Pharmacy Management Drug Policy

SUBJECT: Oncology Biosimilar Drug Policy
POLICY NUMBER: PHARMACY-93
EFFECTIVE DATE: 06/01/2020
LAST REVIEW DATE: 11/19/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Bevacizumab (Avastin), bevacizumab-maly (Alymsys), bevacizumab-adcd (Vegzelma), bevacizumab-awwb (Mvasi), bevacizumab-bvzr (Zirabev) and bevacizumab-nwgd (Jobevne) are recombinant humanized monoclonal IgG1 antibodies that bind to and inhibit the biologic activity of human vascular endothelial growth factor (VEGF). It prevents VEGF from stimulating blood vessel growth to the tumor. Bevacizumab, bevacizumab-awwb, bevacizumab-maly, bevacizumab-adcd, bevacizumab-nwgd and bevacizumab-bvzr bind VEGF and prevent the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. The interaction of VEGF with its receptors leads to endothelial cell proliferation and new blood vessel formation in *in vitro* models of angiogenesis. Administration of bevacizumab, bevacizumab-awwb, bevacizumab-maly, bevacizumab-adcd, bevacizumab-nwgd and bevacizumab-bvzr results in reduction of microvascular growth and inhibition of metastatic disease progression.

Zirabev (bevacizumab-bvzr), Mvasi (bevacizumab-awwb), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd) and Jobevne (bevacizumab-nwgd) are biosimilars of Avastin (bevacizumab).

Trastuzumab (Herceptin), trastuzumab and hyaluronidase-oysk (Herceptin Hylecta), trastuzumab-anns (Kanjinti), trastuzumab-qyyp (Trazimera), trastuzumab-dkst (Ogivri), trastuzumab-dttb (Ontruzant), trastuzumab-pkrb (Herzuma) and trastuzumab-strf (Hercessi) are monoclonal antibodies that selectively bind to human epidermal growth factor receptor 2 protein (HER2). Trastuzumab products are mediators of antibody-dependent cellular cytotoxicity and inhibit the proliferation of human tumor cells with HER2 overexpression.

Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Herzuma (trastuzumab-pkrb) and Hercessi (traztuzumab-strf) are biosimilars of Herceptin (trastuzumab).

Rituximab (Rituxan), rituximab hyaluronidase (Rituxan Hycela), rituximab-pvvr (Ruxience), rituximab-abbs (Truxima), and rituximab-arrx (Riabni) are chimeric human-murine anti-human antigen CD20 monoclonal antibodies. They work as antineoplastic agents that bind specifically to antigen CD20 which is a hydrophobic transmembrane protein located on normal pre-B and mature B lymphocytes. Antigen

CD20 also is expressed on greater than 90% of B-cell non-Hodgkin's lymphomas (NHLs) but is not found on hematopoietic stem cells, early pre-B cells, normal plasma cells, or other normal tissues. Antigen CD20 is involved in the regulation of cell cycle initiation and differentiation and may function as a calcium ion channel. Rituximab, rituximab-pvvr, rituximab-abbs and rituximab-arrx destroy the CD20+ cells by augmenting complement-mediated lysis and participates in antibody-dependent cell-mediated cytotoxicity. This results from its ability to bind the CD20 antigen with a high affinity.

Ruxience (rituximab-pvvr), Truxima (rituximab-abbs), and Riabni (rituximab-arrx) are biosimilars of Rituxan (rituximab).

For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product by extensively analyzing the structure, purity, chemical identity, and bioactivity. It has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/ responses, and assessment of immunogenicity. Biosimilars may be approved for all or a subset of the same indications as the reference product, depending on patent exclusivity. Biosimilars differ from generics in complexity, manufacturing processes, and in the data needed to demonstrate similarity for approval.

POLICY:

Avastin (bevacizumab), Alymsys (bevacizumab-maly), Jobevne (bevacizumab-nwgd) and Vegzelma (bevacizumab-adcd)
Mvasi and Zirabev are the preferred formulations of bevacizumab for all lines of business and **do not require prior authorization.** • Avastin, Alymsys, Jobevne and Vegzelma require prior authorization for all lines of business • Due to the large range of acceptable uses for these medications and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy. • Treatment with Mvasi and Zirabev will be required to be used for all FDA approved and compendia supported indications for Avastin, Alymsys, Jobevne and Vegzelma unless there is adequate medical justification as to why Mvasi and Zirabev cannot be used. Adequate medical justification will be required for **BOTH** preferred formulations prior to coverage of Avastin, Alymsys, Jobevne and Vegzelma (ex. if the patient has tried Mvasi, the patient must also have a trial of Zirabev or medical justification as to why Zirabev cannot be used and vice versa). Requests for use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy. If clinical criteria are met, then Mvasi and Zirabev will be required unless there is adequate medical justification as to why they cannot be used.
Herceptin (trastuzumab), Herceptin Hylecta (trastuzumab and hyaluronidase-oysk), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), Herzuma (trastuzumab-pkrb), and Hercessi (trastuzumab-strf)
Trazimera and Kanjinti are the preferred formulations of trastuzumab for all lines of business and **do not require prior authorization.** • Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Ogivri, and Ontruzant require prior authorization for all lines of business • Due to the large range of acceptable uses for these medications and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy. • Treatment with Trazimera and Kanjinti will be required to be used for all FDA approved and compendia supported indications for Herceptin, Herceptin Hylecta, Hercessi, Ogivri, Ontruzant,

and Herzuma unless there is adequate medical justification as to why Trazimera and Kanjinti cannot be used. Adequate medical justification will be required for **BOTH** preferred formulations prior to coverage of Herceptin, Herceptin Hylecta, Hercessi, Ogivri, Ontruzant, and Herzuma (ex. if the patient has tried Trazimera, the patient must also have a trial of Kanjinti or medical justification as to why Kanjinti cannot be used and vice versa).

Requests for use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy. If clinical criteria are met, then Trazimera and Kanjinti will be required unless there is adequate medical justification as to why they cannot be used.

Rituxan (rituximab), Rituxan Hycela (rituximab hyaluronidase), and Riabni (rituximab-arrx)

Ruxience and Truxima are the preferred formulations of rituximab for all lines of business and **do not require prior authorization.**

- Rituxan, Rituxan Hycela, and Riabni require prior authorization for all lines of business
- Due to the large range of acceptable uses for these medications and because of the complex and fluid nature of the drug regimen recommendations employed in various clinical circumstances, a list of acceptable indications is not contained in this policy.
- Treatment with Ruxience and Truxima will be required to be used for all FDA approved and compendia supported indications for Rituxan and Rituxan Hycela unless there is adequate medical justification as to why Ruxience and Truxima cannot be used. Adequate medical justification will be required for **BOTH** preferred formulations prior to coverage of Rituxan, Rituxan Hycela, and Riabni (ex. if the patient has tried Ruxience, the patient must also have a trial of Truxima or medical justification as to why Truxima cannot be used and vice versa).

Requests for use inconsistent with FDA labeling will be reviewed based on the Off-Label Use of FDA Approved Drugs policy. If clinical criteria are met, then Ruxience and Truxima will be required unless there is adequate medical justification as to why they cannot be used.

APPROVAL TIME PERIODS:

Unless otherwise stated within the drug specific criteria, approval time periods are listed in the table below:

Line of Business	Medical Initial approval	Medical Recertification
Commercial, Exchange, and Safety Net (Medicaid, HARP, Child Health Plus, Essential Plan)	All sites of service – 6 months	All sites of service – 6 months
Medicare Part B	All sites of service – 6 months	All sites of service – 6 months

POLICY GUIDELINES:

1. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications
2. This policy does not apply to Medicare Part D. The drugs in this policy may apply to all other lines of business including Medicare Part B
3. Preferred product requirements apply to:
   a. All lines of business **AND**
   b. New Starts **ONLY**
4. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
5. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website

at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.

6. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit
7. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Recertifications will also be evaluated for the regimen is currently being prescribed (monotherapy, combination therapy, etc.). If this differs from the initial review, the request will be reviewed based on the level of evidence that is available for the current regimen.
8. This policy is subject to frequent revisions as new medications come onto the market.
9. Supportive documentation of previous drug use must be submitted for any criteria which require trial of a preferred agent if the preferred drug is not found in claims history.
10. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
11. All non-oncologic diagnoses will be subjected to review of FDA approved or compendia listed diagnoses and preferred product.
12. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be

taken into consideration.
- The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

13. Doses of Avastin/Mvasi/Zirabev/Alymsys/Vegzelma/Jobevne should not exceed 15 mg/kg IV every 3 weeks or 10 mg/kg IV every 2 weeks.
14. Avastin/Mvasi/Zirabev/Alymsys/Vegzelma/Jobevne should not be initiated until at least 28 days following surgery and once wound healing has occurred. Discontinue Avastin/Mvasi/Zirabev/Alymsys/Vegzelma/Jobevne at least 28 days prior to elective surgery.
15. The safety and effectiveness of Avastin/Mvasi/Zirabev/Alymsys/Vegzelma/Jobevne in pediatric patients have not been established. Requests for Avastin/Mvasi/Zirabev/Alymsys/Vegzelma/Jobevne use in pediatric patients will be reviewed based on the Off-Label Use of FDA Approved Drugs Policy.
16. No prior authorization is required for Avastin when used to treat the eye.
17. Hepatitis B virus (HBV) reactivation with hepatic failure has been reported in patients receiving Rituxan with hematologic malignancies. Patients at high risk for HBV should be screened prior to the initiation of treatment.
18. Abdominal pain, bowel obstruction and perforation, in some cases leading to death, have been observed in patients receiving rituximab and concomitant chemotherapy for DLBCL.
19. The use of Rituxan in patients with Rheumatoid Arthritis who have not had prior inadequate response to one or more TNF antagonists is not recommended.
20. Rituxan carries a Black Box warning documenting the incidence of the following:
    a. Fatal infusion reactions within 24 hours of Rituxan infusions have been reported
    b. Tumor Lysis Syndrome (TLS)- Acute renal failure requiring dialysis with instances of fatal outcomes has been reported following treatment of non- Hodgkin's lymphoma (NHL).
    c. Severe mucocutaneous reactions with some fatal outcomes have been reported,
    d. Progressive multifocal leukoencephalopathy (PML)- JC virus resulting in PML, and death has been reported (thus far in patients with SLE).
21. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32). This includes any request that is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy.
22. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
23. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be covered under all circumstances. Please read the policy and guideline statements carefully. Codes may not all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I). Not medically necessary/appropriate = (NMN).

HCPCS:

Trade Name	Chemical Name	HCPCS Code	Billing Unit
Avastin	bevacizumab	J9035	10 mg
Alymsys	bevacizumab-maly	Q5126	10 mg
Vegzelma	bevacizumab-adcd	Q5129	10 mg
Mvasi	bevacizumab-awwb	Q5107	10 mg
Zirabev	bevacizumab-bvzr	Q5118	10 mg
Jobevne	Bevacizumab-nwgd	J9999 (NOC)	
Herceptin	trastuzumab	J9355	10 mg
Herceptin Hylecta	trastuzumab and hyaluronidase-oysk	J9356	10 mg
Kanjinti	trastuzumab-anns	Q5117	10 mg
Trazimera	trastuzumab-qyyp	Q5116	10 mg
Ogivri	trastuzumab-dkst	Q5114	10 mg
Ontruzant	trastuzumab-dttb	Q5112	10 mg
Herzuma	trastuzumab-pkrb	Q5113	10 mg
Hercessi	Trastuzumab-strf	Q5146	10 mg
Rituxan	rituximab	J9312	10 mg
Rituxan Hycela	rituximab hyaluronidase	J9311	10 mg
Truxima	rituximab-abbs	Q5115	10 mg
Ruxience	rituximab-pvvr	Q5119	10 mg
Riabni	rituximab-arrx	Q5123	10 mg

UPDATES:

Date	Revision
11/19/2025	Revised
09/08/2025	Revised
03/06/2025	Revised
02/06/2025	P&T Committee Review & Approval
02/03/2025	Revised
01/08/2025	Revised
09/13/2024	Revised
06/20/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
01/15/2024	Revised
3/20/2023	Revised
03/03/2023	Revised
02/09/2023	P&T Committee Approval

01/01/2023	Revised
06/2022	Revised
03/2022	Revised
02/2022	Reviewed / P&T Committee Approval
02/11/2021	P&T Committee Approval
12/2020	Revised
11/2020	Revised
10/2020	Revised
12/2019	Revised
11/2019	P&T Committee Approval

REFERENCES:

- DrugDex and NCCN compendium, accessed 12/30/2019, as well as the full prescribing information for each individual drug have been utilized in creating the above policy.