| | |
|---|---|
| **Policy Number** | **RX502.061** |
| **Policy Effective Date** | **07/01/2026** |
| **Policy End Date** | **09/30/2026** |

# Oncology Medications

| Table of Contents |
|---|
| Coverage |
| Policy Guidelines |
| Description |
| Rationale |
| Coding |
| References |
| Policy History |

| Related Policies (if applicable) |
|---|
| ADM1001.034: Specialty Medication Administration Site of Care |
| RX501.087: FDA Approved Drugs & Biologicals |
| RX503.001: Off-label Use of Drugs Without a Medical Policy |
| |
| |

## Disclaimer

*Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of care developed by: nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.*

### Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

**Medical Benefit Therapeutic Alternatives**

Certain prescription drugs administered by a health care provider in a clinical or professional setting have therapeutic equivalents or alternatives. Benefits may be limited to certain therapeutic equivalents or alternatives unless a coverage exception is granted. Members and their providers may visit the plan website for more information or may call the number on the member's ID card for further assistance.

## Legislative Mandates

**EXCEPTION:** For members residing in the state of Louisiana, R.S. 22:999 prohibits excluding coverage for a drug prescribed for the treatment of cancer even where the FDA has not approved the product for that indication so long as that drug is recognized for treatment of the covered indication in a standard reference compendium or in substantially accepted peer reviewed medical literature. Coverage

requirement also includes all medically necessary services related to the administration of the product. Coverage is not required where use of the product for the prescribed indication is contraindicated. "Medical literature" means scientific studies published in a journal specified by the United States Department of Health and Human Services pursuant to Section 1861(t)(2)(B) of the Social Security Action, 107 Stat. 591 (1993), 42 U.S.C. 1395x(t)(2)(B), as amended. "Standard reference compendia" means authoritative compendia as identified by the secretary of the United States Department of Health and Human Services.

**EXCEPTION:** For members residing in the state of Louisiana, R.S. 22:1054.1 requires coverage for a minimum initial treatment period of not less than three months for medically necessary drugs prescribed for the treatment of metastatic or unresectable tumors or other advanced cancers even where the drug is not FDA approved to treat the specific tumor type or a cancer of the location of the body afflicted so long as the drug is FDA approved for the treatment of cancer with the specific genetic mutation. Continued coverage of the prescribed drug shall be provided after the initial treatment period if the treating physician certifies the prescribed drug is medically necessary for the treatment of the patient's cancer based on documented improvement of the patient. Coverage may be denied only if an alternative treatment has proven to be more effective in published randomized clinical trials and is not contraindicated in the patient.

**EXCEPTION: New Mexico**: For plans delivered, or issued for delivery or renewal on or after January 1, 2025, NMSA 1978 §59A-22B-8 (SB 135) prohibits step therapy requirements before authorizing coverage for medication approved by the U.S. Food and Drug Administration (FDA) that is prescribed for the treatment of an autoimmune disorder, cancer, or a substance use disorder, pursuant to a medical necessity determination, except in cases in which a biosimilar, interchangeable biologic or generic version is available. Any approved step therapy exception may be continued for no less than the duration of the therapeutic effect of the drug. This does not prevent a requirement of a member trying biosimilars, interchangeable biologics or generics of a prescription drug before providing coverage for the equivalent brand name prescription drug. This applies to the following: fully insured group business; Individual and Family Market plans, both on- and off-exchange; the State's Medicaid Plan; and the mandatory coverage for IBAC plans (i.e., State of New Mexico, Public Schools Insurance Authority, Albuquerque Public Schools and the New Mexico Retiree Health Care Authority).

**EXCEPTION:** For members residing in the state of Ohio, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

EXCEPTION: For members residing in the state of Arkansas, § 23-79-147 relating to cancer drug step therapy, requires any policy that covers prescription drugs and which provides coverage for the treatment of metastatic cancer to not limit or exclude coverage under the health benefit plan for a drug approved by the United States Food and Drug Administration that is on the prescription drug formulary of the insurance policy by mandating that a covered person with metastatic cancer undergo step therapy unless the preferred drug is consistent with best practices and have an approved indication for the treatment of metastatic cancer or associated conditions by US FDA or the National Comprehensive Cancer Network Drugs and Biologics Compendium or based on evidence-based, peer-reviewed, recognized medical literature. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

EXCEPTION: For members residing in the state of Arkansas, § 23-79-147 relating to off-label prescription drug coverage, requires any plan that covers prescription drugs to provide for the coverage of any anticancer chemotherapeutic regimen ("drug") approved by the U.S. Food and Drug Administration (FDA) when that drug has been recognized as safe and effective for treatment of that specific type of cancer in standard reference compendia, (the American Hospital Formulary Service Drug Information, the National Comprehensive Cancer Network Drugs and Biologics Compendium, The Elsevier Gold Standard's Clinical Pharmacology), or has been recognized as safe and effective for treatment of that specific type of cancer in two [2] articles from medical literature that have not had their recognition of the drug's safety and effectiveness contradicted by clear and convincing evidence presented in another article from medical literature, or other authoritative compendia as identified by the Secretary of the United States Department of Health and Human Services. This coverage must include medically necessary services associated with the administration of the drug, provided that such services are covered by the insurance policy. However, coverage is never required where the FDA has recognized a use to be contraindicated. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

**EXCEPTION:** For members in Insured plans residing in the state of Indiana: § 27 8 20 et seq. requires coverage of any anticancer chemotherapeutic regimen ("drug") approved by the U.S. Food and Drug Administration (FDA) when it is prescribed for a use recognized for a given indication in at least one standard medical reference compendia or when such drug is recommended for that particular type of cancer and found to be safe and effective in formal clinical studies, the results of which have been published in a peer reviewed professional medical journal published in the United States or Great Britain even if the FDA has not approved the drug for that indication. Standard reference compendia are defined as the US Pharmacopeia, the American Medical Association Drug Evaluations, and the American Hospital Formulary Service Drug Information. However, coverage is never required where the FDA has recognized a use to be contraindicated. This applies to Fully Insured Small Group, Mid-Market, Large Group HMO, EPO, PPO, POS, and Student.

**EXCEPTION:** For members residing in the state of Kansas, §40-2,168 requires coverage of a prescription drug for cancer treatment on the grounds the prescription drug has not been approved by the federal food and drug administration for that covered indication if the prescription drug is recognized for treatment of the indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature. For the purposes of this mandate only, "Peer-reviewed medical literature" means a published scientific study in a journal or other publication in which original manuscripts have been published only after having been critically reviewed for scientific accuracy,

validity and reliability by unbiased independent experts, and that has been determined by the international committee of medical journal editors to have met the uniform requirements for manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier. “Standard reference compendia" means the United States pharmacopeia drug information, the American hospital formulary service drug information or the American Medical Association drug evaluation. The prescribing physician shall submit to the insurer documentation supporting the proposed off-label use or uses if requested by the insurer. This applies to FI, SG, MM, LG, Student, HMO, PPO, POS, EPO.

**EXCEPTION:** For members residing in the state of Maine, 24-A s 2837-F and 24-A s 4234-D (for HMOs) requires that coverage for prescription drugs must provide coverage for off-label use in accordance with the following: A) Group insurance policies that provide coverage for prescription drugs may not exclude coverage of any such drug used for the treatment of cancer for a medically accepted indication on the grounds that the drug has not been approved by the federal Food and Drug Administration for that indication, as long as that use of that drug is a medically accepted indication for the treatment of cancer. B) Coverage of a drug required by this subsection also includes medically necessary services associated with the administration of the drug. C) This subsection may not be construed to require coverage for a drug when the federal Food and Drug Administration has determined its use to be contraindicated for treatment of the current indication. D) A drug use that is covered pursuant to paragraph A may not be denied coverage based on a "medical necessity" requirement except for a reason that is unrelated to the legal status of the drug use. E) A contract that provides coverage of a drug as required by this subsection may contain provisions for maximum benefits and coinsurance and reasonable limitations, deductibles and exclusions to the same extent that these provisions are applicable to coverage of all prescription drugs and are not inconsistent with the requirements of this subsection. For this requirement: "Medically accepted indication" includes any use of a drug that has been approved by the federal Food and Drug Administration and includes another use of the drug if that use is supported by one or more citations in the standard reference compendia or if the insurer involved, based upon guidance provided by the federal Department of Health and Human Services Medicare program pursuant to 42 United States Code, Section 1395x(t), determines that that use is medically accepted based on supportive clinical evidence in peer-reviewed medical literature. "Off-label use" means the prescription and use of drugs for medically accepted indications other than those stated in the labeling approved by the federal Food and Drug Administration. "Peer-reviewed medical literature" means scientific studies published in at least 2 articles from major peer-reviewed medical journals that present data that supports the proposed off-label use as generally safe and effective. "Standard reference compendia" means: a). The United States Pharmacopeia Drug Information or information published by its successor organization; or b). The American Hospital Formulary Service Drug Information or information published by its successor organization. This applies to Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO.

**EXCEPTION:** For members residing in the state of Nebraska, §44-788 (Drug Coverage for the Treatment of Cancer and AIDS) mandates that any individual or group policy which provides reimbursement for FDA approved prescription drugs for the treatment of a specific type of cancer OR human immunodeficiency virus or acquired immunodeficiency syndrome shall not exclude coverage of any drug or combination of drugs on the basis that the drug or combination of drugs has not been approved by the federal Food and Drug Administration for the treatment of another specific type of cancer OR human immunodeficiency virus or acquired immunodeficiency syndrome if: (a) the drug or combination of drugs is recognized for treatment of the other specific type of cancer OR human immunodeficiency

virus or acquired immunodeficiency syndrome in the United States Pharmacopeia-Drug Information and the drug or combination of drugs is approved for sale by the federal Food and Drug Administration, or (b) the drug or combination of drugs is recognized for treatment of the other specific type of cancer OR human immunodeficiency virus or acquired immunodeficiency syndrome in medical literature and the drug or combination of drugs is approved for sale by the federal Food and Drug Administration. For purposes of this section, medical literature means two articles from major peer-reviewed professional medical journals that have recognized, based on scientific or medical criteria, the safety and effectiveness of the drug or combination of drugs for treatment of the indication for which it has been prescribed unless two articles from major peer-reviewed professional medical journals have concluded, based on scientific or medical criteria, that the drug or combination of drugs is unsafe or ineffective or that the safety and effectiveness of the drug or combination of drugs cannot be determined for the treatment of the indication for which the drug or combination of drugs has been prescribed. Each article shall meet the uniform requirements for manuscripts submitted to biomedical journals established by the International Committee of Medical Journal Editors or shall have been published in a journal specified by the United States Department of Health and Human Services pursuant to 42 U.S.C. 1395x(t)(2)(B), as amended, as acceptable peer-reviewed medical literature. Peer-reviewed medical literature shall not include publications or supplements that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier. Further, the coverage of a drug or combination of drug under this section shall include medically necessary services associated with the administration of the drug if such services are covered by the policy. This applies to: Fully Insured Small Group, Mid-Market, Large Group, Student PPO, HMO, POS, EPO. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

## Coverage

**NOTE 1: See the Appendix for exception criteria for medications in this class. The Appendix is not applicable to plans regulated by the Illinois Department of Insurance or Medicare or Medicaid plans.**

Oncology medications **may be considered medically necessary** when either of the following criteria is met:

- The drug is approved and being administered in accordance with the U.S. Food and Drug Administration (FDA) labeling for an oncologic indication; or
- The drug has a category 1, 2A or 2B recommendation by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®), or its derivative information product, the NCCN Drugs & Biologics Compendium (NCCN Compendium®). (www.nccn.org)

The following table contains a list of some, but not all, oncologic medications applicable to this policy. This list is **not all-inclusive**.

**Table 1. Oncology Medications and Codes**

| **Oncology Medications** | | |
|---|---|---|
| **Code** | **Generic** | **Brand** |
| 0537T, 0538T, 0539T, 0540T, Q2055 | Idecabtagene vicleucel | Abecma® |

| | | |
|---|---|---|
| J9264 | Paclitaxel Protein-Bound Particles | Abraxane® |
| J3262 | Tocilizumab | Actemra® |
| J9042 | Brentuximab vedotin | Adcetris® |
| J9029 | Nadofaragene firadenovec-vncg | Adstiladrin® |
| C9142, Q5126 | Bevacizumab-maly | Alymsys® |
| Q5169 | Pegfilgrastim-unne | Armlupeg® |
| C9399, J3490, J3590, J9999 | Lifileucel | Amtagvi™ |
| C9169, J3490, J3590, J9028, J9999 | Nogapendekin alfa inbakicept-pmln | Anktiva® |
| J0881 | Darbepoetin alfa | Aranesp® |
| J9302 | Ofatumumab | Arzerra® |
| J9118 | Calaspargase pegol-mknl | Asparlas™ |
| C9301, C9399, J3490, J3590, J9999, Q2058 | Obecabtagene autoleucel | Aucatzyl® |
| Q5161 | Denosumab-kyqq | Aukelso™ |
| J9035 | Bevacizumab | Avastin™ |
| C9399, J3490, J3590, J9999 | Bevacizumab-tnjn | Avzivi® |
| J9023 | Avelumab | Bavencio® |
| J9032 | Belinostat | Beleodaq® |
| J9229 | Inotuzamab ozogamicin | Besponsa™ |
| Q5162 | Denosumab-nxxp | Bilprevda® |
| C9399, J3490, J3590, J9999 | Zenocutuzumab-zbco | Bizengri® |
| J9053 | Belantamab mafodotin-blmf | Blenrep |
| J9039 | Blinatumomab | Blincyto™ |
| Q5158 | Denosumab-bnht | Bomyntra® |
| Q5171 | Denosumab-mobz | Boncresa® |
| 0537T, 0538T, 0539T, 0540T, Q2054 | Lisocabtagene maraleucel | Breyanzi® |
| J9064 | Cabazitaxel (Sandoz) | Cabazitaxel (Sandoz) |
| 0537T, 0538T, 0539T, 0540T, C9098, Q2056 | Ciltacabtagene autoleucel | Carvykti™ |
| J9286 | Glofitamab-gxbm | Columvi™ |
| J1448 | Trilaciclib | Cosela™ |
| J9308 | Ramucirumab | Cyramza® |
| J9348 | Naxitamab-gqgk | Danyelza® |
| J9145 | Daratumumab | Darzalex® |
| J9144 | Daratumumab and hyaluronidase-fihj | Darzalex Faspro™ |
| C9399, J3490, J3590, J9999 | Datopotamab deruxtecan-dlnk | Datroway® |
| Q2050 | Doxorubicin liposomal | Doxil® |
| J9063 | Mirvetuximab soratansine-gynx | Elahere™ |
| J9269 | Tagraxofusp-erzs | Elzonris® |

| | | |
|---|---|---|
| J1323 | Elranatamab-bcmm | Elrexfio™ |
| J9176 | Elotuzumab | Empliciti™ |
| J9326 | Telisotuzumab vedotin-tllv | Emrelis™ |
| J9358 | Fam-trastuzumab deruxtecan-nxki | Enhertu® |
| J9321 | Epcoritamab-bysp | Epikinly™ |
| J0885 | Epoetin alfa | Epogen® |
| J9055 | Cetuximab | Erbitux® |
| J9019 | Asparaginase Erwinia chrysanthemi | Erwinaze® |
| J9155 | Degarelix Acetate | Firmagon® |
| Q5108 | Pegfilgrastim-jmdb | Fulphila® |
| J0641 | Levoleucovorin calcium | Fusilev® |
| J9331 | Sirolimus albumin bound nanoparticles | Fyarro™ |
| Q5130 | Pegfilgrastim-pbbk | Fylnetra® |
| J9301 | Obinutuzumab | Gazyva™ |
| J1447 | Tbo-filgrastim | Granix® |
| J9179 | Eribulin | Halaven® |
| J9355 | Trastuzumab | Herceptin® |
| J9356 | Trastuzumab and Hyaluronidase-oysk | Herceptin Hycleta™ |
| C9399, J3490, J3590, J9999, Q5146 | Trastuzumab-strf | Hercessi™ |
| Q5113 | Trastuzumab-pkrb | Herzuma® |
| C9170, J3490, J3590, J9026, J9999 | Tarlatamab-dlle | Imdelltra™ |
| J9173 | Durvalumab | Imfinzi™ |
| J9347 | Tremelimumab-actl | Imjudo® |
| J9325 | Talimogene Laherparepvect | Imlygic® |
| J9183 | Gemcitabine intravesical system | Inlexzo™ |
| J9207 | Ixabepilone | Ixempra® |
| J9281 | Mitomycin | Jelmyto™ |
| J9272 | Dostarlimab-gxly | Jemperli |
| J9043 | Cabazitaxel | Jevtana® |
| Q5160 | Bevacizumab-nwgd | Jobevne™ |
| Q5166 | Denosumab-desu | Jubereq® |
| J9354 | Ado-trastuzumab emtansine | Kadcyla™ |
| Q5117 | Trastuzumab-anns | Kanjinti™ |
| J9271 | Pembrolizumab | Keytruda® |
| J9277 | Pembrolizumab and berahyaluronidase alfa-pmph | Keytruda Qlex™ |
| J0642 | Levoleucovorin | Khapzory™ |
| J9274 | Tebentafusp-tebn | Kimmtrak® |
| 0537T; 0538T; 0539T; 0540T; Q2042 | Tisagenlecleucel | Kymriah® |

| | | |
|---|---|---|
| J9047 | Carfilzomib | Kyprolis™ |
| J2820 | Sargramostim | Leukine® |
| J9119 | Cemiplimab-rwlc | Libtayo® |
| J3263 | Toripalimab-tpzi | Loqtorzi™ |
| J9350 | Mosunetuzumab-axgb | Lunsumio™ |
| J1950; J1954; J9217; J9218; J9219 | Leuprolide acetate | Lupron®<br>Lutrate® |
| C9399, J3490, J3590, J9999 | Denileukin diftitox-cxdl | Lymphir™ |
| C9399, J3490, J3590, J9601, J9999 | Linvoseltamab-gcpt | Lynozyfic™ |
| J9353 | Margetuximab-cmkb | Margenza™ |
| J9349 | Tafasitamab-cxix | Monjuvi® |
| J2562 | Plerixafor | Mozobil™ |
| Q5107 | Bevacizumab-awwb | Mvasi™ |
| J9203 | Gemtuzumab Ozogamicin | Mylotarg™ |
| J2506 | Pegfilgrastim | Neulasta® |
| J2506, 96377 | Pegfilgrastim | Neulasta®<br>Onpro® |
| J1442 | Filgrastim | Neupogen® |
| Q5110 | Filgrastim-aafi | Nivestym™ |
| Q5148 | Filgrastim-txid | Nypozi® |
| Q5122 | Pegfilgrastim-apgf | Nyvepria™ |
| Q5114 | Trastuzumab-dkst | Ogivri® |
| J9266 | Pegaspargase | Oncaspar® |
| J9205 | Irinotecan Liposome | Onivyde® |
| Q5112 | Trastuzumab-dttb | Ontruzant® |
| J9299 | Nivolumab | Opdivo® |
| C9399, J3490, J3590, J9999 | Nivolumab hyaluronidase-nvhy | Opdivo Qvantig™ |
| J9298 | Relatlimab and nivolumab | Opdualag™ |
| J0129 | Abatacept | Orencia® |
| Q5157 | Denosumab-bmwo | Osenvelt® |
| Q5165 | Denosumab-mobz | Oziltus® |
| J9177 | Enfortumab vedotin-ejfv | Padcev® |
| J9306 | Pertuzumab | Perjeta™ |
| J9316 | Pertuzumab, trastuzumab, and hyaluronidase-zzxf | Phesgo™ |
| C9399, J3490, J3590, J9999 | Pertuzumab-dpzb | Poherdy® |
| J9309 | Polatuzumab vedotin-piiq | Polivy™ |
| J9295 | Necitumumab | Portrazza ™ |
| J9204 | Mogamulizumab-kpkc | Poteligeo |
| J0885 | Epoetin alfa | Procrit® |
| Q2043 | Sipuleucel-T | Provenge® |
| J0896 | Luspatercept-aamt | Reblozyl |

| | | |
|---|---|---|
| J9062 | Amivantamab and hyaluronidase-lpuj | Rybrevant Faspro™ |
| Q5125 | Filgrastim-ayow | Releuko® |
| Q5106 | Epoetin alfa, biosimilar | Retacrit™ |
| Q5123 | Rituximab-arrx | Riabni™ |
| J9312 | Rituximab | Rituxan® |
| J9311 | Rituximab and hyaluronidase human | Rituxan Hycela® |
| J1449 | Eflapegrastim-xnst | Rolvedon® |
| Q5119 | Rituximab-pvvr | Ruxience® |
| J9061 | Amivantamab-vmjw | Rybrevant® |
| J9021 | Asparaginase erwinia chrysanthemi (recombinant)-rywn | Rylaze™ |
| C9399, J0870, J3490, J3590, J9999 | Imetelstat | Rytelo® |
| J9361 | Efbemalenograstim alfa-vuxw | Ryzneuta® |
| J2353 | Octreotide | Sandostatin® LAR |
| J9227 | Isatuximab-irfc | Sarclisa® |
| J1930 | Lanreotide | Somatuline® Depot |
| Q5127 | Pegfilgrastim-fpgk | Stimufend® |
| J1627 | Granisetron | Sustol® |
| J2860 | Siltuximab | Sylvant® |
| J3055 | Talquetamab-tgvs | Talvey™ |
| 0537T; 0538T; 0539T; 0540T; Q2053 | Brexucabtagene autoleucel | Tecartus™ |
| Q2057, C9399, J3490, J3590, J9999 | Afamitresgene autoleucel | Tecelra® |
| J9022 | Atezolizumab | Tecentriq™ |
| C9399, J9204, J3490, J3590, J9999 | Atezolizumab and hyaluronidase-tqjs | Tecentriq Hybreza™ |
| J9380 | Teclistamab-cqyv | Tecvayli® |
| J9258 | Paclitaxel protein-bound particles (Teva) | Paclitaxel protein-bound particles (Teva) |
| C9399, J9329 | Tislelizumab-jsgr | Tevimbra® |
| J9273 | Tisotumab vedotin-tftv | Tivdak® |
| Q5116 | Trastuzumab-qyyp | Trazimera™ |
| J3315 | Triptorelin Pamoate | Trelstar® |
| J9317 | Sacituzumab govitecan-hziy | Trodelvy™ |
| Q5115 | Rituximab-abbs | Truxima® |
| Q5111 | Pegfilgrastim-cbqv | Udenyca® |
| Q5111, 96377 | Pegfilgrastim-cbqv | Udenyca® Onbody™ |
| C9399, J3490, J3590, J9999 | Dinutuximab | Unituxin® |
| C9399, J3490, J3590, J9999 | Cosibelimab-ipdl | Unloxcyt™ |

| | | |
|---|---|---|
| J9225 | Histrelin Acetate | Vantas® |
| J9303 | Panitumumab | Vecitibix® |
| Q5129 | Bevacizumab-adcd | Vegzelma® |
| C9303, C9399, J3490, J3590, J9999 | Zolbetuximab-clzb | Vyloy® |
| J9153 | Daunorubicin and cytarabine | Vyxeos® |
| Q5136 | Denosumab-bbdz | Wyost® |
| Q5159 | Denosumab-dssb | Xbryk™ |
| J0897 | Denosumab | Xgeva® |
| Q5167 | Denosumab-qbde | Xtrenbo™ |
| J9228 | Ipilimumab | Yervoy™ |
| 0537T; 0538T; 0539T; 0540T; Q2041 | Axicabtagene ciloleucel | Yescarta® |
| J9352 | Trabectedin | Yondelis® |
| Q5101 | Filgrastim-sndz | Zarxio® |
| J9223 | Lurbinectedin | Zepzelca™ |
| Q5120 | Pegfilgrastim-bmez | Ziextenzo™ |
| C9302, C9399, J3490, J3590, J9999 | Zanidatamab-hrii | Ziihera® |
| Q5118 | Bevacizumab-bvzr | Zirabev® |
| J9202 | Goseralin Acetate | Zoladex® |
| J9282 | Mitomycin | Zusduri™ |
| J9359 | Loncastuximab tesirine-lpyl | Zynlonta® |
| J9350 | Retifanlimab-dlwr | Zynyz™ |
| C9399, J3490, J3590, J9999 | Unspecified oncology product | N/A |
| C9399, J3490, J3590, J9999 | Penpulimab-kcqx | N/A |

**NOTE 1:** Some drugs may have non-oncologic indications. When they are used for such indications refer to HCSC medical policy, and/or FDA prescribing information for guidance.

## Policy Guidelines

None.

## Description

In the United States, the Food and Drug Administration (FDA) oversees the drug/biologic evaluation process and grants approval for marketing of new drug products. (1) Pharmaceutical companies seeking FDA approval to sell a drug in the U.S. must evaluate the drug in various ways. This includes laboratory and animal testing, and finally, testing in humans to determine if the drug/biologic is safe and effective when used to treat or diagnose a disease.

When testing has been completed, the pharmaceutical company will submit a New Drug Application (NDA) or Biologic Licensing Application (BLA) to the FDA to request consideration for marketing the drug in the U.S. The NDA/BLA includes all the animal and human testing data

and analysis of data as well as information about the drug's behavior in the participant's body, and how the drug will be manufactured. A review team of physicians, chemists, statisticians, microbiologists, pharmacologists, and other experts evaluates the studies the sponsor submitted showing the drug is safe and effective for its proposed use. The FDA may call on an advisory committee of outside experts to review the NDA/BLA and make their recommendations. Traditional approval requires that clinical benefit be shown before approval can be granted. Once the FDA has provided approval, the pharmaceutical company can begin marketing the drug for that specific approved indication.

**Off-Label Indications**

Off-label or unlabeled drug use is the use of a drug/biologic approved by the FDA for other uses or in treatment regimens or patient populations that are not included in approved labeling. When a drug is used for an indication other than those specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well-documented in the literature, and widely used.

Unapproved or unlabeled uses of drugs include a variety of situations ranging from completely unstudied to thoroughly investigated drug uses where the FDA has not been asked for approval, whereas approved uses of drugs have been shown to be safe and effective by the FDA after the review of adequate and controlled clinical trials that have documented their uses.

**National Comprehensive Cancer Network® (NCCN®)**

The National Comprehensive Cancer Network® (NCCN®) is an organization of cancer centers, developing treatment guidelines for most cancers. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) present evidence-based recommendations for the diagnosis and treatment of cancer and cancer care supportive therapies. (2) NCCN provides the following definitions for their categories of evidence and consensus:

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

A majority NCCN Panel vote of at least 85% is required for the uniform NCCN consensus defined in Categories 1 and 2A. A Panel vote of at least 50% (but less than 85%) is required for the NCCN consensus defined in Category 2B. Where there is a strong Panel disagreement regardless of the quality of evidence, NCCN requires a Panel vote of at least 25% to include and designate a recommendation as Category 3. The large majority of the recommendations within the Guidelines are Category 2A. Where not specified within the Guidelines, the default designation for the recommendation is Category 2A. (2)

The NCCN Drugs & Biologics Compendium (NCCN Compendium®) includes FDA approved indications of cancer and cancer supportive recommendations, as well as recommended non-FDA approved uses based on the recommendations contained within the NCCN Guidelines.

## Rationale

The United States Food and Drug Administration (FDA) has responsibility for the review of clinical data prior to approval of a new medication. Once approved, the pharmaceutical company may market that drug based on the FDA approved indications. Oncology medications may be used for other indications not approved by the FDA, based on the National Comprehensive Cancer Network® Panel recommendations, and contained in the NCCN Guidelines® and/or the NCCN Drugs & Biologics Compendium®.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|---|---|
| **CPT Codes** | See Table 1 in Coverage for Applicable Codes |
| **HCPCS Codes** | See Table 1 in Coverage for Applicable Codes |

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

## References


1. FDA –The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective. U.S. Food and Drug Administration. Available at: <https://www.fda.gov> (accessed September 24, 2025).
2. National Comprehensive Cancer Network (NCCN). Development and Update of the NCCN Guidelines®. Available at: <https://www.nccn.org> (accessed September 24, 2025).


## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

## Policy History/Revision

| Date | Description of Change |
|---|---|
| 07/01/2026 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 01/01/2026 | Document updated. The following changes were made to Coverage: 1) Updated list of oncology medications and codes in Table 1; and 2) Removed NOTE 2 experimental, investigational and/or unproven statement. No new references added. |
| 10/01/2025 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 07/01/2025 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 04/01/2025 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 02/01/2025 | Document updated. The following change was made to Coverage: Added language regarding drug shortages/recalls to “Initial Therapy” criteria. No new references added. |
| 01/01/2025 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 10/01/2024 | Document updated. The following changes were made to Coverage: Updated list of oncology medications and codes in Table 1; and 2) Added Hercessi to “non-Preferred” drug list. No new references added. |
| 07/01/2024 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 06/01/2024 | Document updated. The following change was made to Coverage: Removed “through a previously authorized pharmacy or medical benefit” in the Continuation of Coverage statement. No new references added. |
| 04/15/2024 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 04/01/2024 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 01/01/2024 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 07/01/2023 | Document updated. The following changes were made to Coverage: 1) Added Vegzelma to “Non-Preferred” drug list, and 2) Updated list of oncology medications and codes in Table 1. No new references added. |
| 01/15/2023 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 01/01/2023 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |

| | |
|---|---|
| 10/01/2022 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 08/01/2022 | Document updated with preferred drug criteria included. |
| 08/01/2021 | Document updated. The following change was made to Coverage: Updated list of oncology medications and codes in Table 1. No new references added. |
| 04/01/2020 | New medical document. Oncology medications may be considered medically necessary when either of the following criteria are met: the drug is approved and being administered in accordance with labeling by the U.S. Food and Drug Administration (FDA) for an oncologic indication; and/or the drug has a category 1, 2A or 2B recommendation by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®), or its derivative information product, the NCCN Drugs & Biologics Compendium (NCCN Compendium®). A number of drug policies were archived as a result of development of this policy. |

## Appendix

**The Appendix is not applicable to plans regulated by the Illinois Department of Insurance or Medicare or Medicaid plans.**

**Continuation Therapy**
Continuation of therapy with non-preferred agents **is considered medically necessary** for all members (including new members):

- Who are currently receiving the requested medication for an indication listed below; AND
- Who are experiencing benefit from therapy as evidenced by disease stability or disease improvement; AND
- When dosing is in accordance with an authoritative source.

**Initial Therapy:**
Coverage for non-preferred agents will be provided contingent to the criteria in this section. For patients initiating therapy, the following criteria would apply prior to non-preferred agent use:

- Patient has tried and failed, is intolerant to, or has a clinical contraindication to the preferred agent; AND
- Physician attests that in their clinical opinion, the same intolerance, contraindications, lack of clinical efficacy, or adverse event would not be expected to occur with non-preferred agents;

OR

- The preferred drugs are experiencing documented drug shortages or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or the US Food and Drug Administration.

**State specific drug criteria may apply.**

**Oncology Medications:**

| Preferred Drugs | Non-Preferred Drugs |
|---|---|
| Mvasi<br>Zirabev | Avastin<br>Avzivi<br>Alymsys<br>Vegzelma<br>Jobevne |
| Kanjinti<br>Ogivri<br>Trazimera | Herceptin<br>Herceptin Hylecta<br>Hercessi<br>Herzuma<br>Ontruzant |
| Ruxience<br>Riabni<br>Truxima | Rituxan<br>Rituxan Hycela |

**WBC Colony Stimulating Factors:**

| Preferred Drugs | Non-Preferred Drugs |
|---|---|
| Nivestym<br>Zarxio | Neupogen<br>Granix<br>Releuko<br>Nypozi |
| Fulphila<br>Neulasta<br>Neulasta Onpro | Nyvepria<br>Udenyca<br>Udenyca Onbody<br>Ziextenzo<br>Stimufend<br>Fylnetra<br>Rolvedon<br>Ryzneuta<br>Armlupeg |