

<b>Policy and Procedure</b>	
<b>PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH042.0622</b>	<b>MISCELLANEOUS SELF-ADMINISTERED DRUG (SAD) EXCLUSION</b> See <a href="#">Table 1</a> for Medications
<b>Effective Date: 8/1/2022</b>	Review/Revised Date: 05/22 (JL/JLS)
	P&T Committee Meeting Date: 04/22, 06/22
	Original Effective Date: 07/22
	Approved by: Oregon Region Pharmacy and Therapeutics Committee
<b>Robert Gluckman, M.D. Chief Medical Officer</b>	Page 1 of 6

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

Commercial  
Medicaid

**POLICY CRITERIA:**

**COVERED USES:**

For medications without prior authorization requirements: all medically-accepted indications

For medications with prior authorization requirements, those clinical criteria must be met. Note that the approval of the prior authorization for the medication is for self-administration at home, after the monitoring period allowed at the provider’s office.

**REQUIRED MEDICAL INFORMATION:**

Relevant chart notes are required and must document medical rationale for requiring administration by a healthcare professional.

Healthcare provider administration may be considered medically necessary if one of the following criteria is met:

1. History of severe adverse drug reactions or anaphylaxis to prior treatments of the same or similar therapy
2. Documentation that the patient does not have a caregiver to safely administer the drug AND one of the following:
  - a. Mental health or cognitive changes that require increased level of care for the safe administration of medications

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- b. Physical conditions or dexterity issues that impede clean handling of medication and safe administration technique
- c. Inability to recognize symptoms of anaphylaxis and/or act to treat anaphylaxis reactions appropriately

**EXCLUSION CRITERIA:** N/A

**AGE RESTRICTIONS:** Refer to applicable clinical policy and/or formulary documents

**PRESCRIBER RESTRICTIONS:** N/A

**COVERAGE DURATION:**

Authorization and reauthorization for coverage under the medical benefit will be approved for one year

**QUANTITY LIMIT:**

Refer to applicable clinical policy and/or formulary documents

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*Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.*

*Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.*

*Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.*

*Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.*

**INTRODUCTION:**

Definitions:

- Self-administered drugs: Medications which have been identified as being medically appropriate for administration by a patient or caregiver, safely and effectively, without medical supervision

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- Route of administration: the process by which a medication enters the body (such as by mouth or by injection)

**FDA APPROVED INDICATIONS:**

*Refer to package labeling available at*

<https://dailymed.nlm.nih.gov/dailymed/index.cfm>

**POSITION STATEMENT:**

There are benefits to requiring self-administration of some of these drugs including lower drug costs, lower administrative costs, convenience for patients, and on-going patient support through our specialty pharmacy providers. These types of drugs are added to a self-administered drug (SAD) exclusion list

Upon initiation of a drug in the SADs Exclusion List, or approved prior authorization for the drug, the first 60 days will be covered at a provider's office, to allow for the monitoring of new therapy, and to determine suitability for self-administration at home, or member's place of residence. This period will also provide time for patient training in safe and sterile administration techniques, recognition of symptoms of anaphylaxis, and when to seek treatment in the event of a drug reaction. Extended monitoring period beyond 60 days will be allowed for specific drugs, as recommended and labeled by manufacturer. For example, initiation of therapy with Xolair® will be allowed 90 days administration and monitoring at provider's office due to concerns for anaphylactic reactions.

**REFERENCE/RESOURCES:**

1. Relevant package inserts
2. Noridian Healthcare Solutions. Self-Administered Drugs (SADs) Policy. Available at <https://med.noridianmedicare.com/web/jfb/policies/sads> (Accessed January 18, 2022)
3. Global Market Insights. Self-administered Drugs Market Size, Industry Analysis Report, Regional Outlook (U.S., Canada, Germany, UK, France, Spain, Italy, Russia, Japan, China, India, Australia, Brazil, Mexico, Argentina, South Africa, Saudi Arabia, UAE), Application Potential, Price Trends, Competitive Market Share & Forecast, 2022 – 2028 Available at: <https://www.gminsights.com/industry-analysis/self-administered-drugs-market> (Accessed January 18, 2022)
4. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services. Available at <https://www.cms.gov/Regulations-and->

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[Guidance/Guidance/Manuals/Downloads/bp102c15.pdf](#) (Accessed January 18, 2022)

**Table 1.** Self-Administered Drug Exclusion List

These listings are subject to change as new medications come to market or additional medications are identified as safe, effective, and appropriate for self-administration.

<b>Generic Name</b>	<b>Brand Name</b>	<b>HCPC Code</b>
Abaloparatide	Tymlos	J3490
Abatacept	Orencia Clickjet	J0129
Adalimumab	Humira	J0135
adalimumab-afzb	Abrilada	C9399, J3590
adalimumab-atto	Amjevita	C9399, J3590
Alirocumab	Praluent	C9399, J3590
Anakinra	Kineret	J3590
Asfotase alfa	Strensiq	C9399, J3490
Belimumab	Benlysta (SubQ) autoinject or syringe	J0490
Benralizumab	Fasenra	J0517
Brodalumab	Siliq	C9399, J3590
C1 esterase inhibitor	Haegarda	J0599
Caplacizumab-yhdp	Cablivi	C9047, J3590
Corticotropin Inj Gel	Acthar	J0800
Dalteparin Sodium, porcine	Fragmin	J1645
Dulaglutide	Trulicity	C9399, J3590
Dupilumab	Dupixent	C9399, J3590
Enfuvirtide	Fuzeon	J1324
Enoxaparin	Enoxaparin	J1650
enoxaparin	Lovenox	J1650
Erenumab	Aimovig	C9399, J3590
Etanercept	Enbrel	J1438
Etanercept-szzs	Erelzi	C9399, J3590
Etanercept-ykro	Eticovo	C9399, J3590
Evolocumab	Repatha	C9399, J3590
Exenatide	Bydureon	C9399, J3590
Exenatide	Byetta	J3490

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<b>Generic Name</b>	<b>Brand Name</b>	<b>HCPC Code</b>
fondaparinux Sodium	Arixtra	J1652
Fondaparinux Sodium	Fondaparinux Sodium	J1652
fremanezumab-vfrm	Ajovy	J3031
glatiramer	Copaxone	J1595
glatiramer	Glatopa	J1595
Golimumab	Simponi	C9399, J3590
Guselkumab	Tremfya	J1628
Icatibant	Firazyr	J1744
Icatibant	Sajazir	J1744
Icatibant Acetate	Icatibant	J1744
Interferon beta-1a	Avonex	J1826, Q3027
Interferon beta-1a	Rebif	J1826, Q3028
Interferon beta-1b	Betaseron	J1830
Interferon beta-1b	Extavia	J1830
Interferon Gamma-1B, Recomb	Actimmune	J9216
Ixekizumab	Taltz	C9399, J3590
Lanadelumab	Takhzyro	J0593
Liraglutide	Victoza	J3490
Lonapegsomatropin-tcgd	Skytrofa	C9399, J3590
Mecasermin	Increlex	J2170
Mepolizumab	Nucala	J2182
Metreleptin	Myalept	J3490
Omalizumab	Xolair	J2357
Parathyroid Hormone	Natpara	J3490
Pasireotide Diaspartate	Signifor (SubQ)	J3490
Peginterferon alfa-2A	Pegasys	J3590, S0145
Pegvisomant	Somavert	J3590
Pegylated interferon	Plegridy	C9399, J3590
Pramlintide Acetate	Symlin	J3490
risankizumab	Skyrizi	C9399, J3590
Ropeginterferon alfa-2b	Besremi	C9399, J9999
Satralizumab-mwge	Enspryng	C9399, J3590
Secukinumab	Cosentyx	C9399, J3590
Semaglutide	Ozempic	C9399, J3490

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<b>Generic Name</b>	<b>Brand Name</b>	<b>HCPC Code</b>
Somatropin (Recombinant Human Growth Hormone)	Genotropin Humatrope Norditropin NordiFlex Pen Nutropin AQ Omnitrope Saizen Serostim Tev-tropin Zomacton Zorbtive	J2941
Sumatriptan Succinate	Imitrex	J3030
teduglutide	Gattex	J3490
Teriparatide	Forteo	J3110
Tocilizumab	Actemra syr or actpen	J3262
Tralokinumab	Adbry	C9399, J3590
Ustekinumab	Stelara	J3357
Vosoritide	Voxzogo	C9399, J3490