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

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

The quantity limit only program applies to FocusRx.

This is a FlexRx standard and GenRx standard prior authorization.

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

**FDA APPROVED INDICATIONS AND DOSAGE**

<table>
<thead>
<tr>
<th>Topical Diclofenac Gel Agent</th>
<th>Indication</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solaraze® (diclofenac gel 3%)a</td>
<td>Topical treatment of actinic keratosis</td>
<td>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.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Topical Fluorouracil Agent</th>
<th>Indication</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carac®, Fluorouracil Cream 0.5%</td>
<td>Topical treatment of multiple actinic or solar keratosis of the face and anterior scalp</td>
<td>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.</td>
</tr>
<tr>
<td>Efudex® (fluorouracil cream 5%)a</td>
<td>Topical treatment of multiple actinic or solar keratosis.</td>
<td>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.</td>
</tr>
</tbody>
</table>

*a* generic available
<table>
<thead>
<tr>
<th><strong>Topical Fluorouracil Agent</strong></th>
<th><strong>Indication</strong></th>
<th><strong>Dosing</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Fluoroplex®</strong> (fluorouracil cream 1%)</td>
<td>Topical treatment of multiple actinic (solar) keratosis</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Tolak™</strong> (fluorouracil cream 4%)</td>
<td>Topical treatment of actinic keratosis lesions of the face, ears, and scalp</td>
<td>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.</td>
</tr>
</tbody>
</table>

* generic available

<table>
<thead>
<tr>
<th><strong>Topical Imiquimod Agent</strong></th>
<th><strong>Indication</strong></th>
<th><strong>Dosing</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aldara®</strong> (imiquimod 5% cream)*</td>
<td>Clinically typical nonhyperkeratotic, nonhypertrophic actinic keratosis (AK) of face or scalp for immunocompetent adults</td>
<td>Apply 2 times per week for a full 16 weeks. Treatment area is defined as a 25 cm² (5 cm x 5 cm) area on face or scalp.</td>
</tr>
<tr>
<td>Biopsy confirmed primary Superficial basal cell carcinoma (BCC) for immunocompetent adults</td>
<td>Apply 5 times per week for full 6 weeks.</td>
<td><strong>Tumor diameter</strong></td>
</tr>
<tr>
<td>0.5 to &lt;1.0 cm</td>
<td>4 mm (10 mg)</td>
<td></td>
</tr>
<tr>
<td>&gt;1.0 to &lt;1.5 cm</td>
<td>5 mm (25 mg)</td>
<td></td>
</tr>
<tr>
<td>&gt; 1.5 to 2.0 cm</td>
<td>7 mm (40 mg)</td>
<td></td>
</tr>
<tr>
<td>Topical Imiquimod Agent</td>
<td>Indication</td>
<td>Dosing</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td></td>
<td>External genital and perianal warts (condyloma acuminata) for patients age ≥12</td>
<td>Apply a thin layer to wart area 3 times per week until total clearance of warts or for a maximum of 16 weeks</td>
</tr>
<tr>
<td><strong>Zyclara®</strong>&lt;br&gt;(imiquimod 3.75% cream)</td>
<td>Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>External genital and perianal warts (condyloma acuminata) for patients age ≥12</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Zyclara®</strong>&lt;br&gt;(imiquimod 2.5% cream)</td>
<td>Clinically typical, visible or palpable AK of the full face or balding scalp for immunocompetent adults</td>
<td>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.</td>
</tr>
</tbody>
</table>

* generic available

<table>
<thead>
<tr>
<th>Topical Ingenol</th>
<th>Indication</th>
<th>Dosing</th>
</tr>
</thead>
</table>
| **Picato®**<br>(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 cm² (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. National Comprehensive Cancer Network guidelines suggest AKs should be treated at first development. Accepted modalities include cryosurgery, topical 5-FU, topical imiquimod, topical ingenol, photodynamic therapy, curettage, and electrodessication. 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.*]

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).13

**Superficial Basal Cell Carcinoma (BCC)**
NCCN Guidelines 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.12

**Genital Warts**
The 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 clinician skill and treatment availability. The treatment should be changed if a patient has not improved substantially.11,14 The majority of genital warts respond within 3 months of therapy.11

For additional clinical information see Prime Therapeutics Formulary Chapter 14.5Y: Topical Immunomodulators.

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 of 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

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

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code for Prior Authorization</th>
<th>Quantity Limit (applies to all MSC Codes)</th>
</tr>
</thead>
</table>
| 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 pump bottles for up to 6 weeks  
one 15 gm pump bottle 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 pump bottles for up to 6 weeks  
one 15 gm pump bottle for up to 6 weeks  
External genital or perianal warts (condyloma acuminata): 56 packets for up to 8 weeks  
two 7.5 gm pump bottles for up to 8 weeks  
one 15 gm pump bottle for up to 8 weeks |

**Ingenol Gel**
<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code for Prior Authorization</th>
<th>Quantity Limit (applies to all MSC Codes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Picato (ingenol gel) 0.015%</td>
<td>90378035204020</td>
<td>M, N, O, Y</td>
<td>Actinic keratosis (face or scalp): 3 tubes for up to 90 days</td>
</tr>
<tr>
<td>Picato (ingenol gel) 0.05%</td>
<td>90378035204040</td>
<td>M, N, O, Y</td>
<td>Actinic keratosis (trunk or extremities): 2 tubes for up to 90 days</td>
</tr>
</tbody>
</table>

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 (5%) or generic imiquimod cream (5%) in the past 90 days  
   OR  
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%) or generic imiquimod cream (5%)

   AND

2. The patient has diagnosis of actinic keratosis AND ONE of the following:
   a. The quantity and duration prescribed does not exceed the program limit for the requested indication  
   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 (5%) in the past 90 days  
   OR  
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%)

   AND

2. The patient has diagnosis of multiple actinic or solar keratosis AND ONE of the following:
   a. The quantity and duration prescribed does not exceed the program limit for the requested indication  
   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 (5%) in the past 90 days  
   OR
b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%)

**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 and duration prescribed does not exceed the program limit for the requested indication **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 and duration prescribed does not exceed the program limit for the requested indication **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 (5%) in the past 90 days **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%)

**AND**

2. The patient has a diagnosis of multiple actinic or solar keratosis **AND** ONE of the following:
   a. The quantity and duration prescribed does not exceed the program limit for the requested indication **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 (5%) in the past 90 days **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%)

**AND**

2. The patient has a diagnosis of actinic keratosis **AND** ONE of the following:
   a. The quantity and duration prescribed does not exceed the program limit for the requested indication **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 (5%) in the past 90 days
   **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream (5%)

   **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 and duration prescribed does not exceed the program limit for the requested indication
      **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 and duration prescribed does not exceed the program limit for the requested indication
      **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 and duration prescribed does not exceed the program limit for the requested indication
      **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 (5%) in the past 90 days
   **OR**
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream (5%)

   **AND**

2. The patient has a diagnosis of actinic keratosis AND ONE of the following:
   a. The quantity and duration prescribed does not exceed the program limit for the requested indication
   **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 (5%) in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic imiquimod cream (5%) AND

2. ONE of the following:
   a. The patient has a diagnosis of actinic keratosis AND ONE of the following:
      i. The quantity and duration prescribed does not exceed the program limit for the requested indication
      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 (5%) or generic imiquimod cream (5%) in the past 90 days
   OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%) or generic imiquimod cream (5%) 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 and duration prescribed does not exceed the program limit for the requested indication
      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 (5%) or generic imiquimod cream (5%) in the past 90 days

OR

b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to an available generic fluorouracil cream (5%) or generic imiquimod cream (5%)

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 and duration prescribed does not exceed the program limit for the requested indication
      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

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diclofenac Gel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solaraze (diclofenac gel)(^b)</td>
<td>90374035304020</td>
<td>300 grams / 90 days</td>
</tr>
<tr>
<td>3% gel</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fluorouracil Cream</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carac (fluorouracil cream), Flouurouracil Cream 0.5% cream</td>
<td>90372030003705</td>
<td>30 grams / 28 days</td>
</tr>
<tr>
<td>Efudex (fluorouracil cream)(^a), 5% cream</td>
<td>90372030003730</td>
<td>240 grams / 84 days</td>
</tr>
<tr>
<td>Fluoroplex (fluorouracil cream) 1% cream</td>
<td>90372030003710</td>
<td>60 grams / 42 days</td>
</tr>
<tr>
<td>Tolak (fluorouracil cream) 4%</td>
<td>90372030003725</td>
<td>40 grams / 28 days</td>
</tr>
<tr>
<td><strong>Imiquimod Cream</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aldara (imiquimod cream)(^a) 5% cream</td>
<td>90773040003720</td>
<td>96 packets / 120 days</td>
</tr>
<tr>
<td>Zyclara (imiquimod cream) 2.5%</td>
<td>90773040003710</td>
<td>56 packets / 42 days</td>
</tr>
<tr>
<td>two 7.5 gram pumps bottles / 42 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>one 15 gram pump bottle / 42 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Brand (generic) | GPI | Quantity Limit
--- | --- | ---
Zyclara (imiquimod cream) 3.75% | 90773040003715 | 56 packets / 56 days<br>two 7.5 gram pump bottles / 56 days<br>one 15 gram pump bottle / 56 days

### Ingenol Gel

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Picato (ingenol gel) 0.015%</td>
<td>90378035204020</td>
<td>3 tubes / 90 days</td>
</tr>
<tr>
<td>Picato (ingenol gel) 0.05%</td>
<td>90378035204040</td>
<td>2 tubes / 90 days</td>
</tr>
</tbody>
</table>

Here are the (a) generic available and not included in prior authorization program and (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
This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

Please note, this does not include or apply to quantity limit questions.

**Step Therapy Supplement**

**Objective**
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

**Conditions for Approval**
The requested agent will be approved when ONE of the following are met:

1. 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**
2. The patient's medication history include the required prerequisite/preferred agent(s) as indicated by:
   a. Evidence of a paid claim(s) within the past 999 days
   **OR**
   b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event
   **OR**
3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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:** As per program specific criteria