

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Cancer	LAST REVIEW	3/21/23
THERAPEUTIC CLASS	Oncology	REVIEW HISTORY	12/21, 9/20, 9/19, 9/18,
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	5/17, 5/16

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.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Oncology medications account for one of the largest drug 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 purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

****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. For **agents that do not have established prior authorization criteria**, 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).*

Formulary Status (Current as of 3/2023)

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Alkylating Agents				
--	Altretamine (Hexalen)	50 mg capsule	Yes	No
J8510	Busulfan (Myleran, Busulfex)	2 mg tablet 60mg/10mL vial	Yes	Yes (PA)
J9130	Dacarbazine	100mg, 200mg vial	Yes	Yes (PA)
--	Procarbazine (Matulane)	50mg capsule	Yes	No
J8700, J9328	Temozolomide (Temodar)	5mg, 20mg, 100mg, 140mg, 250mg, 280mg capsules 100mg vial	Yes	Yes (PA)
Alkylating Agents - Nitrogen Mustard				
J9033, J9034, J9036	Bendamustine (Belrapzo, Bendeka, Treanda)	100mg/4mL vial 25mg, 100 mg vial	Yes	Yes (PA)
--	Chlorambucil (Leukeran)	2mg tablet	Yes	No
J8530, J9070	Cyclophosphamide	25mg, 50mg capsule 500mg, 1G, 2G vial	Yes	Yes (PA)
--	Melphalan (Alkeran)	2mg tablet	Yes	No
Alkylating Agents - Estrogen/Nitrogen Mustard				
--	Estramustine (Emcyt)	140mg capsule	Yes	No
Alkylating Agents - Nitrosurea				
J9050	Carmustine (BiCNU)	100mg vial	Yes	Yes (PA)
--	Lomustine (Ceenu)	10mg, 40mg, 100mg capsule	Yes	No
J9320	Streptozocin (Zanosar)	1G vial	Yes	Yes (PA)
Alkylating Agents - Platinum Analog				
J9045	Carboplatin (Paraplatin)	600mg/60mL vial	Yes	Yes (PA)

J9060	Cisplatin	50mg/50mL vial	Yes	Yes (PA)
J9263	Oxaliplatin (Eloxatin)	50mg/50mL, 100mg/20mL vial	Yes	Yes (PA)
Anti-Androgens				
--	Abiraterone Acetate (Yonsa, Zytiga)	125mg, 250mg, 500mg tablet	Yes	No
--	Apalutamide (Erleada)	60mg tablet	Yes	No
--	Bicalutamide (Casodex)	50mg tablet	Yes	No
--	Enzalutamide (Xtandi)	40mg capsule	Yes	No
--	Nilutamide (Nilandron)	150mg tablet	Yes	No
--	Flutamide (Euflex)	125mg capsule	Yes	No
Antineoplastic Antibiotic				
J9040	Bleomycin Sulfate (Blenoxane)	15 unit, 30 unit, 0.5mg vial	Yes	Yes (PA)
J9120	Dactinomycin (Cosmegen)	0.5mg vial	Yes	Yes (PA)
J9280	Mitomycin (Mutamycin)	5mg, 20mg, 40mg, 200mg vial	Yes	Yes (PA)
Antineoplastic - Histone Deacetylase Inhibitor				
J9032	Belinostat (Beleodaq)	500mg vial	Yes	Yes (PA)
--	Panobinostat (Farydak)	10mg, 20mg capsule	Yes	No
J9318, J9319	RomiDEPsin (Istodax)	10mg, 27.5mg/5.5mL vial	Yes	Yes (PA)
--	Vorinostat (Zolinza)	100mg capsule	Yes	No
Antineoplastic-Estrogen Receptor Antagonist				
J9395	Fulvestrant (Faslodex)	250mg/5mL vial	Yes	Yes (PA)
Antineoplastic-Estrogen Receptor Antagonist - Selective Estrogen Receptor Modulator (SERM)				
--	Tamoxifen (Novadex, Soltamox)	10mg, 20mg tablet 10mg/5mL solution	Yes	No
--	Toremifene (Fareston)	60mg tablet	Yes	No
Antineoplastic Agent, Antimicrotubular				
J9179	Eribulin (Halaven)	1mg/2mL vial	Yes	Yes (PA)
Antineoplastic Agent, Antimicrotubular - Taxane Derivative				
--	Carbazitaxel (Jevtana)	60mg/1.5mL vial	Yes	Yes (PA)
J9171	Docetaxel (Docefrez)	20mg, 20 mg/ml, 20 mg/2 ml, 80 mg, 80 mg/4 ml, 80 mg/8 ml, 160 mg/8 ml, 160 mg/ 16 ml vial	Yes	Yes (PA)
J9267	Paclitaxel	30 mg/5 ml, 100 mg/16.7 ml, 150 mg/25 ml, 300 mg/50 ml vial	Yes	Yes
J9264	Paclitaxel Protein-Bound (Abraxane)	100mg vial	Yes	Yes (PA)
Antineoplastic Agent, Antimicrotubular - Epothilone B Analog				
J9207	Ixabepilone (Ixempra)	15mg, 45mg vial	Yes	Yes (PA)
Antineoplastic Agent, Antimicrotubular - Vinca Alkaloids				
J9360	Vincristine Sulfate (Vincasar PFS)	1mg/mL vial	Yes	Yes (PA)
J9371	Vincristine Sulfate Liposomal (Marqibo)	5mg/31mL vial	Yes	Yes (PA)
J9390	Vinorelbine Tartrate (Navelbine)	10mg/mL, 50mg/5mL vial	Yes	Yes (PA)
EZH2-Inhibitor, Histone Methyltransferase (HMT) Inhibitor				
--	Tazemetostat (Tazverik)	200mg tablet	Yes	No
Nuclear Export Inhibitor				
--	Selinexor (Xpovio)	40mg, 60mg, 80mg, 100mg tablet	Yes	No
Monoclonal Antibody				
J9228	Ipilimumab (Yervoy)	50mg, 200mg vial	Yes	Yes (PA)
J9306	Pertuzumab (Perjeta)	420mg/14mL vial	Yes	Yes (PA)
J9355	Trastuzumab (Herceptin, Kajinti, Ogivri, Trazimera)	150mg, 420mg vial	Yes	Yes (PA)
J9356	Trastuzumab and Hyaluronidase (Herceptin Hylecta)	600mg SQ	Yes	Yes (PA)
Monoclonal Antibody, Antimicrotubular				

J9354	Ado-Trastuzumab emtansine (Kadcyla)	100mg, 160mg vial	Yes	Yes (PA)
Monoclonal Antibody, Anti-PD-L1				
J9022	Atezolizumab (Tecentriq)	840mg/14mL, 1200mg/20mL vial	Yes	Yes (PA)
J9023	Avelumab (Bavencio)	200mg/10mL vial	Yes	Yes (PA)
J9173	Durvalumab (Imfinzi)	120mg/2.4mL, 500mg/10mL vial	Yes	Yes (PA)
Monoclonal Antibody, Anti-CD20				
J9312	Rituximab (Rituxan)	10mg/mL vial	Yes	Yes (PA)
J9311	Rituximab hyaluronidase	10mg vial	Yes	Yes (PA)
Monoclonal Antibody, Topoisomerase I Inhibitor				
J9358	Fam-Trastuzumab Deruxtecan-NXKI (Enhertu)	100mg vial	Yes	Yes (PA)
Monoclonal Antibody, Topoisomerase I & II Inhibitor				
J9317	Sacituzumab Govitecan-HZIY (Trodelvy)	180mg vial	Yes	Yes (PA)
Topoisomerase II Inhibitor				
Q2049, Q2050, J9000	DOXOrubicin (Adriamycin, Myocet)	2mg/mL, 50mg vial	Yes	Yes (PA)
J9178	EpiRUBicin (Ellence)	50mg/25mL, 200mg/100mL vial	Yes	Yes (PA)
Tyrosine Kinase Inhibitor				
--	Tucatinib (Tukysa)	50mg, 150mg tablet	Yes	No
VEGF Inhibitor, Tyrosine Kinase Inhibitor				
--	Axinitib (Inlyta)	1mg, 5mg tablet	Yes	No
--	Cabozantinib (Cabometyx)	20mg, 40mg, 60mg, 100mg, 140mg tablet	Yes	No
--	Lenvatinib (Lenvima)	4mg, 8mg, 10m, 12mg, 14mg, 18mg, 20mg, 24mg tablet	Yes	No
--	Pazopanib (Votrient)	200mg tablet	Yes	No
--	Regorafenib (Stivarga)	40mg tablet	Yes	No
--	Sorafenib (Nexavar)	200mg tablet	Yes	No
--	Sunitinib (Sutent)	12.5mg, 25mg, 50mg tablet	Yes	No
Epidermal Growth Factor Receptor (EGFR) Inhibitor, Tyrosine Kinase Inhibitor				
	Lapatinib (Tykerb)	250mg tablet	Yes	No
	Neratinib (Nerlynx)	40mg tablet	Yes	No
	Erlotinib (Tarceva)	25mg, 100mg, 150mg tablet	Yes	No
Epidermal Growth Factor Receptor (EGFR)				
J9055	Cetuximab (Erbixub) Inhibitor	200mg/100ml vial	Yes	Yes (PA)
J9295	Necitumumab (Portrazza)	800mg/50ml vial	Yes	Yes (PA)
J9303	Panitumumab (Vectibix)	100mg/5ml vial	Yes	Yes (PA)
EGFR, DNA Methylation Inhibitor				
J9025	Azacitidine (Vidaza)	100 mg vial	Yes	Yes (PA)
J0893, J0894	Decitabine (Dacogen)	50 mg vial	Yes	Yes (PA)
Combination Agents				
J9316	Pertuzumab, Trastuzumab, and Hyaluronidase-ZZXF (Phesgo)	60 mg/60 mg/2,000 units/ml, 80 mg/40 mg/2,000 units/ml vial	Yes	Yes (PA)
Anti-CD19/CD3				
J9039	Blinatumomab (Blincyto)	35mcg vial	Yes	Yes (PA)
Anti-CD20				
J9301	Obinutuzumab (Gazyva)	1000mg vial	Yes	Yes (PA)
Anti-CD30				
J9042	Brentuximab Vedotin (Adcetris)	50mg vial	Yes	Yes (PA)
Anti-CD38				
J9145	Daratumumab (Darzalex)	100mg/5mL, 400mg/20mL vial	Yes	Yes (PA)
J9144	Daratumumab and Hyaluronidase-fihj (Darzalex Faspro)	1,800/30,000 units per 15 mL SQ	Yes	Yes (PA)
Anti-PD1 (programmed cell death protein 1)				

J9299	Nivolumab (Opdivo)	40mg/4mL, 100mg/10mL, 240mg/24mL vial	Yes	Yes (PA)
J9271	Pembrolizumab (Keytruda)	100mg/4mL vial	Yes	Yes (PA)
BRAF Kinase Inhibitor				
--	Darbrafenib (Tafinlar)	50mg, 75mg capsule	Yes	No
--	Encorafenib (Braftovi)	75mg capsule	Yes	No
Mitogen-activated protein kinase (MEK) Inhibitor				
--	Cobimetinib Fumarate (Cotellic)	20mg tablet	Yes	No
--	Trametinib Dimethyl Sulfoxide (Mekinist)	0.5mg, 2mg tablet	Yes	No
Mammalian target of rapamycin (mTOR) Kinase Inhibitor				
--	Everolimus (Afinitor)	2.5mg, 5mg, 7.5mg, 10mg tablet	Yes	No
Vascular Endothelial Growth Factor (VEGF) Inhibitor				
J9035, Q5107, Q5126	Bevacizumab (Avastin, Mvasi, Zirabev)	100mg/4mL, 400mg/16mL vial	Yes	Yes (PA)
Vascular Endothelial Growth Factor Receptor (VEGFR) 2 Inhibitor				
J9038	Ramucirumab (Cyramza)	100mg/10mL, 500mg/50mL vial	Yes	Yes (PA)
Epidermal Growth Factor Receptor (EGFR)				
J9055	Cetuximab (Erbixub) Inhibitor	200mg/100ml vial	Yes	Yes (PA)
J9295	Necitumumab (Portrazza)	800mg/50ml vial	Yes	Yes (PA)
J9303	Panitumumab (Vectibix)	100mg/5ml vial	Yes	Yes (PA)
Anti-metabolites - Purine Analog				
--	Mercaptopurine (Purinethol)	50mg tablets	Yes	No
Anti-metabolites - Pyrimidine Analog				
J8520, J8521	Capecitabine (Xeloda)	150mg, 500mg tablet	Yes	Yes (PA)
J9098, J9100	Cytarabine (Cytosar)	20mg/mL, 100mg/mL vial	Yes	Yes (PA)
J9190	Fluorouracil (Adrucil)	500mg/10mL, 1G/10mL, 2.5G/50mL, 5G/100mL vial	Yes	Yes (PA)
--	Fluorouracil (Carac, Efudex)	0.05%, 0.1%, 0.5% cream 0.2%, 0.5% solution	Yes	No
J9201	Gemcitabine (Gemzar, Infugem)	200 mg, 1G, 2G, 200 mg/2 ml, 200 mg/5.26 ml, 1 gram/10 ml, 1 gram/26.3 ml, 1.5 gram/15 ml, 2 gram/20 ml, 2 gram/52.6 ml, 1200 mg/120 ml, 1300 mg/130 ml, 1400 mg/140 ml, 1500 mg/150 ml, 1600 mg/160 ml, 1700 mg/170 ml, 1800 mg/180 ml, 1900 mg/190 ml, 2000 mg/200 ml, 2200 mg/220 ml vial	Yes	Yes (PA)
Pyrimidine Analog, Thymidine Phosphorylase Inhibitor				
--	Trifluridine and Tipiracil (Lonsurf)	15-16.4 mg, 20-8.19 mg tablet	Yes	No
Antifolate				
J8610, J9260	Methotrexate (Trexall, Xatmep, Rasuvo, Otrexup)	2.5mg, 5mg, 7.5mg, 10mg, 15mg tablet 2.5mg/mL solution 10 mg/0.4 ml, 12.5 mg/0.4 ml, 15 mg/0.4 ml, 17.5 mg/0.4 ml, 20 mg/0.4 ml, 22.5 mg/0.4 ml,	Yes	Yes (PA for J8610)

		25 mg/0.4 ml SQ auto injector 7.5 mg/0.15 ml, 10 mg/0.2 ml, 12.5 mg/0.25 ml, 15 mg/0.3 ml, 17.5 mg/0.35 ml, 20 mg/0.4 ml, 22.5 mg/0.45 ml, 25 mg/0.5 ml, 30 mg/0.6 ml SQ auto injector 50mg/2mL, 250mg/10mL, 1G/40mL, 1G vial		
J9304, J9305, J9314	Pemetrexed (Alimta)	100mg, 500mg vial	Yes	Yes (PA)
--	Thioguanine (Tabloid)	40mg tablet	Yes	No
Aromatase Inhibitors				
--	Anastrozole (Arimidex)	1mg tablet	Yes	No
--	Exemestane (Aromasin)	25mg tablet	Yes	No
--	Letrozole (Femara)	2.5mg tablet	Yes	No
Angiogenesis Inhibitor				
--	Lenalidomide (Revlimid)	2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg capsule	Yes	No
--	Pomalidomide (Pomalyst)	1mg, 2mg, 3mg, 4mg capsule	Yes	No
Gonadotropin-Releasing Hormone (GnRH) Agonist				
J9202	Goserelin Acetate (Zoladex)	3.6mg implant	Yes	Yes (PA)
J9226	Histrelin Acetate (Supprelin LA)	50mg kit	Yes	Yes (PA)
J1950, J9217	Leuprolide Acetate (Lupron Depot)	7.5mg, 22.5mg, 30mg syringe	Yes	Yes (PA)
J9218	Leuprolide Acetate	1mg/0.2mL kit	Yes	Yes (PA)
J3315, J3316	Triptorelin Pamoate (Trelstar)	3.75mg/2mL, 11.25mg/2mL syringe	Yes	Yes (PA)
Poly-ADP ribose polymerase (PARP) Inhibitor				
--	Niraparib (Zejula)	100mg capsule	Yes	No
--	Olaparib (Lynparza)	50mg capsule 100mg, 150mg tablet	Yes	No
--	Talazoparib (Talzenna)	0.25mg, 1mg capsule	Yes	No
Phosphatidylinositol 3-Kinase Inhibitor				
--	Alpelisib (Piqray)	150mg, 200mg, 250mg, 300mg tablet	Yes	No
Protease inhibitor				
J9041	Bortezomib (Velcade)	3.5mg vial	Yes	Yes (PA)
Retinoic Acid Derivative				
--	Bexarotene (Targretin)	75mg capsule	Yes	No
--	Tretinoin (Vesanoid)	10mg capsule	Yes	No
Topoisomerase I Inhibitor, Camptothecin				
J9206	Irinotecan HCl (Camptosar)	40mg/2mL, 300mg/15mL vial	Yes	Yes (PA)
J9205	Irinotecan Liposomal (Onivyde)	43mg/10mL vial	Yes	Yes (PA)
J9351	Topotecan (Hycamtin)	0.25mg, 1mg capsule 4mg/4mL vial	Yes	Yes (PA)
Topoisomerase II Inhibitor - Podophyllotoxin derivative				
J9181	Etoposide (Etopophos)	50mg capsule 100mg vial	Yes	Yes (PA)
Topoisomerase II Inhibitor - Anthracenedione				
J9293	Mitoxantrone	2mg/mL vial	Yes	Yes (PA)
Topoisomerase II Inhibitor - Anthracycline				
J9150, J9151	Daunorubicin (Cerubidine)	5mg/mL vial	Yes	Yes (PA)
J9000	Doxorubicin (Adriamycin)	2mg/mL vial	Yes	Yes (PA)
J9211	Idarubicin (Idamycin)	1mg/mL vial	Yes	Yes (PA)
J9357	Valrubicin (Valstar)	40mg/mL vial	Yes	Yes (PA)
BCR-ABL, Tyrosine Kinase Inhibitor				

--	Bosutinib (Bosulif)	100mg, 400mg, 500mg tablet	Yes	No
--	Dasatinib (Sprycel)	20mg, 50mg, 70mg, 80mg, 100mg tablet	Yes	No
--	Imatinib (Gleevec)	100mg, 400mg tablet	Yes	No
--	Nilotinib (Tasigna)	250mg tablet	Yes	No
--	Ponatinib (Iclusig)	15mg, 45mg tablet	Yes	No
Bruton Tyrosine Kinase Inhibitor				
--	Ibrutinib (Imbruvica)	70mg, 140mg capsules 140mg, 280mg, 420mg, 560mg tablets	Yes	No
Janus Kinase Inhibitors				
--	Ruxolitinib (Jakafi)	5mg, 10mg, 15mg, 20mg, 25mg tablet	Yes	No
Hedgehog Pathway Inhibitors				
--	Vismodegib (Erivedge)	150mg capsule	Yes	No
Proteasome Inhibitors				
J9047	Carfilzomib (Kyprolis)	10mg, 30mg, 60mg vial	Yes	Yes (PA)
--	Ixazomib (Ninlaro)	2.3mg, 3mg, 4mg capsule	Yes	No
Tropomyosin Receptor Kinase (TRK) Inhibitor, Tyrosine Kinase Inhibitor				
--	Entrectinib (Rozlytrek)	100mg, 200mg capsule	Yes	No
--	Larotrectinib (Vitrakvi)	25mg, 100mg capsule 25mg/mL solution	Yes	No
Anaplastic Lymphoma Kinase Inhibitor, Tyrosine Kinase Inhibitor				
--	Alectinib (Alecensa)	150mg capsule	Yes	No
--	Brigatinib (Alunbrig)	30mg, 90mg, 180mg tablet	Yes	No
--	Crizotinib (Xalkori)	200mg, 250mg capsule	Yes	No
--	Lorlatinib (Lorbrena)	25mg, 100mg tablet	Yes	No
FMS-like Tyrosine Kinase 3 (FLT3) Inhibitor, Tyrosine Kinase Inhibitor				
--	Midostaurin (Rydapt)	25mg capsule	Yes	No
Tropomyosin Receptor Kinase (TRK) Inhibitor, Tyrosine Kinase Inhibitor				
--	Entrectinib (Rozlytrek)	100mg, 200mg capsule	Yes	No
--	Larotrectinib (Vitrakvi)	25mg, 100mg capsule, 20mg/mL solution	Yes	No
Cyclin-Dependent Kinase Inhibitor				
--	Abemaciclib (Verzenio)	50mg, 100mg, 150mg, 200mg tablet	Yes	No
--	Palbociclib (Ibrance)	75mg, 100mg, 150mg capsule/tablet	Yes	No
--	Ribociclib (Kisqali)	200mg tablet	Yes	No
Miscellaneous				
J9017	Arsenic Trioxide (Trisenox)	10mg/10mL, 12mg/6mL vial	Yes	Yes (PA)
J9019, J9020	Asparaginase (Erwinaze)	10,000 unit vial	Yes	Yes (PA)
--	Hydroxyurea (Hydrea)	500mg capsule	Yes	No
--	Megestrol Acetate	20mg, 40mg tablet	Yes	No
--	Mitotane (Lysodren)	500mg tablet	Yes	No
J9266	Pegaspargase (Oncaspar)	750 unit/mL vial	Yes	Yes (PA)
J9352	Trabectedin (Yondelis)	1mg vial	Yes	Yes (PA)
Chemotherapy Rescue Agents				
Q5108	Pegfilgrastim-jmdb (Fulphila) Syringe	6mg/0.6mL syringe	Yes	Yes (PA)
Q5111	Pegfilgrastim-cbqv (Udenyca) Syringe	6mg/0.6mL syringe	Yes	Yes (PA)
J2506	Pegfilgrastim (Neulasta, Neulasta Onpro) Syringe	6mg/0.6ml syringe	Yes	Yes (PA)
Q5101	Filgrastim-sndz (Zarxio) Syringe	300 mcg/0.5 mL syringe	Yes	Yes (PA)
J1447	Tbo-filgrastim (Granix) Syringe	300mcg/0.5mL, 480mcg/0.8mL syringe	Yes	Yes (PA)

Q5110	Filgrastim-aafi (Nivestym) <i>IV, Syringe</i>	300 mcg/mL, 480 mcg/1.6 mL, 300mcg/0.5mL, 480mcg/0.8mL vial	Yes	Yes (PA)
J2820	Sargramostim (Leukin) <i>IV</i>	250 mcg vial	Yes	Yes (PA)
J1442	Filgrastim (Neupogen) <i>Syringe</i>	300mcg/0.5mL, 480mcg/0.8mL syringe	Yes	Yes (PA)
Q5120	Pegfilgrastim-bmez (Ziextenzo) <i>Syringe</i>	6mg/0.6mL syringe	Yes	Yes (PA)
Q5122	Pegfilgrastim-apgf (Nyvepria) <i>Syringe</i>	6mg/0.6mL syringe	Yes	Yes (PA)
--	Leucovorin Calcium <i>Tablet</i>	5mg, 10mg, 15mg, 25mg tablet	Yes	No
PA = Prior Authorization; CD = cluster of differentiation; BRAF = v-raf murine saroma viral oncogene homolog B1; BCR-ABL = Breakpoint cluster region – Abelson family				

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, 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 on the setting of administration. **For IV medications that is to be dispensed through an LTC pharmacy or outpatient pharmacy, please submit a pharmacy authorization** to Medi-Cal Rx. 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 a request using one of the five methods provided by Medi-Cal Rx: [https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/PF 5 Ways to Submit a PA Flyer.pdf](https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/PF_5_Ways_to_Submit_a_PA_Flyer.pdf)
2. Include clinic notes documenting diagnosis, past treatment history, and any pertinent laboratory tests.

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.

Alkylating Agents
<i>Altretamine (Hexalen), Busulfan (Myleran, Busulfex), Dacarbazine, Procarbazine (Matulane), Temozolomide (Temodar)</i>

Busulfan capsules, Dacarbazine (J9130):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Alkylating Agents : Nitrogen Mustard
<i>Bendamustine (Bendeka, Treanda), Chlorambucil (Leukeran), Cyclophosphamide, Melphalan (Alkeran)</i>

Cyclophosphamide (J9070):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Alkylating Agents : Platinum Analog
<i>Carboplatin (Paraplatin), Cisplatin, Oxaliplatin (Eloxatin)</i>

Carboplatin (J9045), Cisplatin (J9060):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Anti-metabolites: Pyrimidine Analog
<i>Capecitabine (Xeloda), Cytarabine (Cytosar), Fluorouracil (Adrucil), Gemcitabine (Gemzar, Infugem),</i>

Cytarabine Liposome (J9098), Cytarabine (J9100), Fluorouracil (J9190), Gemcitabine (J9201):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
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: Antifolate
<i>Methotrexate (Trexall, Xatmep, Rasuvo, Otrexup), Pemetrexed (Alimta), Thioguanine (Tabloid)</i>

Methotrexate (J8610, J9260):

- Coverage Criteria:** **2.5mg:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** **50mg:** 4 units per 28 days

- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Antimicrotubular: Taxane Derivative

Carbazitaxel (Jevtana), Docetaxel (Docefrez), Paclitaxel, Paclitaxel Protein-Bound (Abraxane)

Docetaxel (J9171):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.
- Other Notes:** Note Paclitaxel does not need PA on the medical benefit.

Antimicrotubular: Vinca Alkaloids

Vinblastine Sulfate, Vincristine Sulfate (Vincasar PFS), Vincristine Sulfate Liposomal (Marqibo), Vinorelbine Tartrate (Navelbine)

Vinblastine Sulfate (J9360), Vincristine Sulfate (Vincasar PFS) (J9370), Vinorelbine Tartrate (Navelbine) (J9390):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Antineoplastic Antibiotic

Bleomycin Sulfate (Blenoxane), Dactinomycin (Cosmegen), Mitomycin (Mutamycin)

Bleomycin Sulfate (J9040):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

GnRH Agonist

Goserelin Acetate (Zoladex), Histrelin Acetate (Vantas), Leuprolide Acetate (Eligard, Lupron), Triptorelin Pamoate (Trelstar)

Histrelin Acetate implant (J9226):

- Coverage Criteria:** PA is only required when used by a provider outside of the network.
- Required Information for Approval:** None

Goserelin Acetate (J9202), Leuprolide Acetate (J9217):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Topoisomerase I Inhibitor: Camptothecin

Irinotecan HCl (Camptosar), Irinotecan Liposomal (Onivyde), Topotecan (Hycamtin)

Topotecan (J9351):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Topoisomerase II Inhibitor: Anthracycline

Daunorubicin (Cerubidine), Doxorubicin (Adriamycin), Idarubicin (Idamycin), Valrubicin (Valstar)

Daunorubicin (J9150), Doxorubicin (J9000):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Topoisomerase II Inhibitor: Podophyllotoxin derivative

<i>Etoposide (Etopophos)</i>

Etoposide (J9181):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Miscellaneous

<i>Arsenic Trioxide (Trisenox), Asparaginase (Erwinaze), Hydroxyurea (Hydrea), Megestrol Acetate, Mitotane (Lysodren), Pegaspargase (Oncaspar), Trabectedin (Yondelis)</i>
--

Asparaginase (J9019, J9020):

- Coverage Criteria:** PA required unless used for chemotherapy and provider is within the network.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Monoclonal Antibody, Topoisomerase I Inhibitor

<i>Fam-Trastuzumab Deruxtecan (Enhertu)</i>

Fam-Trastuzumab Deruxtecan (J9358):

- Coverage Criteria:** PA required. Medical necessity criteria applies.
- Limits:** None
- Required Information for Approval:** Chart notes documenting the patient's diagnosis, prognosis, lab results, treatment history and outcomes.

Colony Stimulating Factors

<i>1st line— filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta, Neulasta Onpro), tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), pegfilgrastim-jmdb (Fulphila), pegfilgrastim-cbqv (Udenyca), Sargramostim</i> <i>2nd line— filgrastim (Neupogen), pegfilgrastim-bmez (Ziextenzo), pegfilgrastim-apgf (Nyvepria)</i>

1st line— filgrastim-sndz (Zarxio), peg-filgrastim (Neulasta, Neulasta Onpro), tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), pegfilgrastim-jmdb (Fulphila), pegfilgrastim-cbqv (Udenyca), Sargramostim

- Coverage Criteria:** Approval is determined by medical necessity criteria.
- Limits:** None.
- Required Information for Approval:** Chart notes documenting the patient's diagnosis and lab results.
- Other Notes:** None.

2nd line— filgrastim (Neupogen)

- Coverage Criteria:** Reserved for documentation of treatment failure of a 1st line short-acting G-CSF: filgrastim-sndz (Zarxio), tbo-filgrastim (Granix), or filgrastim-aafi (Nivestym).
- Limits:** None.
- Required Information for Approval:** Drug refill history showing fill(s) of a 1st line agent.
- Other Notes:** None.

2nd line— pegfilgrastim-bmez (Ziextenzo), pegfilgrastim-apgf (Nyvepria)

- Coverage Criteria:** Reserved for documentation of treatment failure of a 1st line long-acting G-CSF: peg-filgrastim (Neulasta, Neulasta Onpro), pegfilgrastim-jmdb (Fulphila), or pegfilgrastim-cbqv (Udenyca).
- Limits:** None.
- Required Information for Approval:** Drug refill history showing fill(s) of a 1st line agent.
- Other Notes:** None.

☒ 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.
2. NCCN Guidelines & Clinical Resources. https://www.nccn.org/professionals/physician_gls/default.aspx.
3. FDA Approved Drug Combination for Treating Mesothelioma. Food and Drug Administration Web site. <https://www.fda.gov/news-events/press-announcements/fda-approves-drug-combination-treating-mesothelioma>. Accessed November 18, 2021.
4. FDA approved nivolumab plus ipilimumab and chemotherapy for first-line treatment of metastatic NSCLC. Food and Drug Administration Web site. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nivolumab-plus-ipilimumab-and-chemotherapy-first-line-treatment-metastatic-nsclc>. Accessed November 18, 2021.
5. FDA approves nivolumab plus ipilimumab for first-line mNSCLC (PD-L1 tumor expression ≥1%). Food and Drug Administration Web site. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nivolumab-plus-ipilimumab-first-line-mnsclc-pd-l1-tumor-expression-1>. Accessed November 18, 2021.
6. FDA grants accelerated approval to nivolumab and ipilimumab combination for hepatocellular carcinoma. Food and Drug Administration Web site. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-nivolumab-and-ipilimumab-combination-hepatocellular-carcinoma>. Accessed November 18, 2021.
7. Bevacizumab. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com/>. Accessed November 18, 2021.
8. Trexall (methotrexate) [package insert]. Huntsville, AL: DAVA Pharmaceuticals, Inc.; 2001.
9. Darzalex Faspro (daratumumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; 2021.
10. Darzalex (daratumumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; 2015.
11. Janssen Biotech, Inc. DARZALEX® Monotherapy Dosing and Administration. Updated August 2021. <https://www.darzalexhcp.com/iv/dosing-and-administration/darzalex-monotherapy>. Accessed November 28, 2021.
12. Neupogen (filgrastim) [package insert]. Thousand Oaks, CA: Amgen Inc.; 1991.
13. Zarxio (filgrastim-sndz) [package insert]. Princeton, NJ: Sandoz Inc.; 2003.
14. Nivestym (filgrastim-aafi) [package insert]. Lake Forest, IL: Pfizer; 2018.
15. Granix (tbo-filgrastim) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2012.
16. Neulasta (pegfilgrastim) [package insert]. Thousand Oaks, California: Amgen Inc.; 2002.
17. Fulphila (pegfilgrastim-jmdb) [package insert]. Zurich, Switzerland: Mylan GmbH; 2018.
18. Udenyca (pegfilgrastim-cbqv) [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; 2018.
19. Ziextenzo (pegfilgrastim-bmez) [package insert]. Princeton, NJ: Sandoz Inc.; 2019.
20. Nyvepria (pegfilgrastim-apgf) [package insert]. Lake Forest, IL: Pfizer; 2020.

☒ 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
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2019-09.docx	9/2019	Matthew Garrett, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2020-09.docx	9/2020	Matthew Garrett, PharmD
Update of Policy	HPSJ Coverage Policy – Oncology – Cancer 2021-12.docx	12/2021	Matthew Garrett, PharmD
Update of Policy	Cancer	03/2023	Matthew Garrett, PharmD

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