Capital Health PLAN℠

An Independent Licensee of the Blue Cross and Blue Shield Association

COMMERCIAL

MEDICAL COVERAGE GUIDELINE

PREFERRED BIOSIMILAR & FORMULATION POLICY

Effective Date:

August 1, 2026

Applies To:

Provider-administered drugs billed under the medical benefit for all Commercial, Small Group, and IU65 members in the outpatient setting

Policy Overview

To support high-quality, high value, cost-effective care, this policy establishes preferred biosimilars and formulations for select therapies where there is a high-value biosimilar available for the same FDA approved indications, or there are multiple formulations approved for the same indication with the same chemical moiety, active pharmaceutical ingredient, or enantiomer. This would not include specific products formulations which are uniquely differentiated by recommendations in treatment guidelines (i.e., octreotide long-acting depot for carcinoid tumors vs octreotide subcutaneous). This **policy does not supersede Site of Care MCG.**

Process:

Medications which are non-preferred will be pended and provider will be given the option to utilize a listed Preferred biosimilar or formulation.

Provider may request an exception to the Preferred biosimilar or formulation.

New formulations or new Biosimilars which are not specific are considered non-preferred when they have the same:

Reference product as a Preferred biosimilar

OR

FDA approved indication and same active pharmaceutical ingredient, moiety, or enantiomer as a Preferred formulation

Exception Criteria

Exceptions to the Preferred Biosimilar & Formulation Medical Coverage Guideline will be based on:

1) Product availability whereas the Preferred products are unavailable due to manufacturer supply
2) Documented intolerance to Preferred products
3) Documented inadequate clinical response at therapeutic doses and frequency of listed Preferred biosimilar/formulations
4) Unique patient specific risks in utilizing a Preferred biosimilar formulation supported by sound clinical and scientific reasoning

Step therapy will be required, and the definition of medical necessity met, for the medications listed in the Table(s) below provided ALL the following are met ("1" to "5"):

1. The requested product meets the definition of an outpatient drug; AND

2. The proposed use of the requested product has been determined to be a medically accepted indication; AND

3. The proposed use of the preferred alternative product has been determined to be a medically accepted indication; AND

4. The dose, frequency, and duration of use may not exceed the safety and efficacy data supporting the medically accepted indication for Non-Preferred Drugs:

5. If requested drug is non-preferred, product specific criteria is met (where applicable)

- ONE of the following:
  - Adequate trial of preferred alternative product(s) and patient was intolerant to treatment OR
  - Adequate trial of preferred alternative product(s) and treatment was ineffective OR
  - Preferred product(s) are unavailable OR
  - Contraindication to preferred alternative product(s)

Clinical Standard

Biosimilars and formulations included in this policy meet the standards established by the U.S. Food and Drug Administration by demonstrating no clinically meaningful difference in safety, purity, or potency or FDA labeled indication compared to the non-preferred product.

Biosimilars

Preferred Product(s)		Non-preferred Product(s)*	
• **Mvasi** • **Zirabev** • **Vegzelma**	Q5107 Q5118 Q5129	• Avastin (bevacizumab)* *Oncology indications only Retinal indications do not require PA	J9035
• **Bildyos/Bilprevda** • **Enoby/ Xtrenbo**	Q5162 Q5167	• Prolia/ Xgeva (denosumad) • Jubbonti/Wyost • Stoboclo/Osenvelt • Bomyntra/Conexxence • Ospomyv/Xbryk • Aukelso/Bosaya • Oziltus • Osvyrti/Jubereq • Boncresa	J0897 Q5136 Q5157 Q5158 Q5159 Q5161 Q5165 Q5166 Q5171
• **Truxima** • **Ruxience** • **Riabni**	Q5115 Q5119 Q5123	• Rituxan (rituximab) • Rituxan Hyclea	J9312 J9311

Formulations/Reformulations

Preferred Product(s)		Non-preferred Product(s)*	
• **Testosterone enanthate** • **Testosterone cypionate**	**J3121** **J1071**	• Testopel (testosterone pellet) • Aveed (testosterone undecoate) • Azmiro (testosterone cypionate)	J1073 J3145 J1072
• **Gemzar (Gemcitabine)**	**J9201**	• Gemcitabine (Avyxa) • Gemcitabine (Accord)	J9184 J9196
• **Cyclophosphamide (Dr. Reddy's)** • **Cytoxan (cyclophosphamide)**	**J9073** **J9075**	• Frindovyx (cyclophosphamide) • Cyclophosphamide (Sandoz) • Cyclophosphamide (Baxter)	J9072 J9074 J9076
• **Alimta (Pemetrexed)** • **Pemetrexed (Sandoz)** • **Pemetrexed (Hospira)** • **Pemetrexed (Accord)**	**J9305** **J9297** **J9294** **J9296**	• Axtle (Pemtrexed dipotassium) • Pemfexy (Pemetrexed) • Pemrydi (Pemetrexed)	J9292 J9304 J9324
• **Aloxi (palonosetron)**	**J2469**	• Poser (palonosetron)	J2468

*Any products or codes not listed on the tables above should be considered non-preferred.

Changes From Previous Version:

8/17/2026 Updated Non-Preferred Prolia/ Xgeva (denosumab) biosimilars: Osvyrti/Jubereq, Boncresa/ Oziltus

Medical Necessity Approvals to be made by:

Medical Director
Physician Reviewer
Pharmacist
Medication Management Specialist
Authorized Pharmacy & Therapeutics Department staff when UM criteria are met

These criteria apply to the following products when determined to be included in the member's benefit package:

Commercial