Reference number(s)
5018-C

Initial Prior Authorization with Quantity Limit Opzelura

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Opzelura	ruxolitinib	cream

Indications

FDA-approved Indications

Atopic Dermatitis

Opzelura is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Nonsegmental Vitiligo

Opzelura is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Limitations of Use

Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

Reference number(s)
5018-C

Coverage Criteria

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 12 years of age or older.
- The patient meets ONE of the following:
    - The patient's disease is NOT adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
    - Other topical prescription therapies are NOT advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA).
- 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 28 days.

Nonsegmental Vitiligo

Authorization may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 12 years of age or older.
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA).
- 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 28 days.

Reference number(s)
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Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 12 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)].
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA).
- 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 28 days.

Nonsegmental Vitiligo

Authorization may be granted when the requested drug is being prescribed for nonsegmental vitiligo when ALL the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 12 years of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation).
- The requested drug will NOT be applied to affected areas of greater than 10% body surface area (BSA).
- 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 28 days.

Quantity Limits Apply

60 grams per 21 days or 180 grams per 63 days.

For larger body surface area (BSA) for Vitiligo: 180 grams per 21 days or 540 grams per 63 days.

For larger body surface area (BSA) for Atopic Dermatitis: 240 grams per 21 days or 720 grams per 63 days.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

The intent is for prescriptions of the requested drug to be filled one month at a time for new starts; there should be no 3-month supplies filled for new starts.

Duration of Approval (DOA)

- 5018-C:
  - Nonsegmental Vitiligo: Initial therapy DOA: 7 months; Continuation of therapy DOA: 12 months
  - Atopic Dermatitis: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

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Document History

Written by: UM Development (DFW)

Date Written: 10/2021

Revised: (DRS) 04/2022 (no clinical changes), 07/2022 (added vitiligo indication), 03/2023 (no clinical changes); (KEJ) 11/2023 (updated wording for step in AD coverage criteria to align to label); (DRS) 03/2024 (no clinical changes); KEJ 03/2025 (no clinical changes)

Reviewed: Medical Affairs: (CHART) 10/21/2021, (CHART) 3/31/2022, (CHART) 08/04/2022, 03/30/2023, 11/30/2023, 03/28/2024, 03/27/2025

External Review: 12/2021, 06/2022, 10/2022 (FYI), 06/2023, 12/2023 (FYI), 06/2024, 06/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the request for an adult or pediatric patient 12 years of age or older? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is the requested drug being prescribed for the topical treatment of nonsegmental vitiligo? [If Yes, then go to 4. If No, then go to 11.]	Yes	No
4	Will the requested drug be applied to affected areas of greater than 10 percent body surface area (BSA)? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Is this request for continuation of therapy? [If Yes, then go to 6. If No, then go to 9.]	Yes	No

6	Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Is the requested drug being prescribed to treat a body surface area (BSA) that requires MORE than 60 grams per 28 days? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Does the patient require MORE than the plan allowance of 180 grams per 28 days? [180 grams of the requested drug per 28 days allows for the maximum FDA approved coverage of 10 percent body surface area (BSA).] [No further questions] RPh Note: If yes, then deny and enter a partial approval for 180 grams / 21 days or 540 grams / 63 days of Opzelura.	Yes	No
9	Is the requested drug being prescribed to treat a body surface area (BSA) that requires MORE than 60 grams per 28 days? [If Yes, then go to 10. If No, then no further questions.]	Yes	No
10	Does the patient require MORE than the plan allowance of 180 grams per 28 days? [180 grams of the requested drug per 28 days allows for the maximum FDA approved coverage of 10 percent body surface area (BSA).] [No further questions] RPH Note: If yes, then deny and enter a partial approval for 180 grams / 21 days of Opzelura.	Yes	No
11	Is the requested drug being prescribed for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Will the requested drug be applied to affected areas of greater than 20 percent body surface area (BSA)? [If Yes, then no further questions. If No, then go to 13.]	Yes	No
13	Is this request for continuation of therapy? [If Yes, then go to 14. If No, then go to 17.]	Yes	No
14	Has the patient achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the	Yes	No

	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 Yes, then go to 15. If No, then no further questions.]		
15	Is the requested drug being prescribed to treat a body surface area (BSA) that requires MORE than 60 grams per 28 days? [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 240 grams per 28 days? [240 grams of the requested drug per 28 days allows for the maximum FDA approved dosage of 60 grams per week.] [No further questions] RPh Note: If yes, then deny and enter a partial approval for 240 grams / 21 days or 720 grams / 63 days of Opzelura.	Yes	No
17	Is the patient's disease not adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroids, topical calcineurin inhibitor)? [If Yes, then go to 19. If No, then go to 18.]	Yes	No
18	Are other topical prescription therapies not advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor)? [If Yes, then go to 19. If No, then no further questions.]	Yes	No
19	Is the requested drug being prescribed to treat a body surface area (BSA) that requires MORE than 60 grams per 28 days? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	Does the patient require MORE than the plan allowance of 240 grams per 28 days? [240 grams of the requested drug per 28 days allows for the maximum FDA approved dosage of 60 grams per week.] [No further questions] RPH Note: If yes, then deny and enter a partial approval for 240 grams / 21 days of Opzelura.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**

1.	Deny	Go to 2	Your plan only covers this drug if you will not be taking it with certain other drugs. We have denied your request because you are (or will be) taking therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine. 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. [Short Description: Will be on concurrent therapy]
2.	Go to 3	Deny	Your plan only covers this drug if you are 12 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. [Short Description: Age]
3.	Go to 4	Go to 11	
4.	Deny	Go to 5	Your plan only covers this drug if you are using it on a body surface area of less than 10 percent. 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. [Short Description: Disease severity, Vitiligo]
5.	Go to 6	Go to 9	
6.	Go to 7	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. [Short Description: Continuation: Efficacy]
7.	Go to 8	[PA Approved for 12 months, Approve 60 grams/21 days or 180 grams/63 days]. Approve, 12 Months	
8.	Deny	[PA Approved for 12 months, Approve 180 grams/21 days or 540 grams/63 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 (180 grams per 28 days). 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. [Short Description: Quantity, Exceeds max limit, Partial denial, Vitiligo]
9.	Go to 10	[PA Approved for 7 months, Approve 60 grams/21 days. No 3-month supplies for new starts].	

		Approve, 7 Months	
10.	Deny	[PA Approved for 7 months, Approve 180 grams/21 days. No 3-month supplies for new starts]. Approve, 7 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 (180 grams per 28 days). 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. [Short Description: Quantity, Exceeds max limit, Partial denial, Vitiligo]
11.	Go to 12	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for nonsegmental vitiligo and 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. [Short Description: Diagnosis]
12.	Deny	Go to 13	Your plan only covers this drug if you are using it on a body surface area of less than 20 percent. 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. [Short Description: Disease severity, Atopic Dermatitis]

13.	Go to 14	Go to 17	
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 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. [Short Description: Continuation: Efficacy]
15.	Go to 16	[PA Approved for 12 months, Approve 60 grams/21 days or 180 grams/63 days]. Approve, 12 Months	
16.	Deny	[PA Approved for 12 months, Approve 240 grams/21 days or 720 grams/63 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 (240 grams per 28 days). 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. [Short Description: Quantity, Exceeds max limit, Partial denial, Atopic Dermatitis]
17.	Go to 19	Go to 18	

18.	Go to 19	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried other topical prescription therapies, and B) You do not have a medical reason not to take them. 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. [Short Description: Step therapy]
19.	Go to 20	[PA Approved for 3 months, Approve 60 grams/21 days. No 3-month supplies for new starts]. Approve, 3 Months	
20.	Deny	[PA Approved for 3 months, Approve 240 grams/21 days. No 3-month supplies for new starts]. 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 (240 grams per 28 days). 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. [Short Description: Quantity, Exceeds max limit, Partial denial, Atopic Dermatitis]