

Standard Oncology Criteria Policy Number: Pending

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
03/2016	9/11/2019	9/11/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
	RxPA	Q4 2019 20191030

PRODUCTS AFFECTED: See dosage forms

DRUG CLASS: Antineoplastic

ROUTE OF ADMINISTRATION: Variable per drug

PLACE OF SERVICE:

Retail Pharmacy, Specialty Pharmacy, Buy and Bill- please refer to specialty pharmacy list by drug

AVAILABLE DOSAGE FORMS:

Abraxane (paclitaxel protein-bound)	Caprelsa (vandetanib)	Evomela (melphalan)
Actimmune (interferon gamma-1b)	Casodex (bicalutamide)	Fareston (toremifene)
Adriamycin (doxorubicin)	Cerubidine (danorubicin)	Farydak (panbinostat)
Adrucil (fluorouracil)	Clolar (clofarabine)	Faslodex (fulvestrant)
Afinitor (everolimus)	Cometriq (cabozantinib)	Femara (letrozole)
Alecensa (alectinib)	Copiktra (duvelisib)	Firmagon (degarelix)
Alimta (pemetrexed disodium)	Cosmegen (dactinomycin)	Floxuridine
Aliqopa (copanlisib)	Cotellic (cobimetinib)	Fludara (fludarabine)
Alkeran (melphalan)	Cyamza (ramucirumab)	Folotylin (pralatrexate)
Alunbrig (brigatinib)	Cytosar-U (cytarabine)	Fusilev (levoleucovorin)
Arimidex (anastrozole)	Cytosan (cyclophosphamide)	Gazyva (obinutuzumab)
Aromasin (exemestane)	Dacogen (decitabine)	Gemzar (gemcitabine)
Arranon (nelarabine)	Darzalex (daratumumab)	Gilotrif (afatinib)
Arzerra (ofatumumab)	Daurismo (glasdegib)	Gleevec (imatinib)
Avastin (bevacizumab)	Doxil (doxorubicin)	Gleostine (lomustine)
Azedra (iobenguane I 131)	Eligard (leuprolide acetate)	Gliadel Wafer (carmustine implant)
Bavencio (avelumab)	Elitek (rasburicase)	Halaven (eribulin mesylate)
Beleodaq (belinostat)	Ellence (epirubicin hcl)	Herceptin (trastuzumab)
Bendeka (bendamustine)	Eloxatin (oxaliplatin)	Hycamtin (topotecan)
Besponsa (inotuzumab ozogamicin)	Emcyt (estramustine phosphate sodium)	Hydrea (hydroxyurea)
Bicnu (carmustine)	Empliciti (elotuzumab)	Ibrance (palbociclib)
Blenoxane (bleomycin sulfate)	Erbix (cetuximab)	Iclusig (ponatinib)
Blinicyto (blinatumomab)	Ergamisol (levamisole)	Idamycin (idarubicin)
Bosulif (bosutinib)	Erivedge (vismodegib)	IDHIFA (enasidenib)
Braftovi (encorafenib)	Erleada (apalutamide)	Ifex (ifosfamide)
Busilvex (busulfan)	Erwinaze (asparaginase)	Imbruvica (ibrutinib)
Cabometyx (cabozantinib)	Erwinia chrysantemi)	Imfinzi (durvalumab)
Calquence (acalbrutinib)	Ethyol (amifostine)	Imlygic (talimogene laherparepvec)
Campath (alemtuzumab)	Etopophos (etoposide phosphate)	Inlyta (axitinib)

Prior Authorization Criteria

Istodax (romidepsin)	Photofrin (porfimer sodium)	Intron A (interferon alfa-2b)
Ixempra (ixabepilone)	Platinol (cisplatin)	Vidaza (azacitidine)
Jevtana (cabazitaxel)	Pomalyst (pomalidomide)	Vinblastine
Kadcyla (ado-trastuzumab emtansine)	Portrazza (necitumamab)	Vincasar (vincristine)
Kepivance (palifermin)	Poteligeo (mogamulizumab)	Vinorelbine (navelbine)
Keytruda (pembrolizumab)	Proleukin (aldesleukin)	Vitrakvi (larotrectinib)
Khapzory (levoleucovorin)	Purinethol (mercaptapurine)	Vizimpro (dacomitinib)
Kisqali (ribociclib)	Purixan (mercaptapurine)	Voraxaxe (glucarpidase)
Kymriah (tisagenlecleucel)	Quadramet (samarium SM 153 lexidronam)	Votrient (pazopanib)
Kyprolis (carfilzomib)	Revlimid (lenalidomide)	Vumon (teniposide)
Lartruvo (olaratumab)	Rubraca (rucaparib)	Vyxeos (daunorubicin-cytarabine)
Lenvima (lenvatinib)	Rydapt (midostaurin)	Xalkori (crizotinib)
Leucovorin	Soltamox (tamoxifen)	Xatmep (methotrexate)
Leukeran (chlorambucil)	Sprycel (dasatinib)	Xeloda (capecitabine)
Leustatin (cladribine)	Stivarga (regorafenib)	Xofigo (radium 223)
Libtayo (cemiplimab-rwlc)	Sutent (sunitinib malate)	Xospata (gilteritinib)
Lipodox (doxorubicin)	Sylatron (peginterferon alfa-2b)	Xtandi (enzalutamide)
Lonsurf (trifluridine and tipiracil)	Synribo (omacetaxine mepesuccinate)	Yervoy (ipilimumab)
Lorbrena (lorlatinib)	Tafinlar (dabrafenib)	Yescarta (axicabtagene ciloleucel)
Lumoxiti (moxetumomab)	Tagrisso (osimertinib)	Yondelis (trabectedin)
Lutathera (lutetium LU 177 dotatate)	Talzenna (talazoparib)	Yonsa (abirateron acetate)
Lynparza (olaparib)	Tarceva (erlotinib)	Zaltrap (afibercept)
Lysodren (mitotane)	Targretin (bexarotene)	Zanosar (streptozocin)
Marqibo (vincristine sulfate liposome)	Taxol (paclitaxel)	Zejula (niraparib)
Matulane (procarbazine)	Taxotere (docetaxel)	Zelboraf (vemurafenib)
Megace (megestrol)	Tecentriq (atezolizumab)	Zevalin (ibrutinomab tiuxetan)
Mekinist (trametinib)	Temodar (temozolomide)	Zinecard (dexrazoxane)
Mektovi (binimetinib)	Tepadina (thiotepa)	Zinecard (dexrazoxane)
Mesnex (mesna)	Thalomid (thalidomide)	Zoladex (goserelin)
Mitosol (mitomycin)	Tibsovo (ivosidenib)	Zolinza (vorinostat)
Mustargen (mechlorethamine)	Tice BCG	Zydelig (idelalisib)
Mutamycin (mitomycin)	Toposar (etoposide)	Zykadia (ceritinib)
Myleran (busulfan)	Torisel (temsirolimus)	Zytiga (abiraterone acetate)
Mylotarg (gemtuzumab)	Totect (dexrazoxane)	
Navelbine (vinorelbine)	Treanda (bendamustine)	
Nerlynx (neratinib)	Trelstar (triptorelin pamoate)	
Nexavar (sorafenib)	Trexall (methotrexate)	
Nilandron (nilutamide)	Trisenox (arsenic trioxide)	
Ninlaro (ixazomib)	Tykerb (lapatinib)	
Nipent (pentostatin)	Unituxin (dinutuximab)	
Novantrone (mitoxantrone)	Valstar (valrubicin)	
Odomzo (sonidegib)	Vantas (histrelin implant)	
Oncaspar (pegaspargase)	Vectibix (panitumumab)	
Onivyde (irinotecan liposome)	Velcade (bortezomib)	
Opdivo (nivolumab)	Venclexta (venetoclax)	
Paraplatin (carboplatin)	Verzenio (abemaciclib)	
Perjeta (pertuzumab)	Vesanoid (tretinoin)	

FDA-APPROVED USES: please refer to product package prescribing information

COMPENDIAL APPROVED OFF-LABELED USES: please see individual compendial monographs

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: FDA-approved indications, medically accepted indications will also be considered for approval

REQUIRED MEDICAL INFORMATION:

A. FOR ALL INDICATIONS:

1. Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1 or 2A only).
(NOTE: a category 2B therapy/regimen may be authorized on an exception basis with documented Molina Healthcare medical director or Molina Healthcare oncologist consultation)
AND
2. Documentation of dose and dates of all previous therapies and the resulting outcomes
AND
3. Documentation that the proper succession of the therapies have been considered, have been tried and failed (i.e. intolerance, contraindication, or progression)
(NOTE: the proper succession for this element can be found within compendia monographs, FDA label or NCCN guidelines; IF compendia monographs, FDA label or NCCN guidelines have a formulary/preferred product at therapeutic parity with requested agent a formulary/preferred product should be used first where state regulations allow)
AND
4. Chart notes detailing the members current clinical status
AND
5. Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment.
AND
6. Molina reviewer has verified if this product is included in the split fill program and has adjusted the day supply based on clinical appropriateness and authorization set up with the appropriate specialty pharmacy (Fill #1: one 14 or 15-day supply, Fill #2: one 14 or 15-day supply Fills #3 and #4: 28 or 30-day supply/fill- based on package size)

DURATION OF APPROVAL: Initial authorization: 3 months, Continuation of therapy: 6 months or maximum duration per FDA label or NCCN guideline, whichever is shorter

QUANTITY: FDA-labeled, NCCN, NCI, or AHFS supported dosing regimens or dosing schedules will be evaluated for approval. - refer to Cotiviti J code crosswalk list of maximum quantity limits

PRESCRIBER REQUIREMENTS: Must be prescribed by, or in conjunction with, an oncologist, hematologist, or other specialist treating cancer

AGE RESTRICTIONS: As noted in the package prescribing information and approved compendia

GENDER:

Male and female

CONTINUATION OF THERAPY:**A. FOR ALL INDICATIONS:**

1. -Current chart notes detailing response and adherence to therapy
AND
2. - Documented clinically significant improvements in the disease state, stability on the medication, or lack of disease progression
AND
3. - Documentation that patient is not having intolerable or unacceptable toxicity

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: Criteria for discontinuation of therapy: Patient is non-adherent with medical or pharmacologic therapy, No demonstrable clinically significant improvement in condition has occurred after initiation of therapy

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

APPENDIX: None

Documentation Requirements: *Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

REFERENCES: