

STEP THERAPY POLICY

- POLICY:** Hydrocortisone Acetate Suppository Step Therapy Policy
- Anucort- HC™ (hydrocortisone acetate 25 mg suppository – G&W Laboratories, [branded generic])
 - Anusol-HC® (hydrocortisone acetate 25 mg suppository – Salix Pharmaceuticals, generics)
 - Hemmorex-HC™ (hydrocortisone acetate 25 mg or 30 mg suppository – Laser Pharmaceuticals [branded generic])
 - Hydrocortisone acetate suppository (25 or 30 mg – multiple manufacturers)
 - Proctocort® (hydrocortisone acetate 30 mg suppository – Salix Pharmaceuticals, generics)

REVIEW DATE: 01/20/2021

OVERVIEW

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

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.⁴

Anusol-HC contains 25 mg of hydrocortisone acetate and Proctocort contains 30 mg of hydrocortisone acetate.^{1,2} 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.

POLICY STATEMENT

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.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Hydrocortisone Acetate Suppository Step Therapy Policy

Page 2

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)

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

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.