

Policy and Procedure

**PHARMACY PRIOR AUTHORIZATION
POLICY AND CRITERIA
ORPTCOTHXXX.0422**

MISCELLANEOUS

Self-Administered Drug (SAD) Exclusion
See [Table 1](#) for Medications

Effective Date: 7/1/2022

Review/Revised Date:

P&T Committee Meeting Date: 04/22

Original Effective Date: 07/22

Approved by: Oregon Region Pharmacy and Therapeutics Committee

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Chief Medical Officer

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SCOPE:

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

APPLIES TO:

Commercial
Medicaid

Medicare Part B – Refer to Noridian Healthcare Solutions’ Self-Administered Drugs (SADs) Policy: <https://med.noridianmedicare.com/web/jfb/policies/sads>

POLICY CRITERIA:

COVERED USES:

All Medically-Accepted Indications

REQUIRED MEDICAL INFORMATION:

Documentation must be provided outlining the medical rationale for requiring administration by a healthcare professional (such as poor dexterity) for medications that are on the self-administered drug exclusion list (See [Table 1](#)).

EXCLUSION CRITERIA: N/A

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

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

Authorization for coverage under the medical benefit will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes

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QUANTITY LIMIT: Refer to applicable clinical policy and/or formulary documents

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
- 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 corresponding to their benefit, patients will be covered of have an initial 60-day medical benefit with a simultaneous pharmacy benefit which will continue after the 60-days. This will allow a member to have the drug initially administered by a healthcare provider for training of self-

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administration and monitoring for adverse events. After 60 days, the drug will not be covered under the medical benefit (“incident to” a healthcare provider visit.)

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-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.

Generic Name	Brand Name	HCPC Code
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

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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-szsz	Erelzi	C9399, J3590
Etanercept-ykro	Eticovo	C9399, J3590
Evolocumab	Repatha	C9399, J3590
Exenatide	Bydureon	C9399, J3590
Exenatide	Byetta	J3490
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
Leuprolide Acetate	Leuprolide Acetate	J1950, J9218
Liraglutide	Victoza	J3490
Lonapegsomatropin-tcgd	Skytrofa	C9399, J3590

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Mecasermin	Increlex	J2170
Mepolizumab	Nucala	J2182
Metreleptin	Myalept	J3490
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
Satralizumab-mwge	Enspryng	C9399, J3590
Secukinumab	Cosentyx	C9399, J3590
Semaglutide	Ozempic	C9399, J3490
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
Ustekinumab	Stelara	J3357
Vosoritide	Voxzogo	C9399, J3490