# Prior Authorization Approval Criteria

## *Ontak (denileukin diftitox)*

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| **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<br>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 $\geq$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