Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION AND STEP THERAPY POLICY AND CRITERIA ORPTCONC102B.0224	**ANTINEOPLASTIC AGENTS** **ANTI-CANCER MEDICATIONS – MEDICAL BENEFIT** See Appendix A for Medications covered by policy
Effective Date: 4/1/2024	**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, 05/21, 07/21, 08/21, 12/21, 01/22, 05/22, 08/22, 01/23, 06/23, 08/23, 10/23, 11/23, 01/24 (JCN)
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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:
Medicare Part B

POLICY CRITERIA:

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

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

REQUIRED MEDICAL INFORMATION:
1. For initiation of therapy (new starts):
    a. Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
    b. For non-preferred trastuzumab products (see Appendix A): Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Ogivri® (trastuzumab-dkst) and Trazimera® (trastuzumab-qyyp)
    c. For non-preferred bevacizumab products (see Appendix A): Documented trial and failure, intolerance, or contraindication to the use of both of the preferred products, Mvasi® (bevacizumab-bvzr) and Zirabev® (bevacizumab-awwb)

2. For patients established on the requested product (within the previous year): 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 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 13, 2022.
2. NCCN. Development and Update of Guidelines. https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines Accessed January 5, 2023.
3. Micromedex: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc.; Updated periodically.

PHARMACY PRIOR AUTHORIZATION AND STEP THERAPY POLICY AND CRITERIA ORPTCONC102B	ANTINEOPLASTIC AGENTS ANTI-CANCER MEDICATIONS – MEDICAL BENEFIT See Appendix A for Medications covered by policy

Appendix A

Medication Brand Name	Generic Name	HCPCS Code
Bevacizumab		
Preferred products		
Mvasi®	bevacizumab-awwb	Q5107
Zirabev®	bevacizumab-bvzr	Q5118
Non-preferred products (STEP THERAPY APPLIES)		
Alymsys®	bevacizumab-maly	Q5126
Avastin®	bevacizumab	J9035
Vegzelma	bevacizumab-adcd	Q5129
Trastuzumab		
Preferred products		
Ogivri®	trastuzumab-dkst	Q5114
Trazimera®	trastuzumab-gyyp	Q5116
Non-preferred products (STEP THERAPY APPLIES)		
Herceptin®	trastuzumab	J9355
Herceptin Hylecta®	trastuzumab and hyaluronidase-oysk	J9356
Herzuma®	trastuzumab-pkrb	Q5113
Kanjinti	trastuzumab-anns	Q5117
Ontruzant®	trastuzumab-dttb	Q5112
All other medications covered by policy		
Abraxane®	paclitaxel, albumin bound	J9264/J9258/J9259
Adcetris®	brentuximab vedotin	J9042
Adstiladrin®	nadofaragene firadenovec-vncg	J9029
Aliqopa®	copanlisib	J9057
Alkeran®	melphalan	J9245
Arranon®	nelarabine	J9261
Arzerra®	ofatumumab	J9302
Asparlas®	calaspargase pegol-mknl	J9118
Azedra®	Iobenguane iodine-131	A9590

Bavencio®	avelumab	J9023
Beleodaq®	belinostat	J9032
Belrapzo®	bendamustine HCl	J9036
Bendamustine HCl	bendamustine HCl	J9058
Bendeka®	bendamustine	J9034
Besponsa®	inotuzumab ozogamicin	J9229
Blenrep®	belantamab mafodotin-blmf	J9037
Blincyto®	blinatumomab	J9039
Columvi®	Glofitamab-gxbm	J9286
Cosela®	trilaciclib dihydrochloride	J1448
Cyramza®	ramucirumab	J9308
Dacogen®	decitabine	J0893/J0894
Danyelza®	naxitamab-gqgk	J9348
Darzalex™	daratumumab	J9145
Darzalex Faspro®	daratumumab and hyaluronidase-fihj	J9144
Elahere	mirvetuximab soravtansine-gynx	J9063
Elzonris®	tagraxofusp-erzs	J9269
Empliciti®	elotuzumab lyophilized	J9176
Enhertu® (not interchangeable with other trastuzumab products)	fam-trastuzumab deruxtecan-nxki	J9358
Epkinly®	Epcoritamab-bysp	J9321
Erbitux®	cetuximab	J9055
Evomela	melphalan hcl/betadex sulfobutyl ether sodium	J9246
Faslodex®	fulvestrant	J9393/J9394/J9395
Folotyn®	pralatrexate	J9307
Fyarro®	sirolimus protein-bound	J9331
Halaven®	eribulin mesylate	J9179
Imfinzi®	durvalumab	J9173
Imjudo®	tremelimumab-actl	J9347

Imlygic®	talimogene laherparepvec for intralesional injection	J9325
Istodax®	romidepsin	J9319
Ixempra®	ixabepilone	J9207
Jelmyto®	Mitomycin pyelocalyceal solution	J9281
Jemperli®	Dostarlimab	J9272
Jevtana®	cabazitaxel	J9043, J9064
Kadcyla® (not interchangeable with other trastuzumab products)	ado-trastuzumab emtansine	J9354
Keytruda®	pembrolizumab	J9271
Kimmtrak®	Tebentafusp-tebn	J9274
Kyprolis®	carfilzomib	J9047
Libtayo®	cemiplimab-rwlc	J9119
Loqtorzi®	toripalimab-tpzi	J9999, C9399
Lumoxiti®	moxetumomab pasudotox-tdfk	J9313
Lunsumio®	Mosunetuzumab-axgb	J9350
Lutathera®	lutetium lu^{177} dotatate	A9513
Margenza®	margetuximab-cmkb	J9353
Monjuvi®	tafasitamab-cxix	J9349
Mylotarg®	gemtuzumab ozogamicin	J9203
Onivyde®	liposomal irinotecan	J9205
Opdivo®	nivolumab	J9299
Opdualag®	nivolumab/relatilimab-RMBW	J9298
Padcev®	enfortumab vedotin-ejfv	J9177
Pedmark®	Sodium thiosulfate	J0208
Perjeta®	pertuzumab	J9306
Phesgo®	pertuzumab, trastuzumab, hyaluronidase-zzxf	J9316
Pluvicto®	Lutetium lu-177 vipivotide tetraxetan	A9607

Polivy®	Polatuzumab vedotin-piiq	J9309
Portrazza®	necitumumab	J9295
Poteligeo®	mogamulizumab-kpkc	J9204
romidepsin	romidepsin	J9318
Rybrevant®	amivantamab	J9061
Rylaze®	asparaginase erwinia chrysanthemi (recombinant)-rywn	J9021
Sarclisa®	isatuximab	J9227
Tecentriq®	atezolizumab	J9022
Tivdak	Tisotumab vedotin-tftv	J9273
Torisel®	temsirolimus	J9330
Treanda®	bendamustine	J9033
Trodelvy®	sacituzumab govitecan-hziy	J9317
Vectibix®	panitumumab	J9303
Velcade®	bortezomib	J9041, J9046, J9048, J9049, J9051
Vidaza®	azacitidine	J9025
Vivimusta®	bendamustine HCl	J9056
Vyxeos®	daunorubicin/cytarabine liposomal	J9153
Xofigo®	radium-223	A9606
Yervoy®	ipilimumab	J9228
Yondelis®	trabectedin	J9352
Zaltrap®	ziv-aflibercept	J9400
Zepzelca®	lurbinectedin	J9223
Zynlonta®	loncastuximab tesirine	J9359
Zynyz®	Retifanlimab-dlwr	J9345