuminata **AND** ONE of the following:
        i. The quantity prescribed does not exceed 12 packets/month over 4 months
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

    OR

    b. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
        i. The quantity prescribed does not exceed 12 packets/month over 4 months
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

    OR

    c. The patient has a diagnosis of superficial basal cell carcinoma **AND** ONE of the following:
        i. The quantity prescribed does not exceed 24 packets/month over 2 months
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Zyclara 2.5% will be approved when BOTH of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic imiquimod cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream

AND

2. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
    a. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 6 weeks
    OR
    b. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Zyclara 3.75% will be approved when ALL of the following are met:

1. ONE of the following:
    a. The patient's medication history includes generic imiquimod cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream

    AND
2. ONE of the following:
    a. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
        i. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 6 weeks
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

    OR
    b. The patient has a diagnosis of external genital or perianal warts/condyloma acuminata **AND** ONE of the following:
        i. The quantity prescribed does not exceed 56 packets, two 7.5 gm pumps, or one 15 gm pump over 8 weeks
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Picato 0.015% will be approved when BOTH of the following are met:

1. ONE of the following
    a. The patient's medication history includes generic fluorouracil cream or generic imiquimod cream in the past 90 days
    OR
    b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream

    AND
2. ONE of the following:
    a. The patient has a diagnosis of actinic keratosis of the face or scalp **AND** ONE of the following:
        i. The quantity prescribed does not exceed 3 tubes over 90 days
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Picato 0.05% will be approved when BOTH of the following are met:

1. ONE of the following
    a. The patient's medication history includes generic fluorouracil cream or generic imiquimod cream in the past 90 days
    OR

b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream or generic imiquimod cream

AND

2. ONE of the following:
    a. The patient has a diagnosis of actinic keratosis of the trunk or extremities **AND** ONE of the following:
        i. The quantity prescribed does not exceed 2 tubes over 90 days
        OR
        ii. The quantity exceeds the set quantity and the prescriber has submitted documentation in support of the requested quantities and/or duration of therapy for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: up to 12 months

Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Quantity Limit

OBJECTIVE
The intent of the Topical Diclofenac Gel, Fluorouracil Cream, Imiquimod Cream, and Ingenol Gel Quantity Limit program is to encourage appropriate dosing and duration of therapy according to product labeling, clinical studies and/or guidelines.

TARGET AGENTS
Diclofenac Gel
Solaraze (diclofenac gel)[b]
Fluorouracil Cream
Carac (fluorouracil cream)
Efudex (fluorouracil cream)[a]
Fluorouracil cream
Fluoroplex (fluorouracil cream)
Tolak (fluorouracil cream)
Imiquimod Cream
Aldara (imiquimod cream)[a]
Zyclara (imiquimod cream)
Ingenol Gel
Picato (ingenol gel)
a – generic available and not included in prior authorization program
b – generic available and included in prior authorization program

PROGRAM PRIOR AUTHORIZATION, QUANTITY AND DURATION LIMIT

Brand (generic)	GPI	Quantity Limit
Diclofenac Gel		
Solaraze (diclofenac gel)[b] 3% gel	90374035304020	One 100 gram tube per month for up to 90 days
Fluorouracil Cream		
Carac (fluorouracil cream), Fluorouracil Cream 0.5% cream	90372030003705	One 30 gram tube per month for up to 4 weeks
Efudex (fluorouracil cream)[a], 5% cream	90372030003730	Two 40 gram tubes per month for up to 12 weeks
Fluoroplex (fluorouracil cream) 1% cream	90372030003710	One 30 gram tube per month for up to 6 weeks
Tolak (fluorouracil cream) 4%	90372030003725	One 40 gram tube per month for up to 4 weeks
Imiquimod Cream		
Aldara (imiquimod cream)[a] 5% cream	90773040003720	24 packets per month for up to 4 months
Zyclara (imiquimod cream) 2.5%	90773040003710	56 packets for up to 6 weeks two 7.5 gm pumps for up to 6 weeks one 15 gm pump for up to 6 weeks

Brand (generic)	GPI	Quantity Limit
Zyclara (imiquimod cream) 3.75%	90773040003715	56 packets for up to 8 weeks two 7.5 gm pumps for up to 8 weeks one 15 gm pump for up to 8 weeks
Ingenol Gel		
Picato (ingenol gel) 0.015%	90378035204020	Actinic keratosis (face or scalp): 3 tubes for up to 90 days
Picato (ingenol gel) 0.05%	90378035204040	Actinic keratosis (trunk or extremities): 2 tubes for up to 90 days

a – generic available and not included in prior authorization program
b – generic available and included in prior authorization program

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Quantities above the program set limit will be approved when ONE of the following is met:

1. The prescriber has submitted documentation in support of the requested therapeutic use and quantity for the requested medication which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: up to 12 months

FDA APPROVED INDICATIONS AND DOSAGE[1-8]

Topical Diclofenac Gel Agent	Indication	Dosing
Solaraze (diclofenac gel 3%)[a]	Topical treatment of actinic keratosis	Apply to lesion areas twice daily. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days.

[a] generic available

Topical Fluorouracil Agent	Indication	Dosing
Carac, Fluorouracil Cream 0.5%	Topical treatment of multiple actinic or solar keratosis of the face and anterior scalp	Apply once a day to the skin where actinic keratosis lesions appear, using enough to cover the entire area with a thin film. Fluorouracil agent should be applied up to 4 weeks as tolerated. Continued treatment up to 4 weeks results in greater lesion reduction
Efudex (fluorouracil cream 5%)[a]	Topical treatment of multiple actinic or solar keratosis.	Apply twice daily in an amount sufficient to cover the lesions. The usual duration of therapy is from 2 to 4 weeks. Complete healing of the lesions may not be evident for 1 to 2 months following cessation of therapy.
	Treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites.	Apply twice daily in an amount sufficient to cover the lesions. Treatment should be continued for at least 3 to 6 weeks. Therapy may be required for as long as 10 to 12 weeks before the lesions are obliterated.
Fluoroplex (fluorouracil cream 1%)	Topical treatment of multiple actinic (solar) keratosis	Apply sufficient medication to cover the entire face or other affected areas twice daily. Increasing the frequency of application and a longer period of administration may be required on areas other than the head and neck. A treatment period of 2-6 weeks is usually required.

Topical Fluorouracil Agent	Indication	Dosing
Tolak (fluorouracil cream 4%)	Topical treatment of actinic keratosis lesions of the face, ears, and scalp	Apply once daily in an amount sufficient to cover the lesions of the face, ears, and/or scalp with a thin film, using the fingertips to gently massage the medication uniformly into the skin Cream should be applied for a period of 4 weeks as tolerated

[a] generic available

Topical Imiquimod Agent	Indication	Dosing
Aldara (imiquimod 5% cream)*[a]	Clinically typical nonhyperkeratotic, nonhypertrophic actinic keratosis (AK) of face or scalp for immunocompetent adults	Apply 2 times per week for a full 16 weeks. Treatment area is defined as a 25cm^2 (5 cm x 5 cm) area on face or scalp.
	Biopsy confirmed primary Superficial basal cell carcinoma (BCC) for immunocompetent adults	Apply 5 times per week for full 6 weeks. Tumor diameter: Diameter of cream droplet (mg imiquimod) 0.5 to <1.0 cm: 4 mm (10 mg) ≥1.0 to <1.5 cm: 5 mm (25 mg) ≥ 1.5 to 2.0 cm: 7 mm (40 mg)
	External genital and perianal warts (condyloma acuminata) for patients age ≥12	Apply a thin layer to wart area 3 times per week until total clearance of warts or for a maximum of 16 weeks
Zyclara (imiquimod 3.75% cream)[e]	Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults	Apply a thin film (up to two packets) to treatment area once daily before bedtime to the skin of the affected area (either the face or balding scalp) for two 2-week treatment cycles separated by a 2 week no treatment period.
	External genital and perianal warts (condyloma acuminata) for patients age ≥12	Apply a thin layer (up to one packet) once a day to the external genital/perianal warts until total clearance or for up to 8 weeks.
Zyclara (imiquimod 2.5% cream)[e]	Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults	Apply a thin film (up to two packets) to treatment area once daily before bedtime to the skin of the affected area (either the face or balding scalp) for two 2-week treatment cycles separated by a 2 week no treatment period.

*generic available

Topical Ingenol	Indication	Dosing
Picato® (ingenol gel 0.015%, 0.05%))	Topical treatment of actinic keratosis	Face or scalp with 0.015%: apply once daily for 3 consecutive days Trunk or extremities with 0.05%: apply once daily for 2 consecutive days For application of up to one contiguous skin area of approximately 25 cm^2 (5 cm x 5 cm) using one unit dose tube

CLINICAL RATIONALE
Actinic Keratosis (AK)
Topical therapies for AK include 5-fluorouracil [5-FU], imiquimod, ingenol mebutate, diclofenac[9]. National Comprehensive Cancer Network [NCCN, U.S., 2017] guidelines suggest AKs should be treated aggressively at first development. Accepted modalities include cryosurgery, topical fluorouracil (5-FU), topical imiquimod, photodynamic therapy, curettage, and electrodessication. [Category 2A: based on lower level evidence, uniform NCCN consensus that the intervention is appropriate.] Other modalities that may be considered include diclofenac*, chemical peel (trichloroacetic acid), and ablative skin resurfacing (laser, dermabrasion). [*Category 2B: based on lower level evidence, NCCN consensus that the intervention is appropriate.] [10]

A long-term follow up study assessed 12-month recurrence rates associated with ingenol mebutate gel treatment in patients who previously had achieved complete clearance of AK. In total, 108 patients with complete clearance of face or scalp lesions in the original trial and 76 patients with complete clearance of trunk or extremity lesions in the original trial were enrolled in the 12-month observational follow-up study. Of these, 100 patients (face or scalp) and 71 patients (trunk or extremities) completed all 12 months. Sustained lesion reduction rates vs. baseline were 87.2% for the face or scalp and 86.8% for the trunk or extremities. The estimated median times to recurrence were 365 days (face or scalp) and 274 days (trunk or extremities).[17]

Superficial Basal Cell Carcinoma (BCC)
Overall there has been very little good quality research on treatments for BCC. Most trials have only evaluated BCCs in low risk locations. Surgery and radiotherapy appear to be the most effective treatments, with surgery showing the lowest failure rates. Other treatments might have some use but few have been compared to surgery.[12] Although surgery and radiotherapy remain the treatments of choice for most high risk lesions, topical and non-surgical treatments are options to treat low risk lesions.[11]

NCCN Guidelines (U.S., 2016) suggest in patients with low risk, superficial basal cell skin cancer, where surgery or radiation is contraindicated or impractical, topical therapies such as 5-fluorouracil, imiquimod, photodynamic therapy, or vigorous cryotherapy may be considered, even though the cure rate may be lower.[17]

Genital Warts
Several guidelines state there is no definitive evidence that any of the available treatments are superior to others and no single treatment is ideal for all patients or all warts.[13,14,15] For all available treatments except surgical removal, the initial response rate is 60-70% and 20-30% will have a recurrence.[14]

The Centers for Disease Control and Prevention (CDC, U.S., 2010) suggests that treatment of genital warts should be guided by the preference of the patient, available resources, and the experience of the health care provider. Factors that might influence selection of treatment include wart size, wart number, anatomic site of wart, wart morphology, patient preference, cost of treatment, convenience, adverse effects, and provider experience. The treatment should be changed if a patient has not improved substantially. The majority of genital warts respond within 3 months of therapy.[13]

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