Urea Cream
Policy Number: C14551-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/1/2018	8/1/2018	43678
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
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PRODUCTS AFFECTED:
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%

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

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 IN GROWN NAILS:
   1. Failure of a consistent trial of Terabinafine 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

GENDER:
Male and female

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

REFRENCES:

1. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier. 2018. Available from: http://www.clinicalpharmacology.com