UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2163-10
Program	Prior Authorization/Medical Necessity - Devices
Medication	Alevicyn*, Alevicyn Dermal Spray*, Alevicyn SG*, Aquoral*, Atopaderm*, Atopiclair*, Atrapro Antipruritic Hydrogel*, Atrapro CP*, Atrapro Dermal Spray*, Caphosol*, Ceracade*, Ceramax*, Derpixa*, Dexeryl*, Eletone*, Emulsion SB*, Entty Spray*, EpiCeram*, Halucort*, HPR*, HPRPlus*, Hyclodex*, Hylaguard, Hylatopic Plus*, Hypocyn Dermal Spray*, Iliderm*, KamDoy Rx*, Kendall Amorphous Hydrogel*, Keragel*, Keragelt*, Kivik*, MediHoney*, Microcyn*, Neocera*, Neosalus*, NeutraSal*, Nutraseb*, Penlen*, Phlag*, PR Cream*, Presera*, Promiseb*, Pruclair*, Prumyx*, RadiaPlexRx*, SalivaMax*, Strata GRT*, Suvicort*, Synerderm*, Tetrix*, Vexasyn*, Zanabin*
P&T Approval Date	4/2019, 7/2019, 4/2020, 8/2020, 12/2020, 2/2021, 8/2021, 9/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

The U.S. Food and Drug Administration (FDA) classifies devices as products that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease that do not achieve their purpose through chemical action and are not dependent on metabolism to achieve their purpose. Devices are typically benefit exclusions. This program only applies when devices are covered by the plan.

2. Coverage Criteria[a]:

A. **Initial Therapy**

1. **Alevicyn*, Alevicyn SG*, Atopaderm*, Atopiclair*, Atrapro Antipruritic Hydrogel*, Atrapro CP*, Ceracade*, Ceramax*, Dexeryl*, Eletone*, Emulsion SB*, Entty Spray*, EpiCeram*, Halucort*, HPR*, HPRPlus*, Hylaguard, Hylatopic Plus*, Iliderm*, KamDoy Rx*, Kivik*, Neocera*, Neosalus*, Nutraseb*, Penlen*, Phlag*, PR Cream*, Presera*,Promiseb*, Pruclair*, Prumyx*, Synerderm*, Tetrix*, and Zanabin*** will be approved based on **all** of the following criteria:

   a. Diagnosis of **one** of the following:

      (1) atopic dermatitis
      (2) allergic contact dermatitis
      (3) radiation dermatitis
      (4) seborrheic dermatitis

-AND-

   b. History of failure or contraindication to **two** OTC emollients (e.g. Aquaphor,

Eucerin, Lubriderm, white petroleum; document name and duration of trial)

-AND-

c. History of failure or contraindication to **two** topical corticosteroids. Document topical corticosteroid name and duration of trial

Authorization will be issued for 12 months

2. **Aquoral*, Caphosol*, NeutraSal* and SalivaMax*** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

      (1) Diagnosis of xerostomia

      -AND-

      (2) History of failure or contraindication to **both** of the following:

         (a) saliva stimulants (e.g. sugar-free hard candies or gum)

         -AND-

         (b) **Two** OTC saliva substitutes (e.g. Biotene, Mouth Kote, Oasis, SalivaSure, Salivea) Document name and duration of trial

      -OR-

   b. **Both** of the following:

      (1) Diagnosis of oral mucositis

      -AND-

      (2) History of failure or contraindication to **both** of the following:

         (a) topical lidocaine
         (b) salt and sodium bicarbonate rinse

   Authorization will be issued for 12 months

3. **Alevicyn Dermal Spray*, Atrapro Dermal Spray*, Hyclodex*, Hypocyn Dermal Spray* and Microcyn*** will be approved based on the following criteria:

   a. History of failure or contraindication to **two** OTC antiseptics (e.g. Betadine, Dakin's Solution, Hibiclens). Document name and duration of trial

   Authorization will be issued for 12 months

4. **Derpixa*, Kendall Amorphous Hydrogel*, Keragel*, Keragelt*, MediHoney*, RadiaPlexRx*, Strata GRT*, Vexasyn*** and **Suvicort*** will be approved based on the following criteria:

   a. History of failure or contraindication to **two** OTC emollients (e.g. Aquaphor, Eucerin, Lubriderm, white petroleum; document name and duration of trial)

Authorization will be issued for 12 months

B. **Reauthorization**

1. The requested device will be approved based on the following criteria:

   a. Documentation of a positive response to therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Devices are typically excluded from coverage.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. U.S. Food and Drug Administration. Classify Your Medical Device. Last updated 2/7/2020. Retrieved from https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device. Accessed October 4, 2024.
2. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.
3. Fonacier L, Bernstein D, Pacheco K, et al. Atopic dermatitis: A practice parameter update 2015. J Allergy Clin Immunol 2015;3:S1-S39.
4. McGuire D, Fulton J, Park J, et al. Systematic review of basic oral care for the management of oral mucositis in cancer patients. Support Care Cancer 2013 (31); 3165-3177.

Program	Prior Authorization/Medical Necessity- Devices
Change Control	
4/2019	New program.
7/2019	Aquoral added to program.
4/2020	Synerderm added to program. Added seborrheic dermatitis as an approvable indication.

8/2020	Halucort added to program.
12/2020	Caphosol, Hyclodex and Penlen added to program.
2/2021	Hylaguard added to program.
8/2021	Alevicyn, Alevicyn Dermal Spray, Alevicyn SG, Atopiclair, Atrapro Antipruritic Hydrogel, Atrapro CP, Atrapro Dermal Spray, Carrasyn Hydrogel, Ceracade, Ceramax, Deripixa, Dexeryl, Emulsion SB, HPR, Iliderm, Kendall Amorphous Hydrogel, Keragel, Keragelt, Kivik, MediHoney, Microcyn, Phlag, PR Cream, Presera, Pruclair, Prumyx, RadiaPlexRX, Strata GRT, Suvicort Vexasyn, and Zanabin added to program.
9/2022	Hypocyn Dermal Spray added to program.
11/2023	Annual review. Updated references.
11/2024	Removed Carrasyn Hydrogel as it is off the market. Increased initial authorization to 12 months.