

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.

PA Criteria	Criteria Details
Covered Uses	<p>Covered uses (approvable diagnoses) are limited to FDA approved indications, unless off-label requirements are met. See “Other Criteria” below for off-label requirements.</p> <p>FDA approved uses can be found at:</p> <ul style="list-style-type: none"> • https://dailymed.nlm.nih.gov/dailymed/index.cfm • https://www.pdr.net/ • https://nctr-crs.fda.gov/fdalabel/ui/search
Exclusion Criteria	<ol style="list-style-type: none"> 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	<p>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):</p> <ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1) Per FDA approved uses. 2) Outside of 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	<p>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:</p> <ol style="list-style-type: none"> 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 6) The prescriber’s area of expertise or scope of practice. <p>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:</p> <ol style="list-style-type: none"> 1) FDA approved indications 2) National treatment guidelines

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3) 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 industry-standard clinical resources, including (but not limited to):

- Lexi-Drug
- Elsevier/Gold Standard Clinical Pharmacology
- NCCN (National Comprehensive Cancer Network)
- UpToDate
- Facts and Comparisons

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:

- 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.

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Medical Billing: Note: 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: Not Otherwise Classified drugs, utilizing a NOC code for TARs and billing purposes (also known as unclassified or miscellaneous codes). These codes are not drug-specific. CMS (Centers for Medicare and Medicaid) has established many different NOC codes, but PHC only uses a portion of them. A crosswalk for NOC (Not Otherwise Classified, aka unclassified) drug codes is below, showing which NOC code to use for PHC TARs/Claims.

If a provider is referencing a CMS HCPC code resource, there will many NOC codes shown. In lieu of the variety of CMS HPCPS NOC codes, **PHC only accepts A9699, J3490, J3590, and J3535.**

Unaccepted CMS NOC Code	NOC Code Description	Use instead for PHC
C9399	Unclassified drugs or biologicals	J3490 (drugs) or J3590 (biologics)
J7599	Immunosuppressive drug, not otherwise classified	J3490 (eg, mycophenolate IV)
J7699	Not otherwise classified drugs, inhalation solution administered through DME	J3490 (eg, sodium chloride, aztreonam/Cayston™)
J7799	Not otherwise classified drugs, other than inhalation drugs, administered through DME	J3490 (eg, pegcetacoplan/Empaveli™, administered via subcutaneous pump)
J7999	Compounded drug, not otherwise classified	J3490
J8498	Antiemetic drug, rectal/suppository, not otherwise specified	J3490 (promethazine suppositories)
J9999	Not otherwise classified, antineoplastic drug	J3490 (drugs) or J3590 (biologics)

The billing units for NOC codes vary by drug and package size for PHC's reimbursement systems, so it is understandable if providers do not include the specific number of billing units needed on the TAR. Usually, the billing units will be per ml or per gram, but this isn't always the case; sometimes it is per full package size or per vial. PHC will calculate the number of billing units necessary based on the dose (in mg or g), how the concentration of the NDC requested (eg, # mg/ml), and how PHC's reimbursement is set up for the NDC (by package, by vial, by ml, by g, etc).