Original Effective Date: 11/22/2024
Current Effective Date: 11/22/2024
Last P&T Approval/Version: N/A
Next Review Due By: 01/2025
Policy Number: C28790-A

Standard Oncology Criteria MS ONLY

PRODUCTS AFFECTED

See dosage forms

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the beneficiary'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 beneficiary 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:
N/A

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 beneficiary 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. When the requested drug product for coverage is dosed by weight, body surface area or other beneficiary specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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,

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DRUGDEX Information System, National Comprehensive Cancer Network (Categories 1 or 2A only), or pediatric consortium (e.g., Children's Oncology Group [COG], St. Jude Consortium, Dana-Farber Cancer Institute [DFCI]).
(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 OR the beneficiary has advanced metastatic disease
AND
3. Documentation of ONE of the following:
a. That the proper succession of the therapies has been considered or have been tried and failed (i.e., serious side effects, contraindication, or progression)
OR
b. The beneficiary has advanced metastatic disease
(NOTE: The proper succession for this element can be found within compendia monographs, FDA label or NCCN guidelines. For conditions other than advanced metastatic disease. If compendia monographs, FDA label or NCCN guidelines have a preferred product at therapeutic parity with requested agent a 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. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN ADMINISTERED MEDICATION: BIOSIMILAR DRUGS are preferred when requested as a physician administered drug per applicable state regulations and/or there is a lack of data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs. A reference medication is approved under the following conditions:
    a. Treatment with at least two associated biosimilar drug(s) has been ineffective, resulted in serious side effects, 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 a non-preferred biologic product or biosimilar and therapeutic failure while taking the preferred biologic product or biosimilar documented by patient 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).]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or beneficiary 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
AND
2. Documented clinically significant improvements in the disease state, stability on the medication, or lack of disease progression
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

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

AGE RESTRICTIONS:
Must be prescribed within FDA or compendia supported labeled age maximums or minimums

QUANTITY:
FDA-labeled, NCCN, NCI, or AHFS supported dosing regimens or dosing schedules will be evaluated for approval.

PLACE OF ADMINISTRATION:
N/A

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 beneficiary 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.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Imbruvica (ibrutinib) Accelerated Approval Withdrawal
On April 6, 2023, Janssen Pharmaceuticals announced the withdrawal of indications for Imbruvica for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy, and for the

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treatment of patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. This decision was made in consultation with the U.S. Food and Drug Administration (FDA), consistent with FDA procedural guidance on accelerated approvals. This decision does not affect any other approved indications for Imbruvica. NCCN clinical practice guidelines for B-Cell Lymphomas still lists ibrutinib as other recommended regimen for second line or subsequent therapy for MCL and MZL and notes "Head-to-head clinical trials in other B-cell malignancies have demonstrated a more favorable toxicity profile for acalabrutinib and zanubrutinib compared to ibrutinib without compromising efficacy." The NCCN guidelines were last updated on February 8, 2023 and this timeline should be considered during review determinations for Imbruvica for these withdrawn indications.
The NCCN 6.2023 version of B-Cell Lymphomas has kept this recommendation after the withdrawal. For both MCL (MS-88) and MZL (MS-65), ibrutinib has been moved from a preferred regimen to other recommended regimen.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of antineoplastic agents are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. See individual drug monographs for contraindications.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
Various	Physician Administered Medication List

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AVAILABLE DOSAGE FORMS:

Abraxane (paclitaxel protein- bound)
Actimmune (interferon gamma-1b)
Adriamycin (doxorubicin)
Alferon N (interferon alfa-n3)
Alimta (pemetrexed disodium)
Aliqopa (copanlisib)
Alkeran (melphalan)
Alymsys (bevacizumab)
Arranon (nelarabine)
Arzerra (ofatumumab)
Asparlas (calaspargase pegol-mknl)
Avastin (bevacizumab)
Azedra (iobenguane I 131)*
Bavencio (avelumab)
Beleodaq (belinostat)
Belrapzo (bendamustine)
Bendeka (bendamustine)
Besponsa (inotuzumab ozogamicin)
Besremi (ropeginterferon alfa-2b)
Bicnu (carmustine)
Blenrep (belantamab)*
Blincyto (blinatumomab)*
Busulfex (busulfan)
Camptosar (irinotecan) Clolar (clofarabine) Columvi (glofitamab) Cosmegen (dactinomycin)
Cyramza (ramucirumab)*
Dacarbazine
Dacogen (decitabine)
Danyelza (naxitamab-gqgk)*
Darzalex (daratumumab)
Doxil (doxorubicin)
Elahere (mirvetuximab)
Elitek (rasburicase)
Ellence (epirubicin hcl)
Elrexfio (elranatamab)
Elzonris (Tagraxofusp-erzs)
Empliciti (elotuzumab)*
Enhertu (fam-trastuzumab deruxtecan-nxki)
Epkinly (epcoritamab)
Erbitux (cetuximab)
Erwinase (asparaginase)
Erwinaze (asparaginase)
Ethyol (amifostine)
Etopophos (etoposide phosphate)
Evomela (melphalan)
Faslodex (fulvestrant)
Firmagon (degarelix)
Floxuridine
Fludara (fludarbine)
Folotyn (pralatrexate)
Fyarro (Sirolimus Protein-Bound)
Gazyva (obinutuzumab)
Gliadel Wafer (carmustine implant)
Halaven (eribulin mesylate)
Herceptin (trastuzumab) Herzuma (trastuzumab-pkrb)
Hycamtin (topotecan)
Hydroxyprogesterone caproate
Idamycin (idarubicin) Idhifa (enasidenib) Ifex (ifosfamide)
Imbruvica (ibrutinib) Imfinzi (durvalumab)*
Imjudo (tremelimumab)
Imlygic (talimogene laherparepvec)
Infugem (gemcitabine)
Intron A (interferon alfa-2b)
Istodax (romidepsin)
Ixempra (ixabepilone)
Jelmyto (mitomycin)
Jemperli (dostarlimab)
Jevtana (cabazitaxel)
Kadcyla (ado-trastuzumab emtansine)
Kanjinti (trastuzumab-anns)
Kepivance (palifermin)
Keytruda (pembrolizumab)*
Khapzory (levoleucovorin)
Kimmtrak (tebentafusp)
Kyprolis (carfilzomib)
Lartruvo (olaratumab)
Leucovorin
Libtayo (cemiplimab-rwlc)
Loqtorzi (toripalimab)
Lumoxiti (moxetumomab)*
Lunsumio (mosunetuzumab)
Margenza (margetuximab)
Marqibo (vincristine sulfate liposome)
Mesnex (mesna)
Monjuvi (tafasitamab-cxix)*
Mutamycin (mitomycin)
Mvasi (bevacizumab-awwb)
Mylotarg (gemtuzumab ozogamicin)
Navelbine (vinorelbine)
Ogivri (trastuzumab-dkst)
Oncaspar (pegaspargase)
Onivyde (irinotecan lipsome)
Ontruzant (trastuzumab-dttb)
Opdivo (nivolumab)

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Opdualag (nivolumab-relatlimab)
Pemfexy (pemetrexed)
Perjeta (pertuzumab)
Phesgo (pertuzumab; trastuzumab;hyaluronidase)
Photofrin (porfimer sodium)
Polivy (polatuzumab vedotin)
Portrazza (necitumamab)
Poteligeo (mogamulizumab)*
Proleukin (aldesleukin)
Quadramet (samarium SM 153 lexidronam)
Rybrevant (amivantamab)
Rylaze (asparaginase)
Sarclisa (isatuximab)
Sylvant (siltuximab)
Synribo (omacetaxine mepesuccinate)
Targretin (bexarotene)
Tecentriq (atezolizumab)*
Tecvayli (teclistamab)
Temodar (temozolomide)
Tepadina (thiotepa) Tice BCG
Tivdak (tisotumab vedotin)
Toposar (etoposide)
Torisel (temsirolimus)
Totect (dexrazoxane)
Trazimera (trastuzumab-qyyp)
Treanda (bendamustine)
Trelstar (triptorelin pamoate)
Unituxin (dinutuximab)
Uvadex (methoxsalen)
Valstar (valrubicin)

Vantas (histrelin)
Vectibix (panitumumab)
Vegzelma (bevacizumab)
Velcade (bortezomib)
Vidaza (azacitidine)
Vinblastine
Vincasar (vincristine)
Vivimusta (bendamustine)
Vyxeos (daunorubicin-cytarabine)
Xofigo (radium 223)

Yervoy (ipilimumab)
Yondelis (trabectedin)
Zaltrap (aflibercept) Zanosar (streptozocin) Zepzelca (lurbinectedin) Zevalin (ibritumomab tiuxetan)
Zirabev (bevacizumab-bvzr)
Zynyz (retifanlimab)

*High risk alert

REFERENCES

1. Mississippi Legislature (2024). Mississippi Senate Bill 2140. Mississippi Legislature 2024 Regular Session. Retrieved from https://legiscan.com/MS/text/SB2140/id/2939501
2. Mississippi Legislature (2024). Mississippi House Bill 1143. Mississippi Legislature 2024 Regular Session. Retrieved from https://legiscan.com/MS/bill/HB1143/2024

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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2024

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