Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCONC102.0421	**ANTINEOPLASTIC AGENTS** **INJECTABLE ANTI-CANCER MEDICATIONS** See Appendix A for Medications covered by policy
Effective Date: 7/1/2021 **Robert Gluckman, M.D.** **Chief Medical Officer**	Review/Revised Date: 04/16, 07/16, 12/16, 01/17, 08/17,12/17, 04/18, 12/18, 01/19, 08/19, 01/20, 01/20, 06/20, 07/20, 09/20, 12/20, 01/21, 03/21 (JH/JLS) P&T Committee Meeting Date: 04/16, 08/16, 02/16, 02/17, 06/17, 08/17, 10/17, 02/18, 04/18, 12/18, 02/19, 06/19, 08/19, 10/19, 12/19, 02/20, 04/20, 06/20, 08/20, 10/20, 12/20, 02/21, 04/21 Original Effective Date: 10/16 Approved by: Oregon Region Pharmacy and Therapeutics Committee Page 1 of 7

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

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

For off-label use criteria, please see the Chemotherapy Treatment Utilization Criteria; Coverage for Non-FDA Approved Indications ORPTCOPS105.

For bevacizumab given via intravitreal injection: See payment policy 97.0 Compound Drugs Administered in the Physician's Office

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. For requests for trastuzumab or bevacizumab: Documented trial and failure, intolerance, or contraindication to the use of both of the preferred biosimilar medications, as follows:
    a. Trastuzumab preferred products: Ogivri® (trastuzumab-dkst) and Kanjinti® (trastuzumab-anns)

b. Bevacizumab preferred products: Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb)

For patients established on therapy: documentation of adequate response to the medication must be provided.

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with an oncologist

COVERAGE DURATION:
Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.

For off-label use criteria please see the Chemotherapy Treatment Utilization Criteria; Coverage for Non-FDA Approved Indications ORPTCOPS105.

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:
Medications used in the treatment of cancer pose a risk for serious side effects; their efficacy is indeterminate outside of indications for which clinical trial evidence available. Additionally, many medications to treat cancer are high in cost. Prior authorization review of oncology medication allows for an assessment of safety and efficacy data for medication(s) requested for a member.

FDA APPROVED INDICATIONS:
Refer to Micromedex® for FDA approved indications of individual medications.

POSITION STATEMENT:
Use of oncology medications outside of the FDA approved indication may be supported by clinical trial data. National Comprehensive Cancer Network (NCCN) provides evidence-based Clinical Practice Guidelines in Oncology (NCCN Guidelines®) steered by consensus from a panel of subspecialists. FDA labeled and non-FDA approved indications are included. Guidelines are reviewed annually and updated as new data becomes available. The NCCN Drugs & Biologics Compendium (NCCN Compendium®), based directly on NCCN Guidelines®, lists indications for each individual medication for which there is a recommendation for use, with the category of recommendation (see description below) included. The NCCN Guidelines® and NCCN Compendium® are intended to aid clinicians and payers in decisions regarding treatment of cancer.

National Comprehensive Cancer Network (NCCN) Categories for Recommendations

	Description of Evidence and Consensus
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

The NCCN Compendium® is one reference utilized in Providence Health Plan's coverage determination process, based on the operational policy: Chemotherapy Treatment Utilization Criteria; Coverage for Non-FDA Approved Indications ORPTCOPS105.

REFERENCE/RESOURCES:

1. About the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). https://www.nccn.org/professionals/physician_gls/default.aspx Accessed January 20, 2020.

2. NCCN Categories of Evidence and Consensus. http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp. Accessed January 8, 2019.
3. Micromedex: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc.; Updated periodically.

APPENDIX A

Medication Brand Name	Generic Name	Jcode
Bevacizumab		
Preferred products		
Zirabev®	bevacizumab-bvzr	Q5118
Mvasi®	bevacizumab-awwb	Q5107
Non-preferred products		
Avastin®	bevacizumab	J9035
Trastuzumab		
Preferred products		
Ogivri®	trastuzumab-dkst	Q5114
Kanjinti	trastuzumab-anns	Q5117
Non-preferred products		
Herceptin®	trastuzumab	J9355
Herzuma®	trastuzumab-pkrb	Q5113
Ontruzant®	trastuzumab-dttb	Q5112
Trazimera®	trastuzumab-gyyp	Q5116
Herceptin Hylecta®	trastuzumab and hyaluronidase-oysk	J9356
All other medications covered by policy		
Abraxane®	paclitaxel, albumin bound	J9264
Actimmune®	interferon gamma-1B subcutaneous injection	J9216
Adcetris®	brentuximab vedotin	J9042
Aliqopa®	copanlisib	C9030/J9057
Alkeran®	melphalan	J9245
Arranon®	nelarabine	J9261

Arzerra®	ofatumumab	J9302
Asparlas®	calaspargase pegol-mknl	J9118
Azedra®	Iobenguane iodine-131	A9699/C9408
Bavencio®	avelumab	J9023
Beleodaq®	belinostat	J9032
Bendeka®	bendamustine	J9034
Besponsa®	inotuzumab ozogamicin	J9229
Blenrep®	belantamab mafodotin-blmf	C9069
Blincyto®	blinatumomab	J9039
Cyramza®	ramucirumab	J9308
Dacogen®	decitabine	J0894
Danyelza®	naxitamab-gqgk	J3590/J9999/ C9399
Darzalex™	daratumumab	J9145
Darzalex Faspro®	daratumumab and hyaluronidase-fihj	C9062/J9144
Empliciti®	elotuzumab lyophilized	J9176
Enhertu® (not interchangeable with other trastuzumab products)	fam-trastuzumab deruxtecan-nxki	J9358
Erbitux®	cetuximab	J9055
Faslodex®	fulvestrant	J9395
Folotyn®	pralatrexate	J9307
Halaven®	eribulin mesylate	J9179
Imfinzi®	durvalumab	C9492/J9173
Imlygic®	talimogene laherparepvec for intralesional injection	J9325
Istodax®	romidepsin	J9315
Ixempra®	ixabepilone	J9207
Jelmyto®	Mitomycin pyelocalyceal solution	J9281
Jevtana®	cabazitaxel	J9043
Kadcyla® (not	ado-trastuzumab emtansine	J9354

interchangeable with other trastuzumab products)		
Keytruda®	pembrolizumab	J9271
Kyprolis®	carfilzomib	J9047
Lartruvo®	olaratumab	J9285
Libtayo®	cemiplimab-rwlc	J9119, C9044
Lumoxiti®	moxetumomab pasudotox-tdfk	J9313
Lutathera®	lutetium lu^{177} dotatate	C9031/A9513
Monjuvi®	tafasitamab-cxix	C9070
Onivyde®	liposomal irinotecan	J9205
Opdivo®	nivolumab	J9299
Padcev®	enfortumab vedotin-ejfv	J9177
Perjeta®	pertuzumab	J9306
Phesgo®	pertuzumab, trastuzumab, hyaluronidase-zzxf	J9316
Polivy®	Polatuzumab vedotin-piiq	J9309
Portrazza®	necitumumab	J9295
Poteligeo®	mogamulizumab-kpkc	C9038/J9204
Sarclisa®	isatuximab	J9227
Sylatron ®	peginterferon alfa-2b subcutaneous injection	J9999/C9399
Synribo®	omacetaxine subcutaneous injection	J9262
Tecentriq®	atezolizumab	J9022
Temodar® IV	temozolomide	J9328
Torisel®	temsirolimus	J9330
Treanda®	bendamustine	J9033
Vectibix®	panitumumab	J9303
Velcade®	bortezomib	J9041
Vidaza®	azacitidine	J9025
Vyxeos®	daunorubicin/cytarabine liposomal	C9024/ J9153
Xofigo®	radium-223	A9606

Yervoy®	ipilimumab	J9228
Yondelis®	trabectedin	J9352
Zaltrap®	ziv-aflibercept	J9400
Zepzelca®	lurbinectedin	J9223