

Initial Prior Authorization

Antiviral Topical

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
Denavir	penciclovir	all
Xerese	acyclovir / hydrocortisone	all
Zovirax	acyclovir	cream, ointment

Indications

FDA-approved Indications

Denavir

Denavir is a deoxynucleoside analog HSV DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age or older.

Xerese

Xerese, a combination of acyclovir, a herpes simplex virus deoxynucleoside analog DNA polymerase inhibitor, and hydrocortisone, a corticosteroid, is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older).

Zovirax Cream

Zovirax Cream is a herpes simplex virus (HSV) deoxynucleoside analogue DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.

Zovirax Ointment

Zovirax Ointment 5% is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous HSV infections in immunocompromised patients.

Coverage Criteria

Genital Herpes, Mucocutaneous Herpes Simplex Virus (HSV)

Authorization may be granted when the requested drug is being prescribed for the management of initial genital herpes OR mucocutaneous herpes simplex virus (HSV) infection in an immunocompromised patient when the following criteria is met:

- The request is for Zovirax Ointment (acyclovir ointment).

Recurrent Herpes Labialis (Cold Sores)

Authorization may be granted when the requested drug is being prescribed for the treatment of recurrent herpes labialis (cold sores) when ONE of the following criteria are met:

- The request is for Xerese (acyclovir/hydrocortisone) and the following criteria is met:
 - The patient is 6 years of age or older.
- The request is for Denavir (penciclovir) and the following criteria is met:
 - The patient is 12 years of age or older.
- The request is for Zovirax Cream (acyclovir cream) and ALL of the following criteria are met:
 - The patient is immunocompetent.
 - The patient is 12 years of age or older.

Duration of Approval (DOA)

- 1492-A: DOA: 12 months

References

1. Denavir [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2018.
2. Xerese [package insert]. Bridgewater, NJ: Bausch Health US, LLC; August 2020.
3. Zovirax Cream [package insert]. Bridgewater, NJ: Bausch Health US, LLC; February 2021.
4. Zovirax Ointment [package insert]. Bridgewater, NJ: Bausch Health US, LLC; October 2020.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.

6. Lexicomp Online, Lexi Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 10, 2024.
7. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).

Document History

Written by: UM Development (KM)

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Revised: (KM) 06/2017 (no clinical changes); (KC) 04/2018 (no clinical changes), 02/2019 (no clinical changes), (DFW) 02/2020 (removed MDC designation from title/document); (KC) 12/2020 (no clinical changes); (DS) 09/2021 (no clinical changes); (MRS) 09/2022 (no clinical changes); (DRS) 09/2023 (no clinical changes); (DFW) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (MC) 06/2016, (CHART) 02/27/20, 12/31/20, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

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CRITERIA FOR APPROVAL

1	Is this request for Xerese (acyclovir/hydrocortisone)? [If Yes, then go to 2. If No, then go to 4.]	Yes	No
2	Is the requested drug being prescribed for the treatment of recurrent herpes labialis (cold sores)? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is the patient 6 years of age or older? [No further questions]	Yes	No
4	Is this request for Denavir (penciclovir)? [If Yes, then go to 5. If No, then go to 6.]	Yes	No
5	Is the requested drug being prescribed for the treatment of recurrent herpes labialis (cold sores)? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
6	Is this request for Zovirax Cream (acyclovir cream)? [If Yes, then go to 7. If No, then go to 9.]	Yes	No

7	Is the requested drug being prescribed for the treatment of recurrent herpes labialis (cold sores) in an immunocompetent patient? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Is the patient 12 years of age or older? [No further questions]	Yes	No
9	Is this request for Zovirax Ointment (acyclovir ointment) being prescribed for the management of initial genital herpes OR mucocutaneous herpes simplex virus (HSV) infection in an immunocompromised patient? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Go to 4	
2.	Go to 3	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for recurring cold sores. 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.</p> <p>[Short Description: Diagnosis - cold sores]</p>
3.	Approve, 12 Months	Deny	<p>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.</p> <p>[Short Description: Age - 6 years old]</p>
4.	Go to 5	Go to 6	

5.	Go to 8	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for recurring cold sores. 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.</p> <p>[Short Description: Diagnosis - cold sores]</p>
6.	Go to 7	Go to 9	
7.	Go to 8	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for recurring cold sores when you do not have a weak immune system. 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.</p> <p>[Short Description: Diagnosis - Zovirax cream]</p>
8.	Approve, 12 Months	Deny	<p>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.</p> <p>[Short Description: Age - 12 years old]</p>
9.	Approve, 12 Months	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are for first genital herpes infection or a herpes infection on the skin near mucous membranes when you have a weak immune system. 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.</p>

Reference number(s)
1492-A

			<p>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.</p> <p>[Short Description: Diagnosis - Zovirax ointment]</p>
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