

Standard Requirements for Self-Administered Drugs

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	<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 administered to the member in a medical setting (not taken 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	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).
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.

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.

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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.**

PHC is currently only using the following unclassified/NOC (Not Otherwise Classified) codes:

Code	Description	TAR?	Definition	Examples	Billing Units
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.	Example classes are analgesics, antibiotics, antihypertensives, oral antineoplastics and antihistamines to name just a few.	Varies by product. 1 billing unit may be any one of: 1 ml, 1 g, 1 tab, 1 vial, 1 full package.
J3590	Unclassified Biologics	Yes	Large molecule drugs, aka biologics not having a specific code. These are large complex molecules (such as monoclonal antibodies), and are often obtained through advanced biotechnical processes.	A few common examples are Aimovig™, Praluent™, Lantus™, Trulicity™ and Dupixent™.	
J3535	Drug administered through a metered dose inhaler (MDI)	Yes	Products commercially available in MDI	Serevent™, ProAir™, Flovent™, Advair™	
A9699	Radiopharmaceutical, therapeutic, not otherwise classified	No	Radiopharmaceuticals used for treatment rather than diagnostic purposes, not otherwise having a specific code.	The only product falling under A9699 as of 6/1/22 is Pluvicto™ IV solution (lutetium Lu 177 vipivotide tetraxetan)	1 unit is 1 vial (this is specific to Pluvicto™; future products may be billed differently)

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)
J7699	Not otherwise classified drugs, inhalation solution administered through DME	J3490
J7799	Not otherwise classified drugs, other than inhalation drugs, administered through DME	J3490 (eg, pegcetacoplan/Empaveli™, administered via subcutaneous pump)
J8498	Antiemetic drug, rectal/suppository, not otherwise specified	J3490 (promethazine suppositories)
J8499	Prescription drug, oral, non-chemotherapeutic	J3490
J8999	Prescription drug, oral, chemotherapeutic	J3490
J9999	Not otherwise classified, antineoplastic drug	J3490 (drugs) or J3590 (biologics)

References:

1. PHC Utilization Management Program Description
2. PHC Policy MCRP4068 Medical Benefit TAR
3. PHC Policy MPRP4001 Pharmacy & Therapeutics Committee



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- Centers for Medicare & Medicaid (CMS) Self-Administered Drugs – *Process to Determine Which Drugs are Not Usually Self-Administered by the Patient* #A53893, 10/1/2015
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53893&Ctrctr=All&UpdatePeriod=794&bc=AQAAEAAAAAAAA>