

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Cancer	LAST REVIEW	9/11/18
THERAPEUTIC CLASS	Oncology	REVIEW HISTORY	5/17, 5/16
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Oncology medications account for one of the largest drug category spend in the United States. In more recent years, drug innovative companies have had tremendous success—releasing numerous new drugs on the market each year—with the latest goal to develop targeted cancer tumor cells as opposed to the traditional, cytotoxic chemotherapy agents. The below criteria, limits, and requirements for HPSJ’s formulary oncology agents.

****Note:** *This coverage policy strictly reviews the agents used specifically for the treatment or management of cancer. For **Antiemetic Agents**, please refer to Coverage Policy – Gastrointestinal Disorders – Nausea. For **ESAs** (i.e. Epogen), please refer to Coverage Policy – Renal – Anemia.*

Formulary Chemotherapy Agents: (Current as of 6/2018)

Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days
Alkylating Agents	Altretamine (Hexalen) Capsule	50mg	PA, SP	\$3,604.52*
	Busulfan (Myleran, Busulfex) Tablet, IV	PO: 2mg IV: 60mg/10ml	PA, SP	\$35982.0*
	Carmustine (BiCNU) IV	100mg Vial	PA, SP	\$3084.3*
	Chlorambucil (Leukeran) Tablet	2mg	PA, SP	\$368.89*
	Cyclophosphamide Capsule	25mg, 50mg	--	\$585.32
	Cyclophosphamide Vial	500mg	--	\$854.58
	Estramustine (Emcyt) Capsule	140mg	PA, SP	\$3,372.60*
	Hydroxyurea (Hydrea) Capsule	500mg	--	\$42.87
	Lomustine (Ceenu) Capsule	10mg, 40mg, 100mg	PA, SP	\$1,775.58
	Melphalan (Alkeran) Tablet	2mg	PA, SP	\$2,335.5*
	Oxaliplatin (Eloxatin) IV	50mg/10ml, 100mg/20ml	PA, SP	\$352.92*
	Procarbazine (Matulane) Capsule	50mg	PA	\$2,429.63
	Streptozocin (Zanosar)	1gram	PA, SP	\$1676.00
Temozolomide (Temodar) Capsule, IV	PO: 5mg, 20mg, 100mg, 140mg, 280mg 250mg IV: 100mg	PA, SP	\$1,415.85	
Anti-androgens	Bicalutamide (Casodex) Tablet	50mg	--	\$20.12
	Nilutamide (Nilandron) Tablet	150mg	PA, SP	\$8,696.34*
	Flutamide (Euflex) Capsule	125mg	PA, SP	\$231.61
Antineoplastic Antibiotic	Bleomycin Sulfate (Blenoxane) IV	15 unit, 30 unit	PA, SP	\$440.00*
	Dactinomycin (Cosmegen) IV	0.5 mg	PA, SP	\$3,040.50*
	Mitomycin (Mutamycin) IV	5mg, 20mg, 40mg	PA, SP	\$1,415.64*

Monoclonal Antibody	Anti-CD20	Rituximab (Rituxan) <i>IV</i>	10mg/ml	PA, SP	\$12,624.69*
	Anti-HER2+	Pertuzumab (Perjeta) <i>IV</i>	420mg/14ml	PA, SP	\$18,045.00*
		Trastuzumab (Herceptin) <i>IV</i>	150mg, 440mg	PA, SP	\$9,644.09*
	Anti-PD-L1	Atezolizumab (Tecentriq) <i>IV</i>	1200 mg/20 mL	PA, SP	\$10,656.65*
		Avelumab (Bavencio) <i>IV</i>	200 mg/10 ml	PA, SP	\$1,859.52*
		Durvalumab (Imfinzi)	120mg/2.4ml, 500mg/10ml	PA,SP	\$11,774.00*
	EGFR Inhibitor	Cetuximab (Erbix) <i>IV</i>	200mg/100ml	PA, SP	\$17,583.58*
		Necitumumab (Portrazza) <i>IV</i>	800mg/50ml	PA, SP	\$20,372.00*
		Panitumumab (Vectibix) <i>IV</i>	100mg/5ml	PA, SP	\$11,969.40*
	VEGF Inhibitor	Bevacizumab (Avastin) <i>IV</i>	100 mg/4 ml, 400 mg/16 ml	PA, SP	\$3,346.00*
Anti-metabolites	Capecitabine (Xeloda) <i>Tablet</i>	150mg, 500mg	PA, SP	\$1,552.78*	
	Fluorouracil (Carac, Efudex) <i>Cream, Solution</i>	Cream: 0.05%, 0.1%, 0.5% Solution: 0.2%, 0.5%	--	\$63.45	
	Mercaptopurine <i>Tablet</i>	50mg	--	\$95.35	
	Methotrexate <i>Tablet, SQ</i>	PO: 2.5mg SQ: 25mg/ml	--	\$58.91	
	Pemetrexed (Alimta) <i>IV</i>	100mg, 500mg	PA, SP	\$7,022.47*	
	Thioguanine (Tabloid) <i>Tablet</i>	40mg	PA, SP	\$902.39*	
Aromatase Inhibitors	Anastrozole <i>Tablet</i>	1mg	--	\$6.81	
	Exemestane (Aromasin) <i>Tablet</i>	25mg	PA, SP	\$292.89	
	Letrozole <i>Tablet</i>	2.5mg	--	\$9.01	
MEK inhibitor	Cobimetinib Fumarate (Cotellic) <i>Tablet</i>	20 mg	PA, SP	\$6,677.33*	
	Trametinib Dimethyl Sulfoxide (Mekinist) <i>Tablet</i>	0.5mg, 2mg	PA, SP, 2mg	\$10,832.36*	
mTOR Kinase Inhibitor	Everolimus (Afinitor) <i>Tablet</i>	2.5mg, 5mg 7.5mg, 10mg	PA, SP	14,179.76	
Topoisomerase I Inhibitor	Irinotecan HCl (Camptosar) <i>IV</i>	40mg/2ml, 300mg/15ml	PA, SP	\$207.60	
	Irinotecan Liposomal (Onivyde) <i>IV</i>	43mg/10ml	PA, SP	\$13,234.26*	
	Topotecan (Hycamtin) <i>Capsule, IV</i>	PO: 0.25mg 1mg IV: 4mg/4mL	PA, SP	\$9,589.39*	
Topoisomerase II Inhibitor	Etoposide (Etopophos) <i>Capsule, Vial</i>	PO: 50mg IV: 100mg	PA, SP	\$154.77*	
	Mitoxantrone <i>Vial</i>	2mg/ml	PA, SP	\$121.75*	
	Daunorubicin (Cerubidine) <i>IV</i>	5 mg/ml	PA, SP	--	
	Doxorubicin (Adriamycin) <i>IV</i>	10mg, 50mg, 2mg/ml	PA, SP	\$819.14	
	Epirubicin (Ellence) <i>IV</i>	50mg, 200mg, 50mg/25ml	PA, SP	\$13,909.20*	
	Idarubicin (Idamycin) <i>IV</i>	1mg/ml	PA, SP	\$ 3057.60	
	Valrubicin (Valstar) <i>IV</i>	40mg/ml	PA, SP	\$6,635.7	
Angiogenesis Inhibitor	Lenalidomide (Revlimid) <i>Capsule</i>	2.5mg, 5mg, 10mg 15mg, 20mg, 25mg	PA, SP	\$16,060.65*	

GnRH Agonist	Goserelin Acetate (Zoladex) <i>Implant</i>	3.6mg, 10.8mg	PA, SP	\$726.00
	Histrelin Acetate (Vantas) <i>Kit</i>	50mg	PA, SP	\$4,615.43*
	Leuprolide Acetate (Eligard) <i>Syringe</i>	7.5mg, 22.5mg, 30mg, 45mg	PA, SP	\$542.03
	Leuprolide Acetate (Lupron Depot) <i>Syringe Kit</i>	7.5mg, 22.5mg, 30mg	PA, SP	\$4,209.16
	Leuprolide Acetate <i>Kit</i>	1mg/0.2ml	PA, SP	\$316.8
	Triptorelin Pamoate (Trelstar) <i>Syringe</i>	3.75mg/2ml, 11.25mg/2ml	PA, SP	\$975.89*
Antineoplastic-Enzyme Inhibitors	Bortezomib (Velcade) <i>Vial</i>	3.5mg	PA, SP	\$17,299.30*
	Dasatinib (Sprycel) <i>Tablet</i>	20mg, 50mg, 70mg 80mg 100mg, 140mg	PA, SP	\$13,046.35*
	Erlotinib (Tarceva) <i>Tablet</i>	25mg, 100mg, 150mg	PA, SP	\$8,166.55*
	Imatinib (Gleevec) <i>Tablet</i>	100mg, 400mg	PA, SP	\$4,847.05*
	Lapatinib (Tykerb) <i>Tablet</i>	250mg	PA, SP	\$4,852.90*
	Nilotinib (Tasigna) <i>Tablet</i>	250mg	PA, SP	\$12,053.15*
	Sorafenib (Nexavar) <i>Tablet</i>	200mg	PA, SP	\$22,404.44*
	Sunitinib (Sutent) <i>Capsule</i>	12.5mg, 25mg, 50mg	PA, SP	\$20,423.03
Antineoplastic-Histone Deacetylase Inhibitor	Vorinostat (Zolinza) <i>Capsule</i>	100mg	PA, SP	\$ 18,011.52*
Antineoplastic-Estrogen Receptor Antagonist	Fulvestrant (Faslodex) <i>Intramuscular injection</i>	250mg/5ml	NF	\$1,375.5*
	Tamoxifen <i>Oral Solution, Tablet</i>	IR: 10mg, 20mg Soln: 10mg/5ml	-- Soln is NF	\$17.67
	Tormifene (Fareston) <i>Tablet</i>	60mg	NF	\$1,272.97
Retinoic Acid Derivative	Bexarotene (Targretin)	75 mg	PA, SP	\$35,800
	Tretinoin (Vesanoid) <i>Capsule</i>	10mg	PA, SP	\$2,636.32
Taxane Derivative	Docetaxel (Docefrez) <i>IV</i>	20mg, 80mg	PA, SP	\$139.59*
	Paclitaxel Protein-Bound (Abraxane) <i>IV</i>	100mg	PA, SP	\$3,385.20*
Vinca Alkaloids	Vinblastine Sulfate <i>IV</i>	1mg/ml	PA, SP	\$423.00
	Vincristine Sulfate (Vincasar PFS) <i>IV</i>	1mg/ml	PA, SP	\$81.00
	Vincristine Sulfate Liposomal (Marqibo) <i>IV</i>	5mg/31ml	PA, SP	--
	Vinorelbine Tartrate (Navelbine) <i>IV</i>	10mg/ml	PA, SP	\$2,593.00*
Antineoplastic-Miscellaneous	Asparaginase (Erwinaze) <i>IV</i>	10,000 Unit	PA, SP	\$18,237.40*
	Estramustine (Emcyt) <i>Capsule</i>	140mg	PA, SP	\$3,372.60*
	Ixabepilone (Ixempra) <i>IV</i>	15mg, 45mg	PA, SP	\$ 18,011.84*
	Megestrol Acetate <i>Tablet</i>	20mg, 40mg	--	\$15.72
	Mitotane (Lysodren) <i>Tablet</i>	500mg	PA, SP	\$2,294.78*

Chemotherapy Rescue Agents	Filgrastim (Neupogen, Granix, Zarxio) Syringe, IV	300mcg/ml, 300mcg/0.5ml, 480mcg/0.8ml, 480mcg/1.6ml	PA, SP	\$2,290.31*
	Peg-Filgrastim (Neulasta) Syringe	6mg/0.6ml	PA, SP	\$5,489.94*
	Leucovorin Calcium Tablet	5mg, 10mg, 15mg, 25mg	--	\$49.62
<i>PA = Prior Authorization Required SP = Restricted to Specialty Pharmacy</i> <i>* Based on standard pricing (AWP or MAC); for weight dosing, used 70kg or 1.73m² to estimate standard dose</i> <i>EGFR=Epidermal Growth Factor Receptor VEGF=Vascular Endothelial Growth Factor MEK mitogen-activated extracellular kinase</i>				

⊞ **EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**
For agents that do not have established prior authorization criteria or agents that are “Non-Formulary,” HPSJ will make the determination based on the **National Comprehensive Cancer Network (NCCN) Guidelines** and **Medical Necessity criteria** as described in HPSJ Medical Review Guidelines (UM06)—see below for details.

The following general Medical Necessity criteria are used when there are no diagnosis-or procedure-specific criteria applicable to the situation. All criteria below must be met for the service to be considered medically necessary.

1. The services are prescribed by a licensed health care practitioner practicing within the scope of his/her license in the context of his/her treatment of the individual.
2. The services are safe, effective, and consistent with nationally accepted standards of medical practice.
3. The services are not experimental or investigational.
4. The services are individualized, specific, and consistent with the individual’s signs, symptoms, history, and diagnosis.
5. The services follow peer reviewed evidence based literature that support medical necessity. These services are reasonably expected, in a clinically meaningful way, to:
 - i. Help restore or maintain the individual’s health, or
 - ii. Improve or prevent deterioration of the individual’s disorder or condition, or
 - iii. Delay progression of a disorder or condition characterized by a progressively deteriorating course when that disorder or condition is the focus of treatment for this episode of care.
6. The individual complies with the essential elements of treatment.
7. The services are not primarily for the convenience of the individual, practitioner, caregiver, family, or another party.
8. Services are not being sought as a way to potentially avoid legal proceedings, incarceration, or other legal consequences.
9. The services are not predominantly domiciliary or custodial.
10. No exclusionary criteria are met.

IV Medications—Submitting UM (Medical) Authorization vs. Pharmacy Authorization:

Most IV medications can be covered under both medical and pharmacy benefits—depending the setting of administration. **For IV medications that is to be dispensed through a LTC pharmacy or outpatient pharmacy, please submit a pharmacy authorization.** For all other administration settings (including buy-and-bill), please submit a UM authorization.

How to submit a PHARMACY (RX) prior authorization form for review:

1. Submit request through HPSJ’s **Pharmacy Medication Prior Authorization Request** form which can be obtained from www.hpsj.com
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests
3. Fax both the completed prior authorization form and the clinic documents to HPSJ Pharmacy Department: 209.762.4704.

How to submit a MEDICAL (UM) prior authorization form for review:

1. Submit request through HPSJ's **Medical Authorization Request form** which can be obtained from www.hpsj.com
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests
3. Fax both the completed prior authorization form and the clinic documents to HPSJ Medical Department: 209.942.6302.

Colony Stimulating Factors

1st line—filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta); 2nd line—filgrastim (Neupogen), tbo-filgrastim (Granix)

1st line— filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta)

- Coverage Criteria:** Medical necessity
- Limits:** None
- Required Information for Approval:** filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta) will be approved based upon medical necessity.
- Other Notes:** None

2nd line— filgrastim (Neupogen), tbo-filgrastim (Granix)

- Coverage Criteria:** filgrastim (Neupogen), tbo-filgrastim (Granix) are reserved for documentation of treatment failure of a 1st line agent (filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta)).
- Limits:** None
- Required Information for Approval:** Drug refill history showing fill(s) of a 1st line agent
- Other Notes:** None

Alkylating Agents

Cylophosphamide, Hydroxyurea

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Altretamine, Busulfan, Carmustine, Chlorambucil, Estramustine, Lomustine, Mephalan, Oxaliplatin, Procarbazine, Temozolomide, Streptozocin

- Coverage Criteria:** PA required, approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Anti-androgens

Bicalumide

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Nilutamide, Flutamide

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Antibiotics***Bleomycin Sulfate, Dactinomycin and Mitomycin***

- Coverage Criteria:** PA required, approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Anti-Monoclonal Antibodies***Rituximab, Pertuzumab, Trastuzumab, Atezolizumab, Avelumab, Durvalumab, Cetuximab, Nectinimumab, Panitumumab and Bevacizumab***

- Coverage Criteria:** PA required, approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Anti-metabolites***Flurouracil, Mercaptopurine and Methotrexate***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Capecitabine, Premetrexed, Thioguanine

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Aromatase Inhibitors***Anastrozole, Letrozole***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Exemestane

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

MEK Inhibitors***Cobimetinib, Trametinib***

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

mTOR Inhibitors

Everolimus

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Topoisomerase I Inhibitor

Irinotecan, Topotecan

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Topoisomerase II Inhibitor

Etoposide, Mitoxantrone, Daunorubicin, Doxorubicin, Epirubicin, Idarubicin, Valrubicin

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Angiogenesis Inhibitor

Lenalidomide

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

GnRH Agonist

Goserelin, Histrelin, Leuprolide, Triptorelin

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Enzyme Inhibitors

Bortezomib, Dastinib, Erlotinib, Imatinib, Lapatinib, Nilotinib, Sorafenib, Sunitinib

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Histone Deacetylase Inhibitor

Vorinostat

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Estrogen Receptor Antagonist

Fulvestrant, Tamoxifen, Tormifene

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Retinoic Acid Derivative

Bexarotene, Tretinoin

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Vinca Alkaloids

Vinblastine Sulfate, Vincristine Sulfate, Vinorelbine Tartrate

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

Antineoplastic - Miscellaneous

Asparaginase, Estramustine, Ixabepilone, Megestrol Acetate, Mitotane

- Coverage Criteria:** Approval is determined by medical necessity criteria
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy.

REFERENCES

1. Blackwell K, Semiglazov V, Krasnozhan D, et al. Comparison of EP2006, a filgrastim biosimilar, to the reference: a phase III, randomized, double-blind clinical study in the prevention of severe neutropenia in patients with breast cancer receiving myelosuppressive chemotherapy. *Ann Oncol.* 2015;26(9):1948-53.

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Oncology – Cancer 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2018-09.docx	9/2018	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy