



## Prior Authorization Approval Criteria

### *Ontak (denileukin diftitox)*

<b>Generic name:</b>	Denileukin diftitox
<b>Brand name:</b>	Ontak
<b>Medication class:</b>	Antineoplastic agent, interleukin
<b>FDA-approved uses:</b>	Treatment of persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor
<b>Available dosage forms:</b>	300mcg/2ml single use vial
<b>Usual dose:</b>	9 or 18 mcg/kg/day given via IV infusion for 5 consecutive days every 21 days for 8 cycles
<b>Approximate cost per cycle:</b> (based on AWP 2010)	9 mcg/kg/day = \$27,144 18 mcg/kg/day = \$45,240
<b>Duration of therapy:</b>	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  $\geq 3.0$ g/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
- Each cycle will require updated clinical notes and lab values for authorization

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 09/08/10