Prior Authorization Approval Criteria

Ontak (denileukin diftitox)

Generic name: Denileukin diftitox
Brand name: Ontak
Medication class: Antineoplastic agent, interleukin
FDA-approved uses: Treatment of persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor
Available dosage forms: 300mcg/2ml single use vial
Usual dose: 9 or 18 mcg/kg/day given via IV infusion for 5 consecutive days every 21 days for 8 cycles
Approximate cost per cycle:
(based on AWP 2010)
9 mcg/kg/day = $27,144
18 mcg/kg/day = $45,240
Duration of therapy: Maximum of 8 cycles
Criteria for use (bullet points below are all inclusive unless otherwise noted):
• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
• Diagnosis of persistent or recurrent cutaneous T-cell lymphoma
• Serum albumin level must be ≥3.0g/dL
• No evidence of systemic disease
Criteria for continuation of therapy:
• Disease is in remission
• No evidence of systemic disease
• Patient has not completed a total of 8 cycles
Caution:
• Infusion reactions
• Capillary leak syndrome
• Changes in visual acuity and color vision
Monitoring:
• Monitor for changes in visual acuity and color vision
• Serum albumin levels prior to each treatment cycle
Not approved if:
• Patient does not meet the above stated criteria
• Disease has progressed
• Patient has systemic disease
• Patient has already completed a total of 8 cycles
Special considerations:
• Drug will be approved for 1 cycle at a time

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
• Each cycle will require updated clinical notes and lab values for authorization

Fallon Health Pharmacy and Therapeutics Committee approval: ______________________________

Date: ______________________

Adopted: 09/08/10