Case-by-Case TAR Requirements and Considerations

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	Covered uses (approvable diagnoses) are limited to FDA approved indications, unless off-label requirements are met. See "Other Criteria" below for off-label requirements. FDA approved uses can be found at: • https://dailymed.nlm.nih.gov/dailymed/index.cfm • https://www.pdr.net/ • https://nctr-crs.fda.gov/fdalabel/ui/search
Exclusion Criteria	1) Drugs or indications that are carved out to State Medi-Cal Fee-for-Service 2) Drugs that are excluded from reimbursement as stipulated by the State Plan, State Plan Amendments (SPA), All Plan Letters (APL), Centers for Medicare and Medicaid, &/or California Code of Regulations Title 22 3) TARs which lack adequate documentation of medical necessity or reasons why a preferred therapeutically equivalent agent cannot be used 4) Medications/doses that will be used at home, except when such use is allowed by contract or benefit type (eg, PHC Family Planning Benefit)
Required Medical Information	TAR must include an accurate diagnosis and include all necessary and relevant clinical documentation to support medical justification for the request, such as (but not limited to): 1) Clinic notes 2) Specialist consults 3) Lab reports (baseline, genetic markers, any recommended studies post-treatment initiation to monitor safety/efficacy, etc 4) Imaging reports if relevant 5) Reasons why preferred therapeutic alternatives (if any) cannot be used
Age Restriction	• Per FDA approved uses. • Consideration given for non-FDA-approved age(s) when requested by a specialist who is experienced in using the drug in the specialist's own scope of practice (eg, pediatric cardiologist, pediatric oncologist, pediatric neurologist, etc).
Prescriber Restriction	Appropriate specialist consult may be requested.
Coverage Duration	Determined based on condition being treated and by the information submitted with the TAR.
Other Requirements & Information	Case-by-case means that the medical necessity of the specific product for the individual member on a submitted TAR will be reviewed by considering the member's own medical history, such as: 1) Medication allergies 2) Disease history 3) Treatment history 4) Concurrent medications 5) Concurrent disease state(s) in combination, the member's medical need for urgent dose administration When a drug does not have established criteria, the request will fall under the category of case-by-review and in addition to the case-specific considerations listed above, the TAR request for the drug will be reviewed and approved or denied based on:

1) The prescriber's area of expertise or scope of practice.
2) FDA approved indications
3) National treatment guidelines
4) Availability of preferred therapeutic alternatives, cost effectiveness, &/or PHC policies that have specific guidance on coverage of drug therapies.

In addition to the above, the plan may use other clinical resources, including (but not limited to):

- Lexi-Drug
- Elsevier/Gold Standard Clinical Pharmacology
- NCCN (National Comprehensive Cancer Network)
- UpToDate
- Facts and Comparisons
- State Medi-Cal Fee-For-Service TAR requirements
- CCS (California Children's Services Numbered Letters (CCS TAR requirements)
- Manufacturer's package labeling
- Pre-market clinical trials on which FDA-approval was based
- Post-market clinical trials adequately supporting additional evidence for use of requested drug or preferred alternatives

Trial of preferred therapeutic alternatives: There is no set number of preferred medications that must be tried before a non-preferred medication can be approved, because it depends on each drug as to how many treatment alternatives are available, the pharmacologic and therapeutic similarities between the different treatments, and also depends greatly on the member's reason for failure with any alternatives that have been tried. Sometimes there are numerous alternatives for a particular drug, and other times only one or two. The number of trials required will be based on the clinical judgement of the physician or clinical pharmacist reviewer. Clinical documentation or laboratory evidence supporting an established contraindication to preferred treatment alternative(s) may be required for those who are unable to use preferred alternative(s).

Off-Label (Unlabeled) Uses:
The regulatory body that oversees Medi-Cal programs, DHCS (California Department of Health Care Services) has issued the following regarding the use of FDA-approved drugs for indications (diseases or conditions) that have not been approved for use by the FDA:

> 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:
>
> A. Reference to current medical literature.
> B. Consultation with provider organizations, academic and professional specialists.
>
> Off-label use of medications not approved by the FDA for the diagnosis in question is not covered unless:
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> - FDA approved alternatives have first 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).
> - There are no FDA approved alternatives and the medication requested is the least costly treatment that is demonstrated to be possibly effective in treating the diagnosed condition.
>
> This is a reminder that only medication [services] approved by the FDA for the indication listed as the diagnosis can be [reimbursed], unless the use of that drug can be medically ruled out. Off-label use has been the source of

	lawsuits, manufacturer prosecution from the DOJ, and manufacturer disputes of rebates.

Medical Billing:
The requested quantity must be for the smallest volume necessary for the required dose, using the smallest size packaging available for the requested dose to avoid or minimize waste.

HCPCS Codes: When a drug has a specific HCPCS code, only the specific code is accepted for TARs and claims.

NOC codes: NOC=Not Otherwise Classified. NOC drugs are those that have not been assigned a drug-specific code by CMS, and are also referred to as "Unclassified drugs".. NOC *codes* are sometimes called "Miscellaneous Codes". By definition, NOC codes are not drug-specific, but there are varying levels of *drug type* specificity available for MEDICARE claims; however, PHC uses a limited number of NOC codes for TARs and claims.

Regardless of what NOC code a provider finds for a drug in a CMS HCPC code reference source,
PHC only accepts the drug NOC codes indicated in the chart below:

CMS NOC Code	Code Description	
CMS NOC Codes Accepted by PHC:		**Comments:**
A9698	Non-radioactive contrast imaging material, not otherwise classified, per study dose	Invoice required with claims to determine pricing
A9699	Radiopharmaceutical, therapeutic, not otherwise classified	
J3490	Unclassified drugs	Both oral and injectable unclassified drugs are accepted with J3490.
J3590	Unclassified biologics	PHC allows either J3490 or J3590 for biologics, no preference. Biologics do require a TAR regardless of the code used. The code on the TAR must also be the code use for claims subsequent to an approved TAR.
S5000	Prescription drug, generic	These codes are used only for the Family Planning and Wellness & Recovery benefits.
S5001	Prescription drug, brand	
Z7610	Miscellaneous drugs and medical supplies	For *drugs*, Z7610 and J3490 are interchangeable. For supplies, Z7610 should be used.
CMS NOC Codes NOT ACCEPTED by PHC -- Must use J3490 instead:		
C9399	Unclassified drugs or biologicals	
J7599	Immunosuppressive drug, not otherwise classified	
J7699	Not otherwise classified drugs, inhalation solution administered through DME	
J7799	Not otherwise classified drugs, other than inhalation drugs, administered through DME	
J7999	Compounded drug, not otherwise classified	
J8498	Antiemetic drug, rectal/suppository, not otherwise classified	
J9999	Not otherwise classified, antineoplastic drug	
90749	Unlisted vaccine/toxoid	
J3535	Drug administered through a metered dose inhaler	
J8499	Prescription drug, oral, non-chemotherapeutic, nos	
J8597	Antiemetic drug, oral, not otherwise specified	
J8999	Prescription drug, chemotherapeutic, nos	

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Medical Billing, continued:

Billing Units for NOC drugs: Pricing & units are dependent on how the product is packaged:

Dosage Form	Unit equivalence
Tablets, Capsules	1 tablet/capsule = 1 unit
Vials	System default: 1 vial=1 unit, regardless of size • Single-dose vials: Paid per vial; the submitted count should be the # of vials, rather than the # of ML. • Multi-dose, multi-patient vial: flagged for manual pricing, to be paid using ML pricing rather than full vial price.
IV bags	1 bag=1 unit, regardless of size
Oral liquids	System default: 1 full bottle or unit dose cup/syringe=1 unit, regardless of size • Single-patient use, such as reconstituted antibiotics: 1 unit is reimbursed as the full package size. Submitted count should be 1 per bottle, rather than the # of ML. • Multi-patient use, such as bulk bottles for pharmacy stock, dispensed out in smaller sizes for individual patient use (eg, 480 ml syrups): flagged for manual pricing, to be paid using ML pricing rather than by full package price.
Oral Inhalers (metered dose inhalers, dry powder inhalers)	Dependent on type. See PHC's MDL search tool for specific inhaler unit information. In general, aerosol/HFA types are reimbursed as 1 unit=1 inhaler and disk/dry powder inhalers are 1 unit=1 inhalation.

The following fall under the DHCS provider manual policies regarding double-billing, meaning payment as separate line items may not be allowed even when using the correct NOC or specific billing code, even with an approved TAR:

Anesthesia-related drugs, including local/regional anesthetics, general anesthesia, anesthesia adjuncts such as neuromuscular blockade, sedatives, analgesics, and reversal agents	These are not separately payable when the provider will be submitting a UA/UB modifier with a surgical CPT code because the modifier includes all drug reimbursement. This includes anesthesia-related drugs which require a TAR – TAR authorization does not guarantee payment in addition to the UA/UB modifier.
Ophthalmic eye drops, visual aids	These are not separately payable when the provider will be submitting a UA/UB modifier on a cataract-related surgical CPT because the UA/UB modifier includes drug reimbursement.
Imaging agents (contrast, dyes)	Not payable as separate line items when the diagnostic CPT code includes the rate for the contrast/imaging agent.