

<b>Policy and Procedure</b>	
<b>PHARMACY PRIOR AUTHORIZATION AND STEP THERAPY POLICY AND CRITERIA ORPTCONC102B.0226</b>	<b>ANTINEOPLASTIC AGENTS ANTI-CANCER MEDICATIONS – MEDICAL BENEFIT</b> See <a href="#">Appendix A</a> for Medications covered by policy
<b>Effective Date: 4/1/2026</b>	<b>Review/Revised Date:</b> 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, 04/24, 08/24, 10/24, 12/24 (MTW/JCN), 01/25, 03/25, 06/25, 08/25, 10/25, 01/26 (JEF)
<b>Original Effective Date: 10/16</b>	<b>P&amp;T Committee Meeting Date:</b> 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, 06/21, 08/21, 10/21, 12/21, 02/22, 06/22, 08/22, 10/22, 12/22, 02/23, 06/23, 08/23, 10/23, 12/23, 02/24, 08/24, 10/24, 12/24, 02/25, 04/25, 06/25, 08/25, 10/25, 02/26
<b>Approved by: Oregon Region Pharmacy and Therapeutics Committee</b>	

**SCOPE:**

Providence Health Plan and Providence Health Assurance 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 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:**

1. For initiation of therapy, all the following criteria must be met:
  - a. Use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network (NCCN) guidelines with recommendation 2A or higher
  - b. Dosing and frequency are within FDA-labeled guidelines or supported by NCCN guidelines
  - c. The following drug-specific criteria must be met:
    - i. For non-preferred trastuzumab products (see [Appendix A](#)): Documented trial and failure, intolerance, or contraindication to the use of all of the preferred products, Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp)

**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

- ii. 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)
  - iii. For Docivyx (docetaxel) and Beizray (doxorubicin/albumin): Documented trial and failure, intolerance, or contraindication to the use of preferred product docetaxel (Taxotere) premedicated with oral corticosteroids
  - iv. For Boruzu (bortezomib): Documented trial, failure, intolerance, or contraindication to both generic bortezomib and Velcade (bortezomib)
  - v. For Kyxata (carboplatin): Documented trial, failure, intolerance, or contraindication to generic carboplatin
  - vi. For Avgemsi (gemcitabine): Documented trial, failure, intolerance, or contraindication to generic gemcitabine
2. For patients established on the requested product (within the previous year), the following must be met:
- a. Dosing and frequency must be in accordance with FDA-approved labeling or supported by NCCN guidelines
  - b. Documentation of adequate response to the medication must be provided, such as disease stability or positive response to therapy
  - c. Treatment regimen has been previously approved for coverage or use is supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher

**EXCLUSION CRITERIA:** N/A

**AGE RESTRICTIONS:** N/A

**PRESCRIBER RESTRICTIONS:**

All others: Must be prescribed by, or in consultation with an oncologist

**COVERAGE DURATION:**

For Aphexda: Initial authorization will be approved for three months. No reauthorization will be allowed for Aphexda; initial authorization criteria must be met.

For all other medications: Initial authorization will be approved for one year. Reauthorization will be approved for one year.

**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

*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
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**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

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](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.

Appendix A

HCPCS	Coding Description	Brand Name
<b>Bevacizumab</b>		
Preferred products		
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	Mvasi
Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg	Zirabev
Non-preferred products (STEP THERAPY APPLIES)		
Q5126	Injection, bevacizumab-maly, biosimilar, (alymys), 10 mg	Alymsys
J9035	Injection, bevacizumab, 10 mg	Avastin
Q5160	Injection, bevacizumab-ngwd, 10 mg	Jobevne
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	Vegzelma

**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

<b>Bortezomib</b>		
Preferred products		
J9041	Injection, bortezomib, 0.1 mg	Velcade
Non-preferred products		
J9054	Injection, bortezomib (boruzu), 0.1 mg	Boruzu
<b>Docetaxel</b>		
Preferred products		
J9171	Injection, docetaxel, 1 mg	Taxotere
Non-preferred products		
J9172	Injection, docetaxel (docivyx), 1 mg	Docivyx
J9174	Injection, doxetacel (beizray), 1 mg	Beizray
<b>Trastuzumab</b>		
Preferred products		
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	Ogivri
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	Ontruzant
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	Trazimera
Non-preferred products (STEP THERAPY APPLIES)		
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg	Herceptin
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	Herceptin Hylecta
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	Herzuma
Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg	Hercessi
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	Kanjinti
<b>All other medications covered by policy</b>		
J9264	Injection, paclitaxel protein-bound particles, 1 mg	Abraxane
J9042	Injection, brentuximab vedotin, 1 mg	Adcetris
J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	Adstiladrin
J9057	Injection, copanlisib, 1 mg	Aliqopa
J9245	Injection, melphalan hydrochloride, not otherwise specified, 50 mg	PharmaCompass/Meitheal Pharmaceuticals/Hemarsh Technologies/Dravyom Chemical Company melphalan (brand is obsolete)

**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

J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	Anktiva
J2277	Injection, motixafortide, 0.25 mg	Aphexda
J9261	Injection, nelarabine, 50 mg	Arranon
C9399, J9999	Injection, gemcitabine hydrochloride, 200 mg	Avgemsi
J9118	Injection, calaspargase pegol-mknl, 10 units	Asparlas
J9023	Injection, avelumab, 10 mg	Bavencio
J9174	Injection, docetaxel (beizray), 1 mg	Beizray
J9032	Injection, belinostat, 10 mg	Beleodaq
J9036	Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg	Belrapzo
J9034	Injection, bendamustine hcl (bendeka), 1 mg	Bendeka
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	Besponsa
J9382	Injection, zenocutuzumab-zbco, 1 mg	Bizengri
J9999, C9399	Unclassified drugs or biologicals	Blenrep
J9049	Injection, bortezomib (hospira), not therapeutically equivalent to J9041, 0.1 mg	Hospira 505(b)(2) bortezomib
J9051	Injection, bortezomib (maia), not therapeutically equivalent to J9041, 0.1 mg	Maia/Fosun 505(b)(2) bortezomib
J9064	Injection, cabazitaxel (sandoz), not therapeutically equivalent to J9043, 1 mg	Sandoz 505(b)(2) cabazitaxel
J1448	Injection, trilaciclib, 1 mg	Cosela
J9308	Injection, ramucirumab, 5 mg	Cyramza
J0894	Injection, decitabine, 1 mg	Dacogen
J9348	Injection, naxitamab-gqqgk, 1 mg	Danyelza
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	Darzalex Faspro
J9145	Injection, daratumumab, 10 mg	Darzalex
J9011	Injection, datopotamab deruxtecan-dlnk, 1 mg	Datroway
J0893	Injection, decitabine (sun pharma), not therapeutically equivalent to j0894, 1 mg	Sun Pharma 505(b)(2) decitabine
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	Elahere
J9269	Injection, tagraxofusp-erzs, 10 micrograms	Elzonris
J9176	Injection, elotuzumab, 1 mg	Empliciti
J9326	Injection, telisotuzumab vedotin-tllv, 1 mg	Emrelis
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	Enhertu (not interchangeable with other trastuzumab products)
J9055	Injection, cetuximab, 10 mg	Erbix

**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

J9246	Injection, melphalan (evomela), 1 mg	Evomela
J9395	Injection, fulvestrant, 25 mg	Faslodex
J9307	Injection, pralatrexate, 1 mg	Folotyn
J9394	Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg	Fresenius Kabi 505(b)(2) fulvestrant
J9331	Injection, sirolimus protein-bound particles, 1 mg	Fyarro
J0614	Injection, treosulfan, 50 mg	Grafapex
J9179	Injection, eribulin mesylate, 0.1 mg	Halaven
J9248	Injection, melphalan (hepzato), 1 mg	Hepzato
J9173	Injection, durvalumab, 10 mg	Imfinzi
J9347	Injection, tremelimumab-actl, 1 mg	Imjudo
J9325	Injection, talimogene laherparepvec, per 1 million plaque forming units	Imlygic
C9399/J9999	Gemcitabine (intravesical)	Inlexzo
J9319	Injection, romidepsin, lyophilized, 0.1 mg	Istodax
J9999	Not otherwise classified, antineoplastic drugs	Ivra
J9207	Injection, ixabepilone, 1 mg	Ixempra
J9281	Mitomycin pyelocalyceal instillation, 1 mg	Jelmyto
J9272	Injection, dostarlimab-gxly, 10 mg	Jemperli
J9043	Injection, cabazitaxel, 1 mg	Jevtana
J9354	Injection, ado-trastuzumab emtansine, 1 mg	Kadcyla (not interchangeable with other trastuzumab products)
J9271	Injection, pembrolizumab, 1 mg	Keytruda
J9047	Injection, carfilzomib, 1 mg	Kyprolis
C9399, J9999	Injection, carboplatin (Kyxata), 1 mg	Kyxata
J9119	Injection, cemiplimab-rwlc, 1 mg	Libtayo
J3263	Injection, toripalimab-tpzi, 1 mg	Loqtorzi
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	Lutathera
J9161	Injection, denileukin diftitox-cxdl, 1 mcg	Lymphir
J9353	Injection, margetuximab-cmkb, 5 mg	Margenza
J9349	Injection, tafasitamab-cxix, 2 mg	Monjuvi
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	Mylotarg
J9205	Injection, irinotecan liposome, 1 mg	Onivyde
J9299	Injection, nivolumab, 1 mg	Opdivo
J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy	Opdivo Qvantig
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	Opdualag

**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

J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	Padcev
J0208	Injection, sodium thiosulfate (pedmark), 100 mg	Pedmark
J9306	Injection, pertuzumab, 1 mg	Perjeta
J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	Phesgo
A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	Pluvicto
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	Polivy
J9295	Injection, necitumumab, 1 mg	Portrazza
J9204	Injection, mogamulizumab-kpkc, 1 mg	Poteligeo
J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	Teva 505(b)(2)
J9061	Injection, amivantamab-vmjw, 2 mg	Rybrevant
J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	Rylaze
J9227	Injection, isatuximab-irfc, 10 mg	Sarclisa
J9022	Injection, atezolizumab, 10 mg	Tecentriq
J9024	Injection, atezolizumab, 5 mg and hyaluronidase-tqjs	Tecentriq Hybreza
J9329	Injection, tislelizumab-jsgr, 1mg	Tevimbra
J9273	Injection, tisotumab vedotin-tftv, 1 mg	Tivdak
J9330	Injection, temsirolimus, 1 mg	Torisel
J9033	Injection, bendamustine hydrochloride, 1 mg	Treanda
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	Trodelyv
J9275	Injection, cosibelimab-ipdl, 2 mg	Unloxcyt
J9303	Injection, panitumumab, 10 mg	Vectibix
J9025	Injection, azacitidine, 1 mg	Vidaza
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	Vivimusta
J1326	Injection, zolbetuximab-clzb, 2 mg	Vyloy
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	Vyxeos
A9606	Radium ra-223 dichloride, therapeutic, per microcurie	Xofigo
J9228	Injection, ipilimumab, 1 mg	Yervoy
J9352	Injection, trabectedin, 0.1 mg	Yondelis
J9400	Injection, ziv-aflibercept, 1 mg	Zaltrap
J9223	Injection, lurbinectedin, 0.1 mg	Zepzelca
J9276	Injection, zanidatamab-hrii, 2 mg	Ziihera
J9282	Mitomycin, intravesical instillation, 1 mg	Zusduri
J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	Zynlonta

**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

J9345	Injection, retifanlimab-dlwr, 1 mg	Zynyz
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<b>ADMINISTRATION CODES</b> ◇		
50391	Instill rx agnt into rnal tub	
50684	Injection for ureter x-ray	
51720	Treatment of bladder lesion	
52005	Cystoscopy & ureter catheter	
67028	Injection eye drug	
79101	Nuclear rx iv admin	
96372	Ther/proph/diag inj sc/im	
96374	Ther/proph/diag ing iv push	
96365	Ther/proph/diag iv inf init	
96366	Ther/proph/diag iv inf addon	
96401	Chemo anti-neopl sq/im	
96402	Chemo hormon antineopl sq/im	
96409	Chemo iv push sngl drug	
96411	Chemo iv push addl drug	
96413	Chemo iv infusion 1 hr	
96415	Chemo iv infusion addl hr	
96422	Chemo ia infusion up to 1 hr	
11900	Inject skin lesions </w 7	
11901	Inject skin lesions >7	

◇ Coding/Administration Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations
- Medications listed in medical billing table are subject to claim audit to ensure dosing is within FDA labeling or compendia supported guidelines.