Original Effective Date: 03/2016
Current Effective Date: 03/04/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 01/2027
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 labeled, compendial or consortium supported

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. When the requested drug product for coverage is dosed by weight, body surface area or other member 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.

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Drug and Biologic Coverage Criteria

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), 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
   AND
3. Documentation that the proper succession of the therapies has been considered OR have been tried and failed (i.e., serious side effects, 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.
   MOLINA REVIEWER NOTE: For Connecticut Marketplace or Mississippi Marketplace, please see Appendix.
   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.
   AND
6. (a) IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: If request is for reference product with a biosimilar available for initial or continuation of therapy requests: Documentation of a trial and failure, serious side effects or contraindication to a majority (not more than 3) biosimilar product(s) is required (unless otherwise specified per applicable state regulations and/or there is data demonstrating clinical superiority of reference drugs over the FDA approved biosimilar drugs).
   [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).]
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.
   OR
7. FOR INITIAL OR CONTINUATION OF THERAPY REQUESTS OF A PHYSICIAN

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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 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 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: 6 months or maximum duration per FDA label or NCCN guideline or consortium, whichever is shorter, Continuation of therapy: 6 months or maximum duration per FDA label or NCCN guideline or consortium, whichever is shorter

MOLINA REVIEWER NOTE: For Connecticut Marketplace or Mississippi Marketplace, please see Appendix.

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

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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:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Connecticut (Source: House Bill No. 7023, State of Connecticut)
"Sec. 38a-510. Prescription drug coverage. Mail order pharmacies. Step therapy use. (a) *No insurance company*, hospital service corporation, medical service corporation, health care center or other entity delivering, issuing for delivery, renewing, amending or continuing an individual health insurance policy or contract that provides coverage for prescription drugs *may*:
(1) Require any person covered under such policy or contract to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs; or
(2) *Require*, if such insurance company, hospital service corporation, medical service corporation, health care center or other entity uses step therapy for such drugs, *the use of step therapy for* (A) any prescribed drug for longer than sixty days, or (B) *a prescribed drug for cancer treatment for an insured who has been diagnosed with stage IV metastatic cancer provided such prescribed drug is in compliance with approved federal Food and Drug Administration indications*."

Connecticut (Source: State of Connecticut)
"Sec. 38a-591o. Restrictions applicable to prospective or concurrent review of certain recurring prescription drugs. Exceptions…. (b) No health carrier shall require a prospective or concurrent review of a *recurring prescription drug to directly treat any autoimmune disorder, multiple sclerosis or cancer after such health carrier has certified such prescription drug through utilization review*. Nothing in this section shall require a health carrier to cover: (1) Any prescription drug to treat any autoimmune disorder, multiple sclerosis or cancer if the terms of coverage completely exclude such prescription drug from the policy's covered benefits; (2) a brand name drug when an equivalent generic drug is available; (3) a prescription drug that was certified through prospective or concurrent review (A) by such covered person's previous health carrier, or (B) under a previous employer's fully insured health plan administered by a third-party administrator that provided coverage to such covered person."

Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the

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prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

Mississippi (Source: Mississippi Legislature)
"SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient's health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary. SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.
(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary."

Mississippi (Source: House Bill 856)
"BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:
SECTION 1. Section 83-9-8.1, Mississippi Code of 1972, is reenacted as follows: 83-9-8.1. (1) As used in this section, the following terms shall be defined as provided in this subsection:
(a) "Associated conditions" means the symptoms or side effects associated with advanced, metastatic cancer or its treatment and which, in the judgment of the health care practitioner, further jeopardizes the health of a patient if left untreated.
(b) "Advanced, metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.
(c) "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered by or issued by an insurer to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

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(2) A health benefit plan that provides coverage for advanced, metastatic cancer and associated conditions may not require, before the health benefit plan provides coverage of a prescription drug approved by the United States Food and Drug Administration, that the enrollee:
(a) Fail to successfully respond to a different drug; or
(b) Prove a history of failure of a different drug.
(3) This section applies only to a drug the use of which is:
(a) Consistent with best practices for the treatment of advanced, metastatic cancer or an associated condition;
(b) Supported by peer-reviewed, evidence-based literature; and
(c) Approved by the United States Food and Drug Administration.
SECTION 2. Section 83-9-36, Mississippi Code of 1972, is reenacted as follows:…
4) The provisions of Section 83-9-8.1 shall supersede the provisions of this section to the extent of any conflict between Section 83-9-8.1 and this section."

Appendix 1:

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.

Appendix 2:

Starter Fill Program (Split Fill Program)

Molina Healthcare has identified medications which have a high incidence of adverse effects, frequent dose modifications, or poor tolerability. For member's that are new utilizers of the medication, the program limits the dispensing of the medication to a 14-day supply, until the member has received a cumulative 90-day supply of the medication. This program also monitors to ensure that members fill a cumulative 90-day supply in rolling 6-month periods. If the member's medication adherence falls below this threshold, the member is limited to a 14-day supply until the 90-day cumulative supply is met. This program is intended to reduce medication waste, while also improving member care and medication adherence. Medications identified for this program must also be appropriate for dispensing in a 14-day supply. Medications that must be dispensed in the manufacturer's packaging (i.e., labeled "Dispense in original bottle") would not be eligible for this program.

DRUG	GPI	NEW program x 3 months
Afinitor (everolimus)	215325300003**	14 days per fill
Afinitor Disperz	215325300073**	14 days per fill
Akeega (niraparib/abiraterone acetate)	214099021203**	15 days per fill

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Augtyro (repotrectinib)	215338650001**	15 days per fill
Ayvakit (avapritinib)	214900090003**	15 days per fill
Balversa (erdafitinib)	215322250003**	14 days per fill
Bosulif (bosutinib)	215340120003**	15 days per fill
Brukinsa (zanubrutinib)	215321950001**	15 days per fill
Cabometyx (cabozantinib)	215330101003**	15 days per fill
Calquence (acalabrutinib)	21532103******	15 days per fill
Daurismo (glasdegib)	213700303003**	15 days per fill
Erivedge (vismodegib)	213700700001**	14 days per fill
Exkivity (mobocertinib)	213600506001**	15 days per fill
Fruzaqla (fruquintinib)	213350350001**	15 days per fill
Gavreto (pralsetinib)	215357500001**	15 days per fill
Gleevec (imatinib)	215318351003**	15 days per fill
Inlyta (axitinib)	213350130003**	15 days per fill
Iressa (gefitinib)	213600300003**	15 days per fill
Iwilfin (eflornithine)	217572203003**	15 days per fill
Jaypirca (pirtobrutinib)	215321650003**	15 days per fill
Lorbrena (lorlatinib)	215305560003**	15 days per fill
Lumakras (sotorasib)	215324800003**	15 days per fill
Lysodren (mitotane)	214022500003**	15 days per fill
Nerlynx (neratinib)	215330351003**	15 days per fill
Nexavar (sorafenib)	215330604003**	15 days per fill
Odomzo (sonidegib)	213700602001**	15 days per fill
Ogsiveo (nirogacestat)	215323502003**	15 days per fill
Orserdu (elacestrant)	214037201003**	15 days per fill
Pemazyre (pemigatinib)	215322600003**	14 days per fill
Retevmo (selpercatinib)	21535779******	15 days per fill
Rozlytrek (entrectinib)	215338200001**	15 days per fill
Rubraca (rucaparib)	215355702003**	15 days per fill
Sprycel (dasatinib)	215318200003**	15 days per fill
Tagrisso (osmertinib)	213600682003**	15 days per fill
Talzenna (talazoparib)	215355804001**	15 days per fill
Tarceva (erlotinib)	213600251003**	15 days per fill
Targretin (bexarotene)	217082200001**	15 days per fill
Tazverik (tazemetostat)	215336752003**	15 days per fill
Tibsovo (ivosidenib)	215349400003**	15 days per fill
Truqap (capivasertib)	215303200003**	15 days per fill
Turalio (pexidartinib)	215330450101**	15 days per fill
Vanflyta (quizartinib)	215330471003**	15 days per fill
Vitrakvi (larotrectinib)	21533835******	15 days per fill
Vizimpro (dacomitinib)	213600190003**	15 days per fill
Votrient (pazopanib)	215330421003**	15 days per fill
Welireg (belzutifan)	214210200003**	15 days per fill
Xalkori (crizotinib)	21530517******	15 days per fill
Xtandi (enzalutamide)	21402430******	15 days per fill
Yonsa (abiraterone)	214060102003**	15 days per fill
Zejula (niraparib)	21535550******	15 days per fill

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Zolinza (vorinostat)	215315750001**	15 days per fill
Zykadia (ceritinib)	215305140003**	15 days per fill
Zytiga (abiraterone acetate)	214060102003**	15 days per fill

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 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.

The NCCN 1.2025 version of B-Cell Lymphomas has kept this recommendation after the withdrawal. For both MCL (MS-91) and MZL (MS-66), ibrutinib has been moved from a preferred regimen to other recommended regimen.

The NCCN 1.2026 version of B-Cell Lymphomas continues to show ibrutinib for second line or subsequent therapy for Mantle cell lymphoma as an other recommended regimen (MANT-A 2 of 5). Recommendation in marginal zone lymphoma has been removed in this version of the guideline.

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. All FDA labeled contraindications are exclusion to any therapy.

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*

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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

AVAILABLE DOSAGE FORMS:

Abirtega (abiraterone)
Abraxane (paclitaxel protein- bound)
Actimmune (interferon gamma-1b)
Adcetris (brentuximab vedotin)
Adriamycin (doxorubicin)
Afinitor (everolimus)
Afinitor Disperz (everolimus)
Akeega (niraparib)
Alecensa (alectinib)
Alkeran (melphalan)
Alunbrig (brigatinib)
Alymsys (bevacizumab)
Anktiva (nogapendekin alfa inbak-pmln)
Aromasin (exemestane)
Arranon (nelarabine)
Arzerra (ofatumumab)
Asparlas (calaspargase pegol-mknl)
Augtyro (repotrectinib)
Avastin (bevacizumab)
Avgemsi (gemcitabine)
Avmapki Fakzynja (avutometinib & defactinib)
Axtle (pemetrexed dipotassium)
Ayvakit (avapritinib)
Balversa (erdafitinib)
Bavencio (avelumab)
Beizray (docetaxel & albumin)
Beleodaq (belinostat)
Belrapzo (bendamustine)
Bendeka (bendamustine)
Besponsa (inotuzumab ozogamicin)
Besremi (ropeginterferon alfa-2b)
Bizengri (zenocutuzumab-zbco)
Blenrep (belantamab)*
bleomycin
Blincyto (blinatumomab)*
Boruzu (bortezomib)
Bosulif (bosutinib)
Braftovi (encorafenib)
Brukinsa (zanubrutinib)
Busulfex (busulfan)
Cabometyx (cabozantinib)*
Calquence (acalbrutinib)
Camptosar (irinotecan)
Caprelsa (vandetanib)
carboplatin
carmustine
Casodex (bicalutamide)
cladribine
Columvi (glofitamab)
Cometriq (cabozantinib)
Copiktra (duvelisib)*
Cotellic (cobimetinib)
Cyramza (ramucirumab)*
cytarabine
dacarbazine
dactinomycin
Danyelza (naxitamab-gqgk)*
Danziten (nilotinib)
Darzalex (daratumumab)
Darzalex Faspro (daratumumab-hyaluronidase-fihj)
Datroway (datopotamab deruxtecan-dlnk)
daunorubicin
Daurismo (glasdegib)*
decitabine
dexrazoxane
Docivyx (docetaxel)
Doxil (doxorubicin)
Elahere (mirvetuximab)
Elitek (rasburicase)
Ellence (epirubicin hcl)
Elrexfio (elranatamab)
Elzonris (tagraxofusp-erzs)
Empliciti (elotuzumab)*
Emrelis (telisotuzumab vedotin-tllv)
Enhertu (fam-trastuzumab deruxtecan-nxki)
Ensacove (ensartinib)
Epkinly (epcoritamab)
Erbitux (cetuximab)
Erivedge (vismodegib)
Erleada (apalutamide)
Etopophos (etoposide phosphate)
Evomela (melphalan)
Fareston (toremifene)
-Farydak (panbinostat)
Faslodex (fulvestrant)
Femara (letrozole)
Firmagon (degarelix)
floxuridine
fludarabine
fluorouracil
Folotyn (pralatrexate)

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Fotivda (Tivozanib)
Frindovyx (cyclophosphamide)
Fruzaqla (fruquintinib)
Fyarro (sirolimus protein-bound)
Gavreto (pralsetinib)*
Gazyva (obinutuzumab)
Gilotrif (afatinib)*
Gleevec (imatinib)
Gleostine (lomustine)
Gliadel Wafer (carmustine implant)
Halaven (eribulin mesylate)
Hepzato (melphalan hcl for intra-arterial)
Herceptin (trastuzumab)
Herceptin Hylecta (trastuzumab-hyaluronidase-oysk)
Hercessi (trastuzumab-strf)
Hernexeos (zongertinib)
Herzuma (trastuzumab-pkrb)
Hycamtin (topotecan)
Hydrea (hydroxyurea)
Ibrance (palbociclib)
Ibtrozi (taletrectinib adipate)
Iclusig (ponatinib)
Idamycin (idarubicin)
Idhifa (enasidenib)
Ifex (ifosfamide)
Imbruvica (ibrutinib)
Imdelltra (tarlatamab-dlle)
Imfinzi (durvalumab)*
Imjudo (tremelimumab)
Imkeldi (imatinib mesylate)
Imlygic (talimogene laherparepvec)
Inlexo (gemcitabine hcl intravesical implant)
Inluriyo (imlunestrant tosylate)
Inlyta (axitinib)
Inqovi (decitabine-cedazuridine)
Iressa (gefitinib)
Istodax (romidepsin)
Itovebi (inavolisib)
Ivra (melphalan)
Iwilfin (eflornithine)
Ixempra (ixabepilone)
Jaypirca (pirtobrutinib)
Jelmyto (mitomycin)
Jemperli (dostarlimab)
Jevtana (cabazitaxel)
Jobevne (bevacizumab-nwgd)
Jylamvo (methotrexate)
Kadcyla (ado-trastuzumab emtansine)
Kanjinti (trastuzumab-anns)
Kemoplat (cisplatin)
Kepivance (palifermin)
Keytruda (pembrolizumab)*
Keytruda Qlex (pembrolizumab-berahyaluron-pmph)
Khapzory (levoleucovorin)
Kimmtrak (tebentafusp)
Kisqali (ribociclib)
Komzifti (ziftomenib)
Krazati (adagrasib)
Kyprolis (carfilzomib)
Kyaxta (carboplatin)
Lazcluze (lazertinib mesylate)
Lenvima (lenvatinib)
leucovorin
Leukeran (chlorambucil)
leuprolide acetate
Libtayo (cemiplimab-rwlc)
-Lipodox (doxorubicin)
Lonsurf (trifluridine/tipiracil)
Loqtorzi (toripalimab)
Lorbrena (lorlatinib)*
Lumakras (sotorasib)
Lunsumio (mosunetuzumab)
Lymphir (denileukin diftitox-cxdl)
Lynozyfic (linvoseltamab-gcpt)
Lynparza (olaparib)*
Lysodren (mitotane)
Lytgobi (futibatinib)
Margenza (margetuximab)
Matulane (procarbazine)
Mekinist (trametinib)*
Mektovi (binimetinib)
melphalan
Mesnex (mesna)
mitoxantrone
Modeyso (dordaviprone)
Monjuvi (tafasitamab-cxix)*
Mutamycin (mitomycin)
Mvasi (bevacizumab-awwb)
Myleran (busulfan)
Mylotarg (gemtuzumab ozogamicin)
Nerlynx (neratinib)
Nexavar (sorafenib)
Nilandron (nilutamide)
Ninlaro (ixazomib)
Nipent (pentostatin)
Nubeqa (darolutamide)
Odomzo (sonidegib)
Ogivri (trastuzumab-dkst)
Ogsiveo (nirogacestat)
Ojemda (tovorafenib)
Oncaspar (pegaspargase)
Onivyde (irinotecan lipsome)
Ontruzant (trastuzumab-dttb)
Onureg (azacytidine)
Opdivo (nivolumab)
Opdivo Qvantig (nivolumab-hyaluronidase-nvh
Opdualag (nivolumab-relatlimab)
Orserdu (elacestrant)
oxaliplatin
paclitaxel

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Padcev (enfortumab vedotin)
Pegasys (peginterferon alfa-2a)
Pemazyre (pemigatinib)*
PEMEtrexed Ditromethamine
Pemfexy (pemetrexed)
Pemrydi (pemetrexed disodium)
Perjeta (pertuzumab)
Phesgo (pertuzumab-trastuzumab-hyaluronidase)
Photofrin (porfimer sodium)
Phraygo (dasatinib)
Piqray (alpelisib)
Polivy (polatuzumab vedotin)
Pomalyst (pomalidomide)
Portrazza (necitumamab)
Poteligeo (mogamulizumab)*
Proleukin (aldesleukin)
Purixan (mercaptopurine)
Qinlock (ripretinib)
Retevmo (selpercatinib)
Revlimid (lenalidomide)*
Revuforj (revumenib)
Rezlidhia (olutasidenib)
Rituxan Hycela (rituximab-hyaluronidase)
Romvimza (vimseltinib)
Rozlytrek (entrectinib)
Rubraca (rucaparib)*
Rybrevant (amivantamab)
Rydapt (midostaurin)
Rylaze (asparaginase)
Sarclisa (isatuximab)
Scemblix (asciminib)
Soltamox (tamoxifen)
Sprycel (dasatinib)*
Stivarga (regorafenib)
Sutent (sunitinib malate)
Tabloid (thiguanine)
Tabrecta (capmatinib)*
Tafinlar (dabrafenib)*
Tagrisso (osimertinib)*
Talvey (talquetamab)
Talzenna (talazoparib)
Tarceva (erlotinib)
Targretin (bexarotene)
Tasigna (nilotinib)
Tazverik (tazemetostat)
Tecentriq (atezolizumab)*
Tecentriq Hybreza (atezolizumab-hyaluronidase-tqjs)
Tecvayli (teclistamab)
Temodar (temozolomide)
Tepadina (thiotepa)
Tepmetko (tepotinib)
Tepylute (thiotepa)
Tevimbra (tislelizumab-jsgr)
Thalomid (thalidomide)
Tibsovo (ivosidenib)*
Tice BCG (BCG live intravesical)
Tivdak (tisotumab vedotin)
Toposar (etoposide)
Torisel (temsirolimus)
Torpenz (everolimus)
Trazimera (trastuzumab-qyyp)
Treanda (bendamustine)
Trelstar (triptorelin pamoate)
tretinoin
Trexall (methotrexate)
Trisenox (arsenic trioxide)
Trodelvy (Sacituzumab)
Truqap (capivasertib)
Tukysa (tucatinib)
Turalio (pexidartinib)*
Tykerb (lapatinib)
Unituxin (dinutuximab)
Unloxcyt (cosibelimab-ipdl)
Uvadex (methoxsalen)
Valstar (valrubicin)
Vanflyta (quizartinib)
Vectibix (panitumumab)
Vegzelma (bevacizumab)
Velcade (bortezomib)
Venclexta (venetoclax)
Verzenio (abemaciclib)
Vidaza (azacitidine)
vinblastine
vincristine
vinorelbine
Vitrakvi (larotrectinib)
Vivimusta (bendamustine)
Vizimpro (dacomitinib)
Voranigo (vorasidenib)
Votrient (pazopanib)
Vyloy (zolbetuximab-clzb)
Vyxeos (daunorubicin-cytarabine)
Welireg (belzutifan)
Xalkori (crizotinib)
Xatmep (methotrexate)
Xeloda (capecitabine)
Xospata (gilteritinib)*
Xpovio (selinexor)*
Xtandi (enzalutamide)
Yervoy (ipilimumab)
Yondelis (trabectedin)
Yonsa (abirateron acetate)
Zaltrap (aflibercept)
Zejula (niraparib)
Zelboraf (vemurafenib)
Zepzelca (lurbinectedin)
-Zevalin (ibritumomab tiuxetan)
Ziihera (zanidatamab-hrii)
Zirabev (bevacizumab-bvzr)
Zolinza (vorinostat)
Zusduri (mitomycin for intravesical)

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Zydelig (idelalisib)
Zykadia (ceritinib)
Zynlonta (loncastuximab tesirine)
Zynyz (retifanlimab)
Zytiga (abiraterone acetate)

*High risk alert

REFERENCES

NA

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Continuation of Therapy Background References	Q1 2026
REVISION- Notable revisions: Required Medical Information Duration of Approval Background	Q1 2025
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Place of Administration Appendix Background Available Dosage Forms	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Age Restrictions Place of Administration Appendix Contraindications/Exclusions/Discontinuation Available dosage Forms	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file

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