

## Urea Cream

### Policy Number: C14551-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/1/2018	3/11/2020	3/11/2021
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
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**PRODUCTS AFFECTED:**

See available dosage forms

**DRUG CLASS:**

Emollient/Keratolytic Agent

**ROUTE OF ADMINISTRATION:**

Topical

**PLACE OF SERVICE:**

Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**

Aluvea Cre 39%, Atrac-Tain Cre 10%, Aqua Care Cre 10%, Carb-O-Philc Cre /10, Carmol 20 Cre 20%, Gordons Urea Cre 40%, Gormel Cre 20%, Keralac Cre 47%, Metopic Cre 41%, Nutraplus Cre 10%, Rea Lo 40 Cre 40%, Remeven Cre 50%, Rynoderm Cre 37.5%, U-Kera E Cre 40%, URALISS CRE 35%, URAMAXIN CRE 45%, URE-39 CRE 39%, UREA 20 INTN CRE 20%, UREA CRE 10%, 20%, 39%, 40%, 41%, 45%, 47%, 50%, UREACIN-20 CRE 20%, UREDEB CRE 39%, URE-K CRE 50%, UREMEZ-40 CRE 40%, URESOL CRE 42.5%, UREVAZ CRE 44%, UTOPIC CRE 41%, X-VIATE CRE 40%

**FDA-APPROVED USES:**

Dystrophic nail removal in cases of onychomycosis, damaged, or devitalized and ingrown nails, symptomatic treatment of xerosis

**COMPENDIAL APPROVED OFF-LABELED USES:**

None

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**COVERAGE CRITERIA: INITIAL AUTHORIZATION****DIAGNOSIS:**

Dystrophic nail removal in cases of onychomycosis, damaged, or devitalized and ingrown nails, Xerosis

**REQUIRED MEDICAL INFORMATION:****A. DYSTROPHIC NAIL REMOVAL DUE TO ONYCHOMYCOSIS, DAMAGED OR DEVITALIZED AND INGROWN NAILS:**

1. Failure of a consistent trial of Terbinafine 250mg tablets x 6 weeks.  
AND
2. Failure of a consistent trial of Ciclopirox 8% solution.  
AND
3. For PRESCRIPTION (RX) Urea requests: trial and failure of OTC Urea cream.

**B. XEROSIS:**

1. Failure of a consistent trial of ammonium lactate 12% cream/lotion  
AND
2. Failure of a consistent trial of topical corticosteroids  
AND
3. For PRESCRIPTION(RX) Urea requests: trial and failure of OTC Urea cream

**DURATION OF APPROVAL:**

Initial authorization: 3 months, Continuation of Therapy: 3 months

**QUANTITY:**

As relevant to diagnosis and affected BSA. Suggestions: 1 ounce – Onychomycosis, 3 ounces - Xerosis

**PRESCRIBER REQUIREMENTS:**

No requirements

**AGE RESTRICTIONS:**

No restriction

**CONTINUATION OF THERAPY:****A. FOR ALL INDICATIONS:**

1. Progress notes documenting member's response to therapy.

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of urea are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

**OTHER SPECIAL CONSIDERATIONS:**

Caution in use with pregnancy and breast feeding.

**BACKGROUND:**

Onychomycosis: Topical urea is found useful for thick, dystrophic nails which makes it difficult for patients to trim nails and may lead to pain during ambulation for patients who forgo antifungal treatment and as an adjunctive measure in those who proceed with treatment. Xerosis: Topically, urea promotes the uptake of water by the stratum corneum by allowing it to have a high water-binding capacity. This promotes hydration in dry skin.

**APPENDIX:**

None

**Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

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**REFERENCES:**

1. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. 2020. Available from: <http://www.clinicalpharmacology.com>