General Requirements for Antineoplastic Agents, Not Otherwise Having Specific TAR Criteria

Unless otherwise specified as having renewal requirements, criteria apply to new starts only. Include documentation of continuation of care if member is not new to treatment. Unless otherwise specified, brand names are shown for reference only and the criteria apply to the generic drug ingredient regardless of manufacturer or labeler.

PA Criteria	Criteria Details
Covered Uses	1) Case-Specific. 2) FDA approved indications. 3) Off-Label indications: a. The California Department of Health Care Services (DHCS) requires the Managed Care Plans (MCPs) and County Operated Health Systems (COHS) apply the following requirements to Off-Label use of medications: i. Per Title 22 CCR 51313(4), Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on: 1. Reference to current medical literature 2. Consultation with provider organizations, academic and professional specialists. ii. Off-label use that is not approved by the FDA for the diagnosis in question is not coverable unless: 1. FDA-approved alternatives have been medically ruled out (cannot be used in a particular situation for medical reasons such as allergy, serious drug interactions, previous adverse effects, or other contraindications). 2. There are no FDA-approved alternatives and the medication requested is the least costly treatment that is demonstrated to be possibly effective in treatment of the diagnosed condition. b. Medically accepted off-label indications are defined using the following standard reference compendia, under the Centers for Medicare and Medicaid Services guidance, such as (but not limited to): i. American Hospital Formulary Service-Drug Information (AHFSDI) ii. Truven Health Analytics iii. Micromedex DrugDeX (DrugDex) iv. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (as indicated by a category 1, 2A, or 2B) v. Wolters Kluwer Lexi-Drugs (Lexicomp®, Facts & Comparisons®, and UpToDate®) vi. Elsevier/Gold Standard Clinical Pharmacology vii. 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	1) TARs must include an accurate diagnosis, as provided by the treating clinician, and include all relevant clinical documentation necessary to support medical justification (e.g. clinic notes, member-specific weight and body surface area, treatment history including prior regimen(s), lab reports, specialist consults, imaging reports, etc). 2) TAR must include the amount of drug in metric weight (g, mg, mcg) &/or metric volume (ml, or # of vials if measured by each) to be administered at each dose and the number of doses necessary to complete treatment. For cyclically administered therapy, include the number of doses needed in a cycle, and the number of cycles necessary to complete treatment.
Age Restriction	Agent-specific

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Prescriber Restriction	Prescribed by oncologist, hematologist, hematologist-oncologist, or other relevant specialist with oncology scope of practice), or with specialist consult/recommendation.
Coverage Duration	Case-dependent, based on patient-specific needs, package labeling &/or Compendia or specialty professional treatment guidelines.
Other Requirements & Information	1) **Case-by-case reviews** for anti-neoplastic agents 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. d. Previous treatments tried and failed. e. The manufacturer's FDA approved package labeling &/or published clinical guidelines in regards to indications, administration, place in therapy (eg, 1st, 2nd, 3rd line), typical and maximum doses, study populations, pediatric use, recommended laboratory studies (either pretreatment screening or post-treatment monitoring). f. Drug-specific State Medi-Cal billing policies (Medi-Cal TAR requirements) may be used in lieu of PHC drug-specific criteria to guide the reviewer in establishing that medical necessity has been fully documented in the TAR submission. 2) **Renewals:** a. TAR renewals require clinical documentation that the patient is demonstrating a positive response to the requested therapy, as evidenced by: i. An improvement in the condition being treated without adverse effects causing treatment interruption, or ii. The member has progressed more slowly than anticipated in the original prognosis b. Renewal submissions must include most recent clinic visit notes, which show the current evaluation/assessment of the member's disease and any treatment plan updates. 3) **Biosimilars:** When a biosimilar product is available in the marketplace, the biosimilar product is generally preferred by PHC. TARs for the reference drug (ie, original patented brand product) must include: a. Documentation of trial and failure with the biosimilar product, including the nature of the failure and how the use of the reference drug product would avoid likelihood of the same failure. OR b. The biosimilar has not been FDA approved for the same indication that the original brand is indicated for. OR c. The facility providing the infusion has operational access limitations, such as limited by facility formulary or contracts and is unable to obtain the preferred biosimilar. i. Whenever possible, the TAR should include an estimate as to when biosimilars might be available to the provider, understanding that the reference drug will be authorized as an interim until the biosimilar is available.