Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH042.1225	**MISCELLANEOUS PRODUCTS** **SELF-ADMINISTERED DRUGS (SAD)** See Table 1 for Medications
Effective Date: 2/1/2026	**Review/Revised Date**: 05/22, 11/22, 03/23, 09/23, 09/24, 03/25, 08/25, 11/25 (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, 04/25, 10/25, 12/25
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 August 21, 2025)
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 August 21, 2025)
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 August 21, 2025)

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. Any medication labeled for patient self-administration is subject to a review for medical necessity if healthcare administration is requested.

- The column labeled "Medical Transition Available" column lists medications that are subject to SAD transition period requirements. These medications may require initiation under the medical benefit for a 60- or 90-day (Xolair) transition period to monitor adverse reactions and patient training. Continuation of provider-administration after the transition period is subject to the medical necessity criteria outlined in this policy.

- The column labeled “Pharmacy Benefit Only” column lists self-administered medications that will always start under the pharmacy benefit. These medications are not subject to SAD policy exception requirements because they will always be self-administered from initiation.

HCPCS	Brand Name	Generic Name	Medical Transition Available	Pharmacy Benefit Only
J3490	Tymlos	Abaloparatide		X
J0129*	Orencia Clickjet	Abatacept	X	
J0139	Humira	Adalimumab		X
Q5144	Idacio	Adalimumab-aacf		X
Q5141	Yuflyma	Adalimumab-aaty		X
J3590	Hyrimoz	Adalimumab-adaz		X
Q5143	Cyltezo	Adalimumab-adbm		X
Q5145	Abrilada	Adalimumab-afzb		X
J3590	Yusimry	Adalimumab-aqvh		X
J3590	Amjevita	Adalimumab-atto		X
J3590	Hadlima	Adalimumab-bwwd		X
Q5140	Hulio	Adalimumab-fkjp		X
Q5142	Simlandi	Adalimumab-ryvk		X
J3590	Praluent	Alirocumab		X
J7999	Tri-mix	Alprostadil, Papaverine, Phentolamine		X
J3590	Kineret	Anakinra		X
J3490	Strensiq	Asfotase alfa		X
J0490*, J3590	Benlysta (SubQ) autoinject or syringe	Belimumab	X	
J0517	Fasenra	Benralizumab	X	
J3590	Bimzelx	Bimekizumab	X	
J3590	Siliq	Brodalumab		X
J0599	Haegarda	C1 esterase inhibitor		X
C9047*	Cablivi	Caplacizumab-yhdp	X	
J0717	Cimzia	Certolizumab Pegol	X	
J0801	Acthar	Corticotropin Inj Gel	X	
J1645	Fragmin	Dalteparin sodium, porcine		X
J3490, C9399	Dawnzera	Donidalorsen		X

HCPCS	Brand Name	Generic Name	Medical Transition Available	Pharmacy Benefit Only
J3590	Trulicity	Dulglutide		X
J3590	Dupixent	Dupilumab	X	
J9334	Vyvgart Hytrulo	Efgartigimod alfa and hyaluronidase-qvfc	X	
J3490, C9399	Forzinity	Elamipretide		X
J1324	Fuzeon	Enfuvirtide		X
J1650	Lovenox	Enoxaparin		X
J3490	Wainua	Eplontersen	X	
J3590	Aimovig	Erenumab	X	
J1438	Enbrel	Etanercept		X
J3590	Erelzi	Etanercept-szzs		X
J3590	Eticovo	Etanercept-ykro		X
J3590	Repatha	Evolocumab	X	
J3590	Bydureon	Exenatide		X
J3490	Byetta	Exenatide		X
J1652	Arixtra	Fondaparinux sodium		X
J3031	Ajovy	Fremanezumab-vfrm	X	
J1941	Furoscix Onbody	Furosemide	X	
J3590	Emgality	Galcanezumab-gnlm	X	
J3590	Andembry	Garadacimab	X	
J1595	Copaxone	Glatiramer		X
J1595	Glatopa	Glatiramer		X
J3590	Simponi	Golimumab	X	
J1628*	Tremfya	Guselkumab	X	
J1744	Firazyr	Icatibant acetate		X
J1744	Sajazir	Icatibant acetate		X
J1748	Zymfentra	Infliximab-dyyb	X	
J1811, J1812, J1813, J1814, J1815, J1817, J3490, J3590	All Insulin Products	Insulin		X
J3590	Toujeo	Insulin glargine injection		X

HCPCS	Brand Name	Generic Name	Medical Transition Available	Pharmacy Benefit Only
J1826, Q3027	Avonex	Interferon beta-1a		X
J1826, Q3028	Rebif	Interferon beta-1a		X
J1830	Betaseron	Interferon beta-1b		X
J1830	Extavia	Interferon beta-1b		X
J9216	Actimmune	Interferon gamma-1B, recomb		X
J3590	Taltz	Ixekizumab	X	
J0593	Takhzyro	Lanadelumab-flyo	X	
J3590	Ebglyss	Lebrikizumab-lbkz	X	
J3490	Victoza	Liragludtide		X
J3590	Skytrofa	Lonapegsomatropin-tcgd		X
J2170	Increlex,	Mecasermin		X
J2182	Nucala	Mepolizumab	X	
J3590	Otrexup, Rasuvo	Methotrexate (Solution auto-injector non-chemotherapeutic)		X
J3490	Myalept	Metreleptin		X
J2267*	Omvoh	Mirikizumab-mrkz		X
J3590	Nemluvio	Nemolizumab-ilto	X	
J3590*	Kesimpta	Ofatumumab	X	
J3490	Tryngolza	Olezarsen	X	
J2357	Xolair	Omalizumab	X	
J3490	Yorvipath	Palopegteriparatide	X	
J3490	Natpara	Parathyroid hormone		X
J3490	Signifor	Pasireotide diaspartate		X
J9999/J3590	Sylatron, Pegintron	Peginterferon alfa 2-b		X
J3590, S0145	Pegasys	Peginterferon alfa-2A		X
J3590	Somavert	Pegvisomant		X
J3590	Plegridy	Pegylated interferon		X
J3490	Symlin	Pramlintide acetate		X
J3590*	Skyrizi (subq)	Risankizumab		X
J9999	Besremi	Ropeginterferon alfa-2b	X	
J3590	Kevzara	Sarilumab	X	

HCPCS	Brand Name	Generic Name	Medical Transition Available	Pharmacy Benefit Only
J3590	Enspryng	Satralizumab-mwge	X	
J3590	Cosentyx (subq)	Secukinumab	X	
J3490	Ozempic	Semaglutide		X
J3490	Wegovy	Semaglutide		X
J2940	Protropin	Somatrem		X
J2941	All Recombinant Human Growth Hormone Products	Somatropin (Recombinant Human Growth Hormone)		X
J3590	Winrevair	Sotatercept-csrk	X	
J1747*	Spevigo	Spesolimab-sbzo	X	
J3030	Imitrex	Sumatriptan succinate		X
J3490	Gattex	Teduglutide		X
J3110	Forteo	Teriparatide		X
J2356	Tezspire	Tezepelumab-ekko	X	
J3490	Mounjaro	Tirzepatide		X
J3490	Zepbound	Tirzepatide		X
J3590-JB, J3262-JB	Actemra prefilled syr or ACTpen	Tocilizumab		X
Q5135*	Tyenne	Tocilizumab-aazg	X	
J3590	Adbry	Tralokinumab	X	
J3357	Stelara	Ustekinumab		X
Q9999	Otulfi	Ustekinumab-aauz		X
Q9998*	Selarsdi	Ustekinumab-aekn		X
Q5137	Wezlana	Ustekinumab-auub		X
J3590, C9399	Starjemza	Ustekinumab-hmny		X
Q5100	Yesintek	Ustekinumab-kfce		X
Q5098	Imuldosa	Ustekinumab-srlf		X
Q5099*	SteQeyma	Ustekinumab-stba		X
Q9996	Pyzchiva	Ustekinumab-ttwe		X
J3590	Entyvio Pen	Vedolizumab	X	
J3490	Voxzogo	Vosoritide		X
J3490	Zilbrysq	Zilucoplan	X	

*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