



Coverage Policy Number ..... NPF057

## Step Therapy Hydrocortisone Acetate Suppository

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### Related Coverage Resources

#### 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.

### NPF Medical Necessity

#### Drugs Affected

- Anucort- HC™ (hydrocortisone acetate 25 mg suppository – [branded generic])
- Anusol-HC® (hydrocortisone acetate 25 mg suppository – generics)
- Hemmorex-HC™ (hydrocortisone acetate 25 mg or 30 mg suppository [branded generic])
- Hydrocortisone acetate suppository (25 or 30 mg)
- Proctocort® (hydrocortisone acetate 30 mg suppository, generics)

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Step 1:** Generic hydrocortisone acetate suppository (25 mg or 30 mg), Anucort-HC (25 mg), Hemmorex-HC (25 mg or 30 mg)

**Step 2:** Anusol HC (25 mg), Proctocort (30 mg)

**Cigna covers Step 2 agents as medically necessary when the following criteria are met:**

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

## Conditions Not Covered

Any other exception is considered not medically necessary.

## Background

### Overview

Anusol-HC, Proctocort, and generic hydrocortisone acetate suppositories are indicated for the **management of inflamed hemorrhoids, postirradiation (factual) proctitis**; as an adjunct in the treatment of chronic ulcerative colitis; cryptitis; and other inflammatory conditions of anorectum and pruritus ani.<sup>1-3</sup>

Rectal corticosteroids are used to help relieve swelling, itching, and discomfort associated with rectal problems, including hemorrhoids and inflammation of the rectum caused by radiation therapy and mild or moderate ulcerative colitis. They can also be used in conjunction with systemic (oral or injectable) corticosteroids and/or other medications to treat severe disease or mild to moderate disease that has spread too far to be treated effectively by medicine inserted into the rectum alone.<sup>4</sup>

Anusol-HC contains 25 mg of hydrocortisone acetate and Proctocort contains 30 mg of hydrocortisone acetate.<sup>1,2</sup> Branded generic hydrocortisone acetate suppositories (25 mg and 30 mg) [e.g., Anucort-HC,) and generic hydrocortisone acetate suppositories (25 mg and 30 mg) are available.

## References

1. Anusol-HC® suppository [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC; October 2017.
2. Proctocort® suppository [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC; April 2016.
3. Hydrocortisone acetate suppository [prescribing information]. Pulaski, TN: AvKARE Inc; June 2016.
4. Corticosteroids (rectal route). Updated January 2020. Available at: <http://www.mayoclinic.org/drugs-supplements/corticosteroid-rectal-route/description/drg-20070430>. Accessed on January 15, 2021.

## Revision History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/20/2021

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