GCHP Medi-Cal Clinical Guidelines
Denileukin Diftitox (Lymphir™)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	The treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least one prior systemic therapy.
Exclusion Criteria	Capillary leak syndrome (CLS).
Required Medical Information	**Must meet ALL of the following:** • Diagnosis of relapsed or refractory Stage I-III cutaneous T-cell lymphoma. • Failed or intolerant to other U.S. Food and Drug Administration approved medications such as topical chemotherapeutic agents, and/or electron beam therapy, and/or phototherapy, and/or interferon, and/or topical retinoids, and/or systemic retinoids, and/or extracorporeal photopheresis, and/or single agent chemotherapy, and/or combination chemotherapy. • At least 20% of the malignant cells in any tissue sample expressing the CD25 component of the Interleukin-2 receptor.
Age Restriction	18 years of age and older; < 21 years of age – check CCS eligibility
Prescriber Restrictions	Hematologist, Oncologist
Coverage Duration	Initial: Three months Renewal: Six months
Other Criteria / Information	Adapted from DHCS Pharmacy Manual Chemo Drug d May 2024.

HCPCS	Description	Dosing, Units
J9160	Denileukin diftitox 300 mcg injection (Lymphir)	9 mcg/kg/day IV infusion days 1-5 of 21-day cycle

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/24/2025	N/A	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
Approved	N/A	2/13/2025	Pharmacy & Therapeutics (P&T) Committee	6/1/2025