Clinical Policy Title:	halobetasol propionate
Policy Number:	RxA.41
Drug(s) Applied:	Bryhali™, Lexette™, Ultravate®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Halobetasol propionate (Bryhali™, Lexette™, Ultravate®) is a corticosteroid. It is indicated for the topical treatment of plaque psoriasis.
Bryhali™, and Lexette™ are indicated for topical treatment of plaque psoriasis in patients 18 years of age and older.
Ultravate ® is indicated for topical treatment of plaque psoriasis in patients 12 years of age and older.
Limitations of use: Lexette® and Ultravate®: treatment beyond 2 weeks Is not recommended.
Bryhali: treatment beyond 8 weeks is not recommended.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Halobetasol propionate lotion 0.01% (Bryhali)	Plaque psoriasis (PsO)	Topically apply a thin layer to the affected skin once daily for up to eight weeks	50 g/week
Halobetasol propionate lotion 0.05% (Ultravate), Halobetasol propionate foam 0.05% (Lexette)	Plaque psoriasis (PsO)	Topically apply a thin layer to the affected skin BID for up to two weeks	50 g/week

Dosage Forms

- Bryhali: Lotion (60 g, 100 g): 0.01%
- Ultravate: Lotion (60 mL), Topical Foam (50g): 0.05%
- Lexette: Topical foam (50 g, 100 g): 0.05%

Clinical Policy

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

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all):

1. Diagnosis of Plaque psoriasis;
2. Requests for Bryhali® and Lexette®: age is 18 years or older; Requests for Ultravate®: age is 12 years or

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older.

3. Failure of generic halobetasol propionate and generic clobetasol propionate unless both are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one of the following (a, b, or c):
   a. Bryhali: 100 g per month;
   b. Lexette: one canister (50 g) per week;
   c. Ultravate: one bottle (60 mL) per week.

Approval Duration:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Plaque Psoriasis (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b or c):
   a. Bryhali: 100 g per month;
   b. Lexette: one canister (50 g) per week;
   c. Ultravate: one bottle (60 mL) per week.

Approval Duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PsO: Plaque psoriasis

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
halobetasol propionate 0.05% cream/ointment (Ultravate)	Apply a thin layer to the affected skin ONCE DAILY to twice daily. Treatment should be limited to two 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 twice daily. Treatment for mild to moderate plaque psoriasis should be limited to 2 weeks; moderate to severe treatment up to 4 weeks.	50 g/week

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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

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

Not applicable

References

1. Bryhali Lotion Prescribing Information. Bridgewater, NJ: Dow Pharmaceutical Sciences; June 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d4bbb66a-3f9d-4091-b1b0-1cbc908432d3. Accessed January 25, 2021.
2. Lexette Foam Prescribing Information. Greenville, NC: Mayne Pharma; May 2020. Available at: www.lexette.com. Accessed January 25, 2021.
3. Ultravate Lotion Prescribing Information. Jacksonville, FL: Ranbaxy Laboratories; May 2020. Available at: http://www.ultravatelotion.com/pdf/ultravatelotionpi.pdf. Accessed January 25, 2021.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 25, 2021.
5. Halobetasol. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. http://online.lexi.com/. Updated January 23, 2021. Accessed January 25, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Formatting and references updated	05/07/2020	05/20/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Background was updated to include limitations of use. 3. Initial approval criteria A.2. was added to specify approved age 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by Rxadvance.	01/25/2021	03/09/2021

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5. Appendix B standard verbiage has been changed and updated.		

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