



Drug Quantity Management – Per Days Topical Corticosteroids – Hydrocortisone Butyrate

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Product Identifier(s)

Effective 1/1/23 to 3/21/23: 109532

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Locoid Lipocream® (hydrocortisone butyrate 0.1% cream – generic)
- hydrocortisone butyrate 0.1% lotion – generic)
- hydrocortisone butyrate 0.1% solution – generic only
- hydrocortisone butyrate 0.1% ointment – generic only

This Drug Quantity Management program has been developed to promote dose consolidation, prevent stockpiling and waste, and address potential order entry error of the topical hydrocortisone butyrate products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Package Size	Retail	Home Delivery
		Maximum Quantity per 30 Days	Maximum Quantity per 90 Days
Locoid® Lipocream® (hydrocortisone butyrate cream 0.1%, generic/hydrocortisone butyrate cream 0.1%, generic only)	15 gram tube 45 gram tube 60 gram tube	120 grams*	360 grams
Locoid® (hydrocortisone butyrate lotion 0.1%, generic)	59 mL bottle 118 mL bottle	118 mL*	354 mL
hydrocortisone butyrate ointment 0.1% (generic only)	15 gram tube 45 gram tube	120 grams*	360 grams
hydrocortisone butyrate solution 0.1% (generic only)	20 mL bottle 60 mL bottle	120 mL*	360 mL

* This is enough drug to cover approximately 8% of the body surface area when applying twice daily for 30 days.

Criteria

Cigna covers quantities of topical hydrocortisone butyrate as medically necessary if the individual is using the product for an FDA-approved indication (outlined below) and meets one of the following criteria:

Hydrocortisone butyrate cream (Locoid Lipocream®, generic lipocream and cream)

1. If the individual needs to treat greater than 8% of body surface area OR administer more frequently than twice daily, approve the quantity requested not to exceed 180 grams per 30 days at retail and 540 grams per 90 days at home delivery if the request is for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Note: This provides a quantity sufficient to treat greater than 8% of body surface area twice daily at retail or home delivery or to treat 8% BSA three times daily.

Hydrocortisone butyrate lotion (Locoid® lotion, generic)

1. If the individual needs to treat greater than 8% of body surface area OR administer more frequently than twice daily, approve the quantity requested not to exceed 177 mL per 30 days at retail and 531 mL per 90 days at home delivery if the request is for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Note: This provides a quantity sufficient to treat greater than 8% BSA twice daily at retail or home delivery or to treat 8% body surface area three times daily.

Hydrocortisone butyrate ointment

1. If the individual needs to treat greater than 8% of body surface area OR administer more frequently than twice day, approve the quantity requested not to exceed 180 grams per 30 days at retail or 540 grams per 90 days at home delivery if the request is for the relief of the inflammatory and pruritic manifestations of corticosteroid-response dermatoses.

Note: This provides a quantity sufficient to treat greater than 8% body surface area twice daily at retail or home delivery or to treat 8% BSA three times daily.

Hydrocortisone butyrate solution

1. If the individual needs to treat greater than 8% of body surface area OR administer more frequently than two times a day, approve the quantity requested not to exceed 180 mL per 30 days at retail or 540 mL per 90 days home delivery if the request is for inflammatory manifestations of seborrheic dermatitis.

Note: This provides a quantity sufficient to treat greater than 8% BSA twice a day or to treat 8% of body surface area three times daily.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

1. No overrides are recommended for use in compounded formulations.

Background

Overview

Hydrocortisone butyrate cream/lipocream, lotion, and ointment are indicated for the relief of the inflammatory and pruritic manifestations of **corticosteroid-responsive dermatoses**.¹⁻⁴

Hydrocortisone butyrate solution is indicated for the relief of inflammatory manifestations of **seborrheic dermatitis**.⁵

Dosing

Hydrocortisone butyrate cream/lipocream, ointment, and solution should be applied to the affected area two times daily (BID) to three times daily (TID).^{1,2,4,5} Hydrocortisone butyrate lotion should be applied to the affected area BID.³

Availability

Hydrocortisone butyrate cream/lipocream are available in 15-, 45-, and 60-gram tubes.^{1,2} Hydrocortisone butyrate ointment is available in 15 gram and 45 gram tubes.⁴ Hydrocortisone butyrate lotion is available in 59 mL and 118 mL bottles.³ Hydrocortisone butyrate solution is available in 20 mL and 60 mL bottles.⁵

Application Information

When determining the amount of a topical corticosteroid to apply, a standard measure, the fingertip unit (FTU), is often used.⁶ One FTU is the amount of product that is squeezed out of a standard tube along an adult's fingertip. One FTU is equivalent to approximately 0.5 g and provides enough product to treat an area of skin that is twice the size of one adult hand, or approximately 2% of an adult's total body surface area (BSA). Therefore, it is assumed that 1 g of a topical corticosteroid would provide enough product for one application to approximately 4% of the patient's BSA. For children, an FTU is still the amount of product that will fit on an adult's index fingertip. The amount of BSA that the application will cover depends on the size of the child.

Based on the FTU method, the quantity limits below provide enough topical hydrocortisone butyrate to cover approximately 8% of the patient's BSA when applying twice daily for 30 days at retail or 90 days at home delivery.

References

1. Locoid cream, 0.1% [prescribing information]. Bridgewater, NJ: Bausch Health; October 2019.
2. Locoid Lipocream, 0.1% [prescribing information]. Bridgewater, NJ: Bausch Health; March 2021.
3. Locoid lotion, 0.1% [prescribing information]. Bridgewater, NJ: Bausch Health; March 2021.
4. Hydrocortisone butyrate ointment, 0.1% [prescribing information]. Bridgewater, NJ: Oceanside; December 2020.
5. Hydrocortisone butyrate solution, 0.1% [prescribing information]. Baltimore, MD: Lupin; August 2018.
6. Eichenfeld LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. *J Am Acad Dermatol*. 2014;71:116-132.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<p>Policy was updated to include the existing quantity limits when the product is obtained via home delivery.</p> <p>Brand Locoid 0.1% lotion: The brand product was removed from the policy (obsolete), but the generic remains.</p> <p>Hydrocortisone butyrate 0.1% ointment: This product was added to the policy. The quantity limits are 120 grams per 30 days at retail and 360 grams per 90 days at home delivery. A quantity of 180 grams per 30 days at retail and 540 grams per 90 days at home delivery can be approved if the patient is treating greater than 8% of body surface area or administering more frequently than twice daily for relief of the inflammatory and pruritic manifestations of corticosteroid-response dermatoses.</p>	10/05/2022

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