

Requirements for Self-Administered Drugs

PA Criteria	Criteria Details
Covered Uses	<ol style="list-style-type: none"> 1) FDA approved uses, unless excluded from reimbursement with state or federal funds (eg, any drug when used for the treatment of infertility, erectile dysfunction, or cosmetic use), or unless the requested drug is carved-out to State Fee-for-Service (HIV/AIDS, hemophilia, opiate & alcohol detoxification, antipsychotics and some antidepressants) 2) The drug is to be administered to the member in a medical setting (not used by the member at home)
Exclusion Criteria	Drugs given to a member to self-administer at home, except when such use is allowed by contract or benefit type (eg, Family Planning Benefit).
Required Medical Information	<p>All requests must include:</p> <ol style="list-style-type: none"> 1) Diagnosis (indication for use) 2) Relevant labs, clinic notes, specialist consultations which document medical necessity of the drug treatment 3) Relevant clinical documentation to support medical necessity of the need to administer the medication in a medical setting 4) Reasons why a covered injectable therapeutic alternative is not being used, if a suitable, indicated alternative exists. 5) Reasons why the member must receive the dose(s) from a medical provider instead of receiving from a pharmacy for administration at home, such as: <ol style="list-style-type: none"> a) Teaching self-administration b) Adjusting or titrating the dose c) Monitoring for immediate side effects d) Emergency use
Age Restriction	Per FDA-approved uses, unless exception is requested by a pediatric specialist
Prescriber Restriction	An appropriate specialist (prescribed or recommended by) may be required, particularly for specialty medications.
Coverage Duration	Case-dependent (medical office single dose requested vs outpatient hospital with multiple doses requested). Limited to the number of doses needed until the member is able to resume self-administration at home.
Other Requirements & Information	<p>Definition of a Self-Administered Drug: Drugs that are FDA-approved for self-administration at home rather than necessarily being administered in a healthcare setting by a medical provider.</p> <p>When the predominant use is for a condition that is recurrent, identifiable by the member, given for an either an immediate effect or to maintain a chronic condition, and provided with self-administration instructions in the drug's package insert approved by the US Food & Drug Administration (FDA), the drug is usually self-administered, including injectable medications which do not require clinical expertise to use. Examples of self-injectable drugs include sumatriptan to treat migraine headache, insulin or dulaglutide to treat diabetes and dupilumab to treat eczema or asthma.</p> <p>Considerations for Authorization: Authorization of injected, oral, inhaled or topical medications that are usually self-administered, yet are being requested under the medical benefit as a Physician Administered Drug (PAD), will be considered on a case-by-case basis through the prior authorization process (TAR/Treatment Authorization Request), when the drug is not otherwise included as a covered PAD drug in either PHC's list of covered unclassified drugs (billable with J3490 or J3590) or the PHC Medical Drug List.</p> <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: medication allergies, disease history, treatment history, concurrent medications, and concurrent disease state(s) in combination, the member's medical need for urgent dose administration, as well as the prescriber's area of expertise or scope of</p>

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practice. Case-by-case review may include clinical resources such as (but not limited to):

- Current treatment guidelines published by national professional societies or organizations
- Medical & Pharmaceutical Compendia such as Lexicomp, Facts & Comparisons, UpToDate, Elsevier/Gold Standard Clinical Pharmacology, American Hospital Formulary Service Drug Information (ASFS-DI), and others.
- DHCS State Medi-Cal Prior Authorization Criteria documents

See PHC's document *Case-by-Case TAR Requirements and Considerations* for further details regarding case-by-case TAR reviews.

Requests for self-administered medications to be reimbursed under PHC's medical benefit must also document the following (1 AND 2):

- 1) Documentation of medical necessity for provider administration of a typically self-administered medication, such as:
 - a. the drug is administered as part of a procedure or may be needed during or immediately after a procedure or infusion (such as a pre-medication or medication given to treat an infusion reaction)
 - b. OR the drug provides an immediate clinical benefit from an in-office dose, and it is not reasonable to delay administration until the member can pick up the drug at a pharmacy
 - c. OR the drug is administered continuation of an oral treatment established prior to an outpatient stay or observation, when the patient cannot use on hand doses previously dispensed to them by a pharmacy, and missing a dose is of immediate medical concern (blood pressure medications, transplant rejection medications)
- 2) AND the quantity of medication requested reflects what is administered by the provider and does not extend to home use. Drugs that are packaged in quantities that exceed what is administered by the provider will need to be split or a prescription issued for the member to obtain through the pharmacy benefit. Inhaled and topical medications that are packaged in quantities which will exceed what is administered by the provider should utilize the smallest available package size, such as institutional size packaging.

Medical Drug Billing:

Although most drugs available for pharmacy fulfillment use an unclassified billing code when submitted as medical claims, many actually do have specific HCPCS codes. When a drug has a specific HCPCS code, only the specific code is accepted for TARs and claims.

Submitting the correct units of service (unit count) in accordance with PHC units of reimbursement:

- Solid dosage forms (tabs, caps): Paid as 1 unit=1 tablet or capsule
- Liquids, creams, ointments: Paid as 1 unit=1 package unit-of-use (1 vial, syringe, tube, bottle, unit dose cup, etc)

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Medical Billing, continued:

PHC is currently only using these unclassified codes, also referred to as Not Otherwise Classified (NOC) codes:

HCPCS CODE	CODE DESC.	TAR?	DEFINITION	EXAMPLES
J3490	Unclassified Drugs	Varies by product	Small molecule drugs not having a specific code. Small molecule drugs are those with a relatively simple chemical structure and typically don't require special handling.	Analgesics, antibiotics, antihypertensives, oral antineoplastics and antihistamines to name just a few.
S5000	Prescription Drug, Generic	No	Used for designated benefit claims as defined by their respective policies: Family Planning Benefit drugs, Wellness & Recovery Benefit drugs	Family Planning (including but not limited to): Acyclovir, Doxycycline tabs/caps, Miconazole vaginal cream, Nitrofurantoin capsules. Wellness & Recovery (including but not limited to): Buprenorphine, Naloxone, Acamprosate, Disulfiram, Naltrexone
S5001	Prescription Drug, Brand			
Z7610	Misc. Drugs & Medical Supplies	Varies by product	Accepted as equivalent to J3490 for drug NDCs, and is also used for non-drug supply items, until State Medi-Cal discontinues the use of local codes.	See J3490.
J3590	Unclassified Biologics	Yes	Large molecule drugs, aka biologics not having a specific code. These are large complex molecules and are often obtained through advanced biotechnical processes.	Human-derived molecules (human insulin), monoclonal antibodies, many antineoplastic agents.
A9699	Radiopharmaceuticals, not otherwise classified	No	Radiopharmaceutical used for treatment (not diagnostic agents), not otherwise having a specific code.	No NDCs are crosswalked to A9699 as of 4/6/23.

Note that if providers & staff are referencing a CMS HCPCS code resource (such as IPD Analytics' CodeSource, RJ Health's Reimbursementcodes.com, CMS web materials, etc), there may be additional NOC codes shown which pertain to Medicare claim submissions. Note that PHC only uses J3490 & J3590 at this time for unclassified drug & biologic Medi-Cal claims. Below is a crosswalk showing what PHC uses in lieu of the CMS Medicare NOC codes:

CMS NOC Codes not accepted by PHC:	NOC Code Description	PHC NOC Code Alternatives:
C9399	Unclassified drugs or biologics	<ul style="list-style-type: none"> ➤ J3490: drugs, any type; J3490 is interchangeable with Z7610. ➤ J3590: biologics only ➤ S5000/S5001: drugs available through the Family Planning and Wellness & Recovery Benefits ➤ Z7610: drugs, any type. Z7610 is interchangeable with J3490 <i>when the item is a drug</i>. Non-drug NDCs are billed with Z7610 and should not be billed with J3490.
J7699	NOC drugs, inhalation solution administered through DME	
J7799	NOC drugs, other than inhalation drugs, administered through DME	
J8498	Antiemetic drug, rectal/suppository, not otherwise specified	
J8499	Prescription drug, oral, non-chemotherapeutic, NOS	
J8597	Antiemetic drug, oral, not otherwise specified	
J8999	Prescription drug, oral, chemotherapeutic, NOS	
J9999	Not otherwise classified, antineoplastic drugs	