



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Topical Corticosteroids – Hydrocortisone Butyrate Drug Quantity Management Policy – Per Days
- Locoid Lipocream® (hydrocortisone butyrate 0.1% cream – Bausch Health, generic)
 - hydrocortisone butyrate 0.1% lotion – Bausch Health, generic)
 - hydrocortisone butyrate 0.1% solution – generic only
 - hydrocortisone butyrate 0.1% ointment – generic only

REVIEW DATE: 10/14/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Hydrocortisone butyrate cream/lipocream and ointment are indicated for the relief of the inflammatory and pruritic manifestations of **corticosteroid-responsive dermatoses**.^{1,2,4}

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

Hydrocortisone butyrate lotion is indicated for the treatment of **mild to moderate atopic dermatitis** in patients \geq 3 months of age.³

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 gram, 45 gram, 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 BID for 30 days at retail or 90 days at home delivery.

POLICY STATEMENT

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 Maximum Quantity per 30 Days	Home Delivery Maximum Quantity per 90 Days
Locoid® Lipocream® (hydrocortisone butyrate cream 0.1%, generic/hydrocortisone butyrate lipocream 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
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* This is enough drug to cover approximately 8% of the body surface area when applying twice daily for 30 days.

Topical Corticosteroids – Hydrocortisone Butyrate Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Approval of additional quantities of topical hydrocortisone butyrate is recommended if the patient 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 patient 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 (BSA) twice daily at retail or home delivery or to treat 8% of BSA three times daily.

Hydrocortisone butyrate lotion (Locoid® lotion, generic)

1. If the patient 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 atopic dermatitis.

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

Hydrocortisone butyrate ointment

1. If the patient 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% of body surface area (BSA) twice daily at retail or home delivery or to treat 8% of BSA three times daily.

Hydrocortisone butyrate solution

1. If the patient 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% of body surface area (BSA) twice a day or to treat 8% of BSA three times daily.

EXCLUSIONS

Approval of additional quantities of topical hydrocortisone butyrate products is NOT recommended in the following situations:

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

REFERENCES

1. Hydrocortisone butyrate cream, 0.1% [prescribing information]. Hawthorne, NY: Taro; April 2021.
2. Locoid Lipocream, 0.1% [prescribing information]. Bridgewater, NJ: Bausch Health; March 2021.
3. Locoid lotion, 0.1% [prescribing information]. Bridgewater, NJ: Bausch Health; October 2023.
4. Hydrocortisone butyrate ointment, 0.1% [prescribing information]. Hawthorne, NY: Taro; April 2021.
5. Hydrocortisone butyrate solution, 0.1% [prescribing information]. Hawthorne, NY: Taro; April 2021.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/06/2023
Annual Revision	Hydrocortisone butyrate lotion (Locoid® lotion, generic): Clarification on approval indication to atopic dermatitis (previously relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses).	10/14/2023
Annual Revision	No criteria changes.	10/14/2024

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