Clinical Policy: Halobetasol Propionate (Bryhali, Lexette, Ultravate)

Reference Number: CP.PMN.180
Effective Date: 12.01.18
Last Review Date: 11.23
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Halobetasol propionate (Bryhali™, Lexette™, Ultravate®) is a topical corticosteroid.

FDA Approved Indication(s)

Bryhali, Lexette, and Ultravate are indicated for the topical treatment of plaque psoriasis (PsO). Bryhali is indicated in adults, while Lexette and Ultravate are indicated in patients 12 years of age and older.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Bryhali, Lexette, and Ultravate are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO;
2. Member meets one of the following (a or b):
   a. For Bryhali: Age ≥ 18 years;
   b. For Lexette or Ultravate: Age ≥ 12 years;
3. Member must use generic topical halobetasol propionate (e.g., foam, ointment, cream), unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of generic clobetasol propionate, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a, b, or c):
   a. Bryhali (i and ii):
      i. One tube per 2 weeks;
      ii. 100 g per 2 weeks;
   b. Lexette (i and ii):
      i. One canister per week;
      ii. 50 g per week;
   c. Ultravate: one bottle (60 mL) per week.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Medical justification supports treatment beyond the recommended duration in the prescribing information of the requested product;
4. If request is for a dose increase, new dose does not exceed one of the following (a, b or c):
   a. Bryhali (i and ii):
      i. One tube per 2 weeks;
      ii. 100 g per 2 weeks;
   b. Lexette (i and ii):
      i. One canister per week;
      ii. 50 g per week;
   c. Ultravate: one bottle (60 mL) per week.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PsO: plaque psoriasis

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
halobetasol propionate 0.05% foam/cream/ointment (Ultravate)	Apply a thin layer to the affected skin QD to BID. Treatment should be limited to 2 weeks	50 g/week
clobetasol propionate 0.05% cream/foam/gel/lotion/ointment/shampoo/spray (Clobex®, Olux-E®, Olux®)	Apply a thin layer to the affected skin BID. Treatment should be limited to 2 weeks for mild to moderate PsO and 4 weeks for moderate to severe PsO	50 g/week

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Halobetasol propionate lotion 0.01% (Bryhali)	Topically apply a thin layer to the affected skin QD for up to 8 weeks	50 g/week
Halobetasol propionate lotion 0.05% (Ultravate) or foam 0.05% (Lexette)	Topically apply a thin layer to the affected skin BID for up to 2 weeks	50 g/week

VI. Product Availability

Drug Name	Availability
Halobetasol propionate lotion 0.01% (Bryhali)	Lotion (60 g, 100 g): 0.01%
Halobetasol propionate foam 0.05% (Lexette)	Foam (50 g, 100 g): 0.05%
Halobetasol propionate lotion 0.05% (Ultravate)	Lotion (60 mL): 0.05%

VII. References

1. Bryhali Lotion Prescribing Information. Bridgewater, NJ: Dow Pharmaceutical Sciences; June 2020. Available at: https://pi.bauschhealth.com/globalassets/BHC/PI/Bryhali-PI.pdf. Accessed August 1, 2023.
2. Lexette Foam Prescribing Information. Greenville, NC: Mayne Pharma; May 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/210566s003lbl.pdf. Accessed August 1, 2023.
3. Ultravate Lotion Prescribing Information. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; August 2020. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208183. Accessed August 1, 2023.
4. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed August 1, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19
Added Bryhali (with dosing limited to 100 g per month) and Lexette (with dosing limited to 50 g per week) per SDC and prior clinical guidance.	10.07.19	
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.06.20	11.20
4Q 2021 annual review: added age limits, revised quantity limit of Bryhali from 100 g per month to per 2 weeks per PI; added HIM line of business; RT4: revised age limit for Lexette from 18 years	08.11.21	11.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
to 12 years and older per updated PI; references reviewed and updated.		
4Q 2022 annual review: no significant changes; revised from "failure of" halobetasol propionate to "member must use" language as it is the same active ingredient as the agents in this policy; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.20.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.01.23	11.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.