Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH042.1024	**MISCELLANEOUS PRODUCTS** **SELF-ADMINISTERED DRUGS (SAD)** See Table 1 for Medications
Effective Date: 1/1/2025	**Review/Revised Date**: 05/22, 11/22, 03/23, 09/23, 09/24 (AA)
Original Effective Date: 07/22	**P&T Committee Meeting Date**: 04/22, 06/22, 12/22, 02/23, 04/23, 10/23, 10/24
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance 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 anaphylaxis in the past five years, from any cause, that either required the use of epinephrine or resulted in hospitalization
2. History of allergic reaction to the requested medication
3. Documentation that the patient has one of the following that prevents self-administration:
    a. Mental health or cognitive changes that require increased level of care for the safe administration of medications
    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
d. Needle-phobia diagnosed by a mental health provider that is congruent with the most current DSM criteria for phobia. Please note that this does not include general fear of needles

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
- 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) list

Upon initiation of a drug in the SADs 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.

Fear of needles is common and is not considered a contraindication to self-administration. However, needle phobia that is clinically diagnosed by a mental healthcare professional in accordance with the DSM criteria will be considered.

CODING/BILLING:
Route of Administration Modifier
The use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category will be marked with an asterisk (*) in Table 1 and must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for the subcutaneous injection form of administration. Absent evidence to the contrary, the Contractor presumes that drugs delivered intravenously are not usually self-administered by the patient. Following correct coding guidelines, the Company will process claims with the JA modifier still applying the policy as stated in Medicare Benefit Policy Manual Chapter 15, section 50.2 that not only must the drug be medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary. Subcutaneously administered drugs listed on the Usually Self-Administered list will be denied as a benefit exclusion. Claims for drugs marked with an asterisk (*) in Table 1 billed without either a JA or JB modifier will also be denied.

Claim denials may occur when the appropriate modifier is not applied to a J code/medication, which has more than one route of administration.

JA for Intravenous administration
JB for Subcutaneous administration

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 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. Please note that this list is not all-inclusive. Medications that are customarily always self-administered may not be listed, for example, subcutaneous insulin. Any medication labeled for patient self-administration is subject to a review for medical necessity if healthcare administration is requested.

Generic Name	Brand Name	HCPC Code
Abatacept	Orencia Clickjet	J0129*
Belimumab	Benlysta (SubQ) autoinject or syringe	J0490*
Benralizumab	Fasenra	J0517
Bimekizumab	Bimzelx	J3590, C9399
Caplacizumab-yhdp	Cablivi	C9047
Certolizumab Pegol	Cimzia	J0717
Corticotropin Inj Gel	Acthar	J0800
Dupilumab	Dupixent	C9399, J3590
Eplontersen	Wainua	J3490, C9399
Erenumab	Aimovig	C9399, J3590
Evolocumab	Repatha	C9399, J3590
Fremanezumab-vfrm	Ajovy	J3031
Furosemide	Furoscix Onbody	J1941
Galcanezumab-gnlm	Emgality	J3590
Golimumab	Simponi	C9399
Guselkumab	Tremfya	J1628
Ixekizumab	Taltz	C9399, J3590
Mepolizumab	Nucala	J2182
Mirikizumab-mrkz	Omvoh	J2267*
Ofatumumab	Kesimpta	J3590 C9399
Omalizumab	Xolair	J2357
Risankizumab	Skyrizi (subq)	C9399, J3590*
Ropeginterferon alfa-2b	Besremi	C9399, J9999
Sarilumab	Kevzara	C9399, J3590
Satralizumab-mwge	Enspryng	C9399, J3590
Secukinumab	Cosentyx (subq)	C9399, J3590*
Spesolimab-sbzo	Spevigo	J1747*
Tezepelumab-ekko	Tezspire	J2356

Generic Name	Brand Name	HCPC Code
Tocilizumab-aazg	Tyenne	Q5135
Tralokinumab	Adbry	C9399, J3590
Ustekinumab	Stelara	J3357
Ustekinumab-aekn	Selarsdi	Biosimilar, HCPCS n/a yet
Ustekinumab-auub	Wezlana	Q5137
Ustekinumab-ttwe	Pyzchiva	Biosimilar, HCPCS n/a yet

*Must be billed with the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for the subcutaneous injection form of administration