# STEP THERAPY CRITERIA

**BRAND NAME***
**(generic)**

**ZORYVE CREAM**
**(roflumilast)**

**ZORYVE FOAM**
**(roflumilast)**

***Status: CVS Caremark® Criteria***
***Type: Initial Step Therapy with Quantity Limit;***
***Post Step Therapy Prior Authorization with Quantity Limit*** ***Ref # 5538-E***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

## FDA-APPROVED INDICATIONS

**Zoryve Cream**

Plaque Psoriasis

Zoryve cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

Atopic Dermatitis

Zoryve cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

**Zoryve Foam**

Zoryve foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

## INITIAL STEP THERAPY with QUANTITY LIMIT*

***Include Rx and OTC products unless otherwise stated.***

**INITIAL STEP THERAPY For Zoryve (roflumilast) Cream 0.3%:**

If the patient has filled a prescription for at least a 30-day supply of a topical steroid within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**INITIAL STEP THERAPY For Zoryve (roflumilast) Cream 0.15%:**

If the patient has filled a prescription for at least a one day supply of a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**INITIAL STEP THERAPY For Zoryve (roflumilast) Foam:**

If the patient has filled a prescription for at least a 30-day supply of a topical ketoconazole (i.e., 2% shampoo, 2% cream, 2% foam, 2% gel) or a topical ciclopirox (i.e., 0.77% gel, 1% shampoo) product within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

**If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

**INITIAL LIMIT QUANTITY**
**Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength**

| Drug | 1 Month Limit* | 3 Month Limit* |
|---|---|---|
| Zoryve (roflumilast) 0.15%, 0.3% Cream | 60 grams / 25 days | 180 grams / 75 days |
| Zoryve (roflumilast) 0.3% Foam | 60 grams / 25 days | 180 grams / 75 days |

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

| TABLE 1: EXAMPLES OF TOPICAL CORTICOSTEROIDS FOR TREATMENT OF ATOPIC DERMATITIS [7,8,11] | |
|---|---|
| Medium Potency | betamethasone dipropionate lotion, spray 0.05% |
| | betamethasone valerate cream/lotion 0.1%/foam 0.12% |
| | clocortolone pivalate cream 0.1% |
| | desonide lotion, ointment 0.05% |
| | desoximetasone cream 0.05% |
| | fluocinolone acetonide cream/ointment/kit 0.025% |
| | flurandrenolide cream/ointment/lotion 0.05% |
| | fluticasone propionate cream/lotion 0.05%/ointment 0.005% |
| | hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1% |
| | hydrocortisone probutate cream 0.1% |
| | hydrocortisone valerate cream/ointment 0.2% |
| | mometasone furoate cream/lotion/solution 0.1% |
| | prednicarbate cream/ointment 0.1% |
| | triamcinolone acetonide cream/ointment/lotion/kit 0.1% |
| | triamcinolone acetonide cream/ointment/lotion 0.025% |
| | triamcinolone acetonide ointment 0.05% |
| High Potency | amcinonide cream/ointment/lotion 0.1% |
| | betamethasone dipropionate cream/ointment 0.05% |
| | betamethasone dipropionate augmented cream/lotion 0.05% |
| | betamethasone valerate ointment 0.1% |
| | desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05% |
| | diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05% |
| | halcinonide cream/ointment 0.1% |
| | fluocinonide cream/emulsified cream/ointment/gel/solution 0.05% |
| | mometasone furoate ointment 0.1% |
| | triamcinolone acetonide aerosol solution 0.147 mg/g |
| | triamcinolone acetonide cream/ointment 0.5% |
| Very High Potency | betamethasone dipropionate augmented ointment/gel 0.05% |
| | clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025% |
| | diflorasone diacetate ointment 0.05% |
| | flurandrenolide tape 4mcg/cm2 |

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|---|---|
| | halobetasol propionate cream/ointment/lotion/kit 0.05% |
| | fluocinonide cream 0.1% |

## COVERAGE CRITERIA

**Atopic Dermatitis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.15%
- The patient is 6 years of age or older
- The patient has experienced an inadequate treatment response, intolerance, OR has a contraindication to a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

**Plaque Psoriasis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.3%
- The patient is 6 years of age or older
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response, intolerance OR has a contraindication to a topical steroid
    - The requested drug will be used on sensitive skin areas (e.g., face, genitals or skin folds)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

**Seborrheic Dermatitis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) FOAM
- The patient is 9 years of age or older
- The patient meets ONE of the following:
    - The patient is less than 16 years of age
    - The patient has experienced an inadequate treatment response, intolerance OR has a contraindication to a topical ketoconazole (i.e., 2% shampoo, 2% cream, 2% foam, 2% gel) OR a topical ciclopirox (i.e., 0.77% gel, 1% shampoo) product
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

## CONTINUATION OF THERAPY

**Atopic Dermatitis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The request is for Zoryve (roflumilast) CREAM 0.15%
- The patient is 6 years of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]

- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

**Plaque Psoriasis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of plaque psoriasis when ALL of the following criteria are met:
- The request is for Zoryve (roflumilast) CREAM 0.3%
- The patient is 6 years of age or older
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

**Seborrheic Dermatitis**
Authorization may be granted when the requested drug is being prescribed for the topical treatment of seborrheic dermatitis when ALL of the following criteria are met:
- The request is for Zoryve (roflumilast) FOAM
- The patient is 9 years of age or older
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, improvement from baseline, etc.)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per month

**QUANTITY LIMITS APPLY**
60 grams per 25 days* or 180 grams per 75 days*
For body surface areas requiring more than 60 grams per month: 120 grams per 25 days* or 360 grams per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**DURATION OF APPROVAL (DOA)**
- 5538-E: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

**REFERENCES**

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| Written by: | UM Development (KMB/DFW) |
| Date Written: | 08/2022 |
| Revised: | (DRS) 06/2023 (added COT), 10/2023 (updated age), 12/2023 (added Foam); (KMB) 06/2024 (no clinical changes), 07/2024 (added Zoryve 0.15% - no version change) |
| Reviewed: | Medical Affairs (CHART) 08/18/2022, 06/29/2023, 10/12/2023. 01/04/2024, 06/27/2024, 07/25/2024<br>External Review: 10/2022, 08/2023, 12/2023 (FYI), 01/2024 |

**CRITERIA FOR APPROVAL**

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| 1 | Is the request for Zoryve (roflumilast) cream 0.15 percent?<br>[If Yes, then go to 2. If No, then go to 6.] | Yes | No |
| 2 | Is the requested drug being prescribed for the topical treatment of mild to moderate atopic dermatitis?<br>[If Yes, then go to 3. If No, then no further questions.] | Yes | No |
| 3 | Is the patient 6 years of age or older?<br>[If Yes, then go to 4. If No, then no further questions.] | Yes | No |
| 4 | Is the request for continuation of therapy?<br>[If Yes, then go to 5. If No, then go to 17.] | Yes | No |
| 5 | Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)?<br>[If Yes, then go to 15. If No, then no further questions.] | Yes | No |
| 6 | Is the request for Zoryve (roflumilast) cream 0.3 percent?<br>[If Yes, then go to 7. If No, then go to 11.] | Yes | No |
| 7 | Is the requested drug being prescribed for the topical treatment of plaque psoriasis?<br>[If Yes, then go to 8. If No, then no further questions.] | Yes | No |
| 8 | Is the patient 6 years of age or older?<br>[If Yes, then go to 9. If No, then no further questions.] | Yes | No |

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| 9 | Is the request for continuation of therapy?<br>[If Yes, then go to 10. If No, then go to 18.] | Yes | No |
| 10 | Has the patient achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.)?<br>[If Yes, then go to 15. If No, then no further questions.] | Yes | No |
| 11 | Is the request for Zoryve (roflumilast) FOAM being prescribed for the topical treatment of seborrheic dermatitis?<br>[If Yes, then go to 12. If No, then no further questions.] | Yes | No |
| 12 | Is the patient 9 years of age or older?<br>[If Yes, then go to 13. If No, then no further questions.] | Yes | No |
| 13 | Is the request for continuation of therapy?<br>[If Yes, then go to 14. If No, then go to 20.] | Yes | No |
| 14 | Has the patient achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, improvement from baseline, etc.)?<br>[If Yes, then go to 15. If No, then no further questions.] | Yes | No |
| 15 | Is the requested drug being prescribed to treat a body surface area that requires MORE than 60 grams per month?<br>[If Yes, then go to 16. If No, then no further questions.] | Yes | No |
| 16 | Does the patient require MORE than the plan allowance of 120 grams PER MONTH?<br>[No further questions]<br><br>RPh Note: If yes, then deny and enter a partial approval for 120 grams per 25 days or 360 grams per 75 days. | Yes | No |
| 17 | Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to a topical calcineurin inhibitor OR a medium or higher potency topical corticosteroid?<br>[If Yes, then go to 22. If No, then no further questions.] | Yes | No |
| 18 | Has the patient experienced an inadequate treatment response, intolerance OR does the patient have a contraindication to a topical steroid?<br>[If Yes, then go to 22. If No, then go to 19.] | Yes | No |
| 19 | Is the requested drug being used on sensitive skin areas (e.g., face, genitals or skin folds)?<br>[If Yes, then go to 22. If No, then no further questions.] | Yes | No |
| 20 | Is the patient less than 16 years of age?<br>[If Yes, then go to 22. If No, then go to 21.] | Yes | No |
| 21 | Has the patient experienced an inadequate treatment response, intolerance OR does the patient have a contraindication to a topical ketoconazole (i.e., 2 percent shampoo, 2 percent cream, 2 percent foam, 2 percent gel) OR a topical ciclopirox (i.e., 0.77 percent gel, 1 percent shampoo) product?<br>[If Yes, then go to 22. If No, then no further questions.] | Yes | No |

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| 22 | Is the requested drug being prescribed to treat a body surface area that requires MORE than 60 grams per month?<br>[If Yes, then go to 23. If No, then no further questions.] | Yes | No |
| 23 | Does the patient require MORE than the plan allowance of 120 grams PER MONTH?<br>[No further questions]<br><br>RPh Note: If yes, then deny and enter a partial approval for 120 grams per 25 days or 360 grams per 75 days. | Yes | No |

| Mapping Instructions | | | |
|---|---|---|---|
| | **Yes** | **No** | **DENIAL REASONS** |
| **1.** | Go to 2 | Go to 6 | |
| **2.** | Go to 3 | Deny | Your plan only covers this drug when it is used for certain health conditions. Covered use is for mild to moderate atopic dermatitis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Diagnosis - Atopic Dermatitis] |
| **3.** | Go to 4 | Deny | Your plan only covers this drug if you are 6 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Age - Cream] |
| **4.** | Go to 5 | Go to 17 | |
| **5.** | Go to 15 | Deny | Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Continuation: Efficacy] |
| **6.** | Go to 7 | Go to 11 | |
| **7.** | Go to 8 | Deny | Your plan only covers this drug when it is used for certain health conditions. Covered use is for plaque psoriasis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the |

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| | | | information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Diagnosis - Plaque Psoriasis] |
| **8.** | Go to 9 | Deny | Your plan only covers this drug if you are 6 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Age - Cream] |
| **9.** | Go to 10 | Go to 18 | |
| **10.** | Go to 15 | Deny | Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Continuation: Efficacy] |
| **11.** | Go to 12 | Deny | Your plan only covers this drug when it is used for certain health conditions. Covered use is for seborrheic dermatitis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Diagnosis - Seborrheic Dermatitis] |
| **12.** | Go to 13 | Deny | Your plan only covers this drug if you are 9 years old or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Age - Foam] |
| **13.** | Go to 14 | Go to 20 | |
| **14.** | Go to 15 | Deny | Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us |

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| | | | any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Continuation: Efficacy] |
| **15.** | Go to 16 | [PA Approved for 12 months. Approve 60 grams per 25 days* OR 180 grams per 75 days*]. Approve, 12 Months | |
| **16.** | Deny | [PA Approved for 12 months. Approve 120 grams per 25 days* OR 360 grams per 75 days*]. Approve, 12 Months | We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (120 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Quantity, Exceeds max limit, Partial denial] |
| **17.** | Go to 22 | Deny | Your plan only covers this drug if you have tried a topical calcineurin inhibitor or a medium or higher potency topical corticosteroid, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Step Therapy – TCI/TCS] |
| **18.** | Go to 22 | Go to 19 | |
| **19.** | Go to 22 | Deny | Your plan only covers this drug if you have tried a topical steroid, and it did not work well for you, or the requested drug will be used on sensitive skin. We have denied your request because: A) You have not tried it, B) You do not have a medical reason not to take it, or C) You are not using the requested drug on sensitive skin. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. |

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| | | | [Short Description: Step Therapy - TCS or Sensitive skin] |
| **20.** | Go to 22 | Go to 21 | |
| **21.** | Go to 22 | Deny | Your plan only covers this drug if you have tried other drugs and they did not work well for you, or the requested drug will be used on someone less than 16 years of age. We have denied your request because: A) You have not tried a topical ketoconazole (i.e., 2 percent shampoo, 2 percent cream, 2 percent foam, 2 percent gel) or topical ciclopirox (i.e., 0.77 percent gel, 1 percent shampoo) product, B) You do not have a medical reason not to take them, or C) You are not less than 16 years of age. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Step Therapy - Ketoconazole/Ciclopirox or Age] |
| **22.** | Go to 23 | [PA Approved for 3 months. Approve 60 grams per 25 days* OR 180 grams per 75 days*]. Approve, 3 Months | |
| **23.** | Deny | [PA Approved for 3 months. Approve 120 grams per 25 days* OR 360 grams per 75 days*]. Approve, 3 Months | We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (120 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.<br><br>[Short Description: Quantity, Exceeds max limit, Partial denial] |