GCHP Medi-Cal Clinical Guidelines
General Off-Label Use

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Medically accepted off-label indications are defined using the following standard reference compendia: • Micromedex DrugDex (DrugDex). • National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (as indicated by a category 1, 2A, or 2B). • Wolters Kluwer Lexi-Drugs (Lexicomp®, Facts & Comparisons®, and UpToDate®). • Elsevier / Gold Standard Clinical Pharmacology. • And/or positive results from two peer-reviewed published medical studies.
Exclusion Criteria	Uses without supporting evidence for the stated indication (experimental).
Required Medical Information	**Off-label indications:** 1. The requested unlabeled use must represent reasonable and current prescribing practices based on current medical literature, provider organizations, or academic & professional specialists. 2. In addition, one of the following is required: a. Documentation of trial & failure (or contraindication) to on-label treatments. b. There are no FDA-approved drug treatments for the diagnosis.
Age Restriction	Product specific. For < 21 years of age - check for CCS eligibility.
Prescriber Restrictions	Prescribed by relevant specialist within normal scope of practice.
Coverage Duration	Initial: Three months Renewal: Six months
Other Criteria / Information	Case-by-case reviews for off-label usage of an agent will include consideration of: a. Availability of more cost-effective therapeutic alternatives. b. Member-specific co-morbidities, intolerances, allergies, or other risk factors, which may be relative or absolute contraindications to preferred therapies. c. Previous treatments tried and failed. d. The manufacturer's FDA approved package labeling &/or published clinical guidelines in regard to indications, administration, place in therapy (e.g., 1st, 2nd, 3rd line), typical and maximum doses, study populations, pediatric use, recommended laboratory studies (either pretreatment screening or posttreatment monitoring).

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	01/14/2025	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	03/01/2025