Effective Date: 03/2016
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C16154-A

Standard Oncology Criteria

PRODUCTS AFFECTED

See dosage forms

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

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

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

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT FOR INITIAL OR CONTINUATION OF THERAPY REQUEST: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred pharmacy or medical formulary BIOLOGIC/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s) BIOSIMILAR DRUGS are preferred prior to REFERENCE products (potentially specific biosimilar agents when requested as a physician administered drug and/or pharmacy formulary product per applicable state regulations and there is a lack of data demonstrating clinical

superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication or non-preferred biosimilar is approved under the following conditions:

1. Treatment with at least two (2) associated biosimilar drug(s) has been ineffective, not tolerated, or is contraindicated (i.e. an allergic reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR an adverse reaction to a specific inactive ingredient in the preferred biologic product or biosimilar OR therapeutic success while taking anon-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic productor biosimilar documented by member diary or medical charted notes) [DOCUMENTATION REQUIRED-Document when the preferred biologic product or biosimilar was tried and the length of the trial period, Provide specific clinical documentation of therapeutic failure on the preferred biologic product or biosimilar whenever possible. Describe the medical problem caused by the preferred referenced biologic. Vague and non-descriptive symptoms are not adequate rationale (e.g., stomachache)]

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 2Aonly).
   (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 where applicable
   AND
3. Documentation that the proper succession of the therapies has been considered OR 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. Documentation of related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment.
   AND
5. 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, fill #3: one 14 or 15-day supply, fill #4: one 14- or 15-day supply, Fill #5 one 14 or 15 day supply, Fill #6 one 14 or 15 day supply, Fill #7 28/30 day supply based on package size)

   Molina reviewers and delegates will comply with all regulations and requirements applicable to the review of the request, providing exception to our standard criteria as may be required under state regulations and requirements.

CONTINUATION OF THERAPY:

A. FOR ALLINDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery, treatment of an infection or adverse event mitigation, causing temporary discontinuation (documentation required)
   AND
2. Documented clinically significant improvements in the disease state, stability on

the medication, or lack of disease progression
AND

3. Documentation that member is not having intolerable or unacceptable toxicity

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

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

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

Maximum Quantity Limits – << based on FDA label>>

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered; intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered; subcutaneous or intramuscular injectable medications in this policy will be forpharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility- based location or, if appropriate, patient self-administered; injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products be administered in a place of service that is a non-hospital facility-based location; infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-basedlocation.

Note: Site of Care Utilization Management Policy may apply for drugs reviewed by this policy to channel to the prescription drug benefit for member self-administration as appropriate. For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Variable per drug

DRUG CLASS:
Antineoplastic

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

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

APPENDIX

APPENDIX:

A biosimilar is highly similar version of a brand name biological drug that meets strict controls for structural, pharmaceutical, and clinical consistency. A biosimilar manufacturer must demonstrate that there are no meaningful clinical differences (i.e., safety and efficacy) between the biosimilar and the reference product. Clinical performance is demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.1 As costs for biological specialty drugs continue to rise, the growing biosimilar market will benefit providers and patients by broadening biological treatment options and expanding access to these medications at lower costs. Molina Healthcare, Inc. continues to be committed to continually reevaluating Preferred strategies and applying innovative cost-controls to ensure patients receive safe, effective, and quality healthcare. This commitment includes potentially creating a preference for biosimilars when value can be added without compromising member satisfaction and safety.

1. Food and Drug Administration. Biosimilar and Interchangeable Products. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed October 8, 2019.

DRUG	GPI	NEW program x 3 months
Bosulif (bosutinib)	215340120003**	15 days per fill
Cabometyx (cabozantinib)	215340131003**	15 days per fill
Erivedge (vismodegib)	21370070000120	14 days per fill
Gleevec (imatinib)	215340351003**	15 days per fill
Inlyta (axitinib)	215340080003**	15 days per fill
Iressa (gefitinib)	21534030000320	15 days per fill
Lenvima (lenvatinib)	2153405420B2**	15 days per fill
Mektovi (binimetnib)	21533520000320	15 days per fill
Nerlynx (neratinib)	21534058100320	15 days per fill
Nexavar (sorafenib)	21533060400320	15 days per fill
Odomzo (sonidegib)	21370060200120	15 days per fill
Rubraca (rucaparib)	215355702003**	15 days per fill
Sprycel (dasatinib)	215340200003**	15 days per fill
Sutent (sunitinib)	215330703001**	14 days per fill
Tafinlar (dabrafenib)	215320251001**	15 days per fill
Tagrisso (osmertinib)	215340652003**	15 days per fill
Talzenna (talazoparib)	215355804001**	15 days per fill
Tarceva (erlotinib)	215340251003**	15 days per fill
Targretin (bexarotene)	21708220000120	15 days per fill
Tasigna (nilotinib)	215340602001**	14 days per fill
Tepmetko (tepotinib)	21533073100320	15 days per fill
Uknoniq (umbralisib)	21533080400320	15 days per fill
Verzenio (abemaciclib)	215310100003**	14 days per fill
Vizimpro (dacomitinib)	215340190003**	15 days per fill
Votrient (pazopanib)	21534070100320	15 days per fill
Xalkori (crizotinib)	215340150001**	15 days per fill
Xtandi (enzalutamide)	21402430000120	15 days per fill
Yonsa (abiraterone)	214060102003**	15 days per fill
Zolinza (vorinostat)	21531575000120	15 days per fill
Zykadia (ceritinib)	21534014000130	15 days per fill
Zytiga (abiraterone acetate)	214060102003**	15 days per fill

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
Criteria for discontinuation of therapy: Member 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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
Various	Physician Administered Medication List

AVAILABLE DOSAGE FORMS:

Abraxane (paclitaxel protein-bound)
Actimmune (interferon gamma-1b)
Adriamycin (doxorubicin)
Adrucil (fluorouracil)
Afinitor (everolimus)
Alecensa (alectinib)
Alimta (pemetrexed disodium)
Aliqopa (copanlisib)
Alkeran (melphalan)
Alunbrig (brigatinib)
Aromasin (exemestane)
Arranon (nelarabine)
Arzerra (ofatumumab)
Asparlas (calaspargase pegol-mknl injection)
Avastin (bevacizumab)
Azedra (iobenguane l 131)*
Balversa (erdafitinib)
Bavencio (avelumab)
Beleodaq (belinostat)
Bendeka (bendamustine)
Besponsa (inotuzumab ozogamicin)
Bicnu (carmustine)
Blenoxane (bleomycin sulfate)
Blenrep (belantamab)*
Blincyto (blinatumomab)*
Bosulif (bosutinib)
Braftovi (encorafenib)
Busilvex (busulfan)
Cabometyx (cabozantinib)*
Calquence (acalbrutinib)
Campath (alemtuzumab)
Camptosar (irinotecan)
Caprelsa (vandetanib)
Casodex (bicalutamide)
Cerubidine (danorubicin)
Clolar (clofarabine)
Cometriq (cabozantinib)
Copiktra (duvelisib)*
Cosmegen (dactinomycin)
Cotellic (cobimetinib)
Cyramza (ramucirumab)*
Cytosar-U (cytarabine)
Cytoxan (cyclophosphamide)
Cytoxan (cyclophosphamide)
Dacogen (decitabine)
Danyelza (naxitamab-gqgk)*
Darzalex (daratumumab)
Daurismo (glasdegib)*
Doxil (doxorubicin)
Elitek (rasburicase)
Ellence (epirubicin hcl)
Eloxatin (oxaliplatin)
Emcyt (estramustine phosphate sodium)
Empliciti (elotuzumab)*
Erbitux (cetuximab)
Ergamisol (levamisole)
Erivedge (vismodegib)
Erleada (apalutamide)
Erwinaze (asparaginase)
Erwinia (chrysantemi)
Ethyol (amifostine)
Etopophos (etoposide phosphate)
Evomela (melphalan)
Fareston (toremifene)
Farydak (panbinostat)
Faslodex (fulvestrant)
Femara (letrozole)
Firmagon (degarelix)
Floxuridine
Fludara (fludarbine)
Folotyn (pralatrexate)
Fusilev (levoleucovorin)
Gavreto (pralsetinib)*
Gazyva (obinutuzumab)
Gemzar (gemcitabine)
Gilotrif (afatinib)*
Gleevec (imatinib)
Gleostine (lomustine)
Gliadel Wafer (carmustine implant)
Halaven (eribulin mesylate)

Herceptin (trastuzumab)
Hycamtin (topotecan)
Hydrea (hydroxyurea)
Ibrance (palbociclib)
Iclusig (ponatinib)
Idamycin (idarubicin)
Idhifa (enasidenib)
Ifex (ifosfamide)
Imbruvica (ibrutinib)
Imfinzi (durvalumab)*
Imlygic (talimogene laherparepvec)
Inqovi (decitabine;cedazuridine)
Inlyta (axitinib)
Intron A (interferon alfa-2b)
Iressa (gefitinib)
Istodax (romidepsin)
Ixempra (ixabepilone)
Jevtana (cabazitaxel)
Kadcyla (ado-trastuzumab emtansine)
Kepivance (palifermin)
Keytruda (pembrolizumab)*
Khapzory (levoleucovorin)
Kisqali (ribociclib)
Kyprolis (carfilzomib)
Lartruvo (olaratumab)
Lenvima (lenvatinib)
Leucovorin
Leukeran (chlorambucil)
Leustatin (cladribine)
Libtayo (cemiplimab-rwlc)
Lipodox (doxorubicin)
Lonsurf (trifluridine and tipiracil)
Lorbrena (lorlatinib)*
Lumoxiti (moxetumomab)*
Lutathera (lutetium LU 177dotatate)*
Lynparza (olaparib)*
Lysodren (mitotane)
Marqibo (vincristine sulfate liposome)
Matulane(procarbazine)
Megace (megestrol)
Mekinist (trametinib)*
Mektovi (binimetinib)
Mesnex (mesna)
Mitosol (mitomycin)
Monjuvi (tafasitamab-cxix)*
Mustargen (mechlorethamine)
Mutamycin (mitomycin)
Myleran (busulfan)
Nerliynx (neratinib)
Nexavar (sorafenib)
Nilandron (nilutamide)
Ninlaro (ixazomib)
Nipent (pentostatin)
Novantrone (mitoxantrone)
Odomzo (sonidegib)
Ogivri (trastuzumab-dkst)
Oncaspar (pegaspargase)
Onivyde (irinotecan lipsome)
Ontruzant (trastuzumab-dttb)
Opdivo (nivolumab)
Paraplatin (carboplatin)
Pemazyre (pemigatinib)*
Perjeta (pertuzumab)
Phesgo (pertuzumab; trastuzumab;hyaluronidase)
Photofrin (porfimer sodium)
Platinol (cisplatin)
Pluvicto (lutetium Lu 177 vipivotide tetraxetan)*
Pomalyst (pomalidomide)
Portrazza (necitumamab)
Poteligeo(mogamulizumab)*
Proleukin (aldesleukin)
Purinethol (mercaptopurine)
Purixan (mercaptopurine)
Qinlock (ripretinib) Quadramet (samarium SM 153 lexidronam)
Revlimid (lenalidomide)*
Rubraca (rucaparib)*
Rydapt (midostaurin) Soltamox (tamoxifen) Sprycel (dasatinib)*
Stivarga (regorafenib)
Sutent (sunitinib malate)
Sylatron (peginterferon alfa-2b)
Sylvant (siltuximab)
Synribo (omacetaxine mepesuccinate)
Tabrecta (capmatinib)* Tafinlar (dabrafenib)* Tagrisso (osimertinib)* Talzenna (talazoparib) Tarceva (erlotinib)
Targretin (bexarotene)
Tasigna (nilotinib)
Taxol (paclitaxel)
Taxotere (docetaxel) Tecentriq (atezolizumab)*
Temodar(temozolomide)
Tepadina (thiotepa) Thalomid (thalidomide) Tibsovo (ivosidenib)*
Tice BCG
Toposar (etoposide)
Torisel (temsirolimus)
Totect (dexrazoxane)
Treanda (bendamustine)
Trelstar (triptorelin pamoate)
Trexall (methotrexate)
Trisenox (arsenic trioxide)
Turalio (pexidartinib)*
Tykerb (lapatinib)
Ukoniq (umbralisib)*
Unituxin (dinutuximab)
Valstar (valrubicin)
Vantas (histrelin implant)
Vectibix (panitumumab)
Velcade (bortezomib)
Venclexta (venetoclax)
Verzenio (abemaciclib)
Vesanoid (tretinoin)
Vidaza (azacitidine)
Vinblastine
Vincasar (vincristine)
Vinorelbine (navelbine)
Vizimpro (dacomitinib)
Voraxaxe (glucarpidase)
Votrient (pazopanib)
Vumon (teniposide)
Vyxeos (daunorubicin-cytarabine)
Xalkori (crizotinib)
Xatmep (methotrexate)
Xeloda (capecitabine)
Xofigo (radium 223)
Xospata (gilteritinib)*
Xpovio (selinexor)*
Xtandi (enzalutamide)
Yervoy (ipilimumab)
Yondelis (trabectedin)
Yonsa (abirateron acetate)
Zaltrap (aflibercept)
Zanosar (streptozocin)
Zejula (niraparib)
Zelboraf (vemurafenib)
Zepzelca (lurbinectedin)
Zevalin (ibritumomab tiuxetan)
Zinecard (dexrazoxane)
Zoladex (goserelin)
Zolinza (vorinostat)
Zydelig (idelalisib)
Zykadia (ceritinib)
Zynlonta(loncastuximab tesirine)
Zytiga (abiraterone acetate)

REFERENCES