DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Bimzelx Drug Quantity Management Policy – Per Days
- Bimzelx® (bimekizumab-bkzx subcutaneous injection – UCB)

REVIEW DATE: 11/05/2025; selected revision 11/19/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Bimzelx, an interleukin (IL)-17A and IL-17F blocker, is indicated for the following uses:[1]
- **Ankylosing spondylitis**, in adults with active disease.
- **Hidradenitis suppurativa**, in adults with moderate to severe disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.
- **Psoriatic arthritis**, in adults with active disease.
- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.

Dosing

Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis: The recommended dosage is 160 mg by subcutaneous (SC) injection every 4 weeks (Q4W).[1]

Hidradenitis Suppurativa: The recommended dosage is 320 mg by SC injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then Q4W thereafter.[1]

Psoriatic Arthritis: The recommended dosage is 160 mg by SC injection Q4W.[1] For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing regimen for adult patients with plaque psoriasis.

Plaque Psoriasis: The recommended dosage is 320 mg at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter.[1] For patients weighing ≥ 120 kg, consider a dose of 320 mg once every 4 weeks after Week 16.

Availability

Bimzelx is available as 160 mg/1 mL single-dose auto-injectors and prefilled syringes and 320 mg/2 mL single-dose auto-injectors and prefilled syringes.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Bimzelx. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail or Home Delivery Maximum Quantity per 56 Days
Bimzelx® (bimekizumab-bkzx subcutaneous injection	160 mg/1 mL auto-injector	2 mL (2 auto-injectors or syringes)
	160 mg/1 mL prefilled syringe	
	320 mg/2 mL auto-injector	2 mL (1 auto-injector or syringes)
	320 mg/2 mL prefilled syringe	

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Bimzelx 160 mg/1 mL and 320 mg/2 mL auto-injectors and prefilled syringes

1. If the patient is initiating treatment with Bimzelx for plaque psoriasis or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims for Bimzelx in the past 130 days, approve a one-time override of 8 mL for 112 days at retail or home delivery.

Note: This override provides a quantity sufficient for a total of 4 doses (i.e., a dose of 320 mg once every 4 weeks at Weeks 0, 4, 8, and 12).

2. If the patient weighs ≥ 120 kg and requires a dose of 320 mg once every 4 weeks for plaque psoriasis, approve 2 mL per 28 days at retail or 6 mL per 84 days at home delivery.

3. If the patient is initiating treatment with Bimzelx for hidradenitis suppurativa or requires additional induction dosing for hidradenitis suppurativa, as verified by the absence of claims for Bimzelx in the past 130 days, approve a one-time override of 16 mL for 112 days at retail or home delivery.
Note: This override provides a quantity sufficient for a total of 8 doses (i.e., a dose of 320 mg once every 2 weeks at Weeks 0, 2, 4, 6, 8, 10, 12, and 14).

4. If the patient is requesting Bimzelx for the treatment of hidradenitis suppurativa, approve 2 mL per 28 days at retail or 6 mL per 84 days at home delivery.

REFERENCES

1. Bimzelx® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; June 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/10/2024
Early Annual Revision	**Bimzelx 160 mg/1 mL auto-injectors and prefilled syringes:** • The override criteria were updated to approve 4 mL (4 syringes or auto-injectors) per 56 days for a total of 112 days at retail or home delivery for a patient who is initiating treatment with Bimzelx for plaque psoriasis or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims in the past 130 days. Previously, these criteria approved 2 syringes or auto-injectors per 28 days for a total of 112 days at retail or 6 prefilled syringes or auto-injectors per 84 days for a total of 168 days at home delivery, if the patient is initiating treatment with Bimzelx or requires additional induction dosing, as verified by the absence of claims in the past 130 days. • Existing override criteria for a patient who weighs ≥ 120 kg and requires a dose of 320 mg once every 4 weeks was updated to apply to patients with plaque psoriasis only. • New override criteria were added to approve 8 mL (8 syringes or auto-injectors) per 56 days for a total of 112 days at retail or home delivery, if the patient is initiating treatment with Bimzelx for hidradenitis suppurativa or requires additional induction dosing for hidradenitis suppurativa. • New override criteria were added to approve 2 mL (2 syringes or auto-injectors) per 28 days at retail or 6 mL (6 syringes or auto-injectors) per 84 days at home delivery, if the patient is treating hidradenitis suppurativa.	12/18/2024
Selected Revision	**Bimzelx 160 mg/1 mL auto-injectors and prefilled syringes:** References to the number of syringes or auto-injectors were removed from the override criteria. **Bimzelx 320 mg/2 mL auto-injectors and prefilled syringes:**	01/08/2025

	• New quantity limit of 2 mL per 56 days at retail or home delivery. • New override criteria were added to approve 4 mL per 56 days for a total of 112 days at retail or home delivery for a patient who is initiating treatment with Bimzelx for plaque psoriasis or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims in the past 130 days. • New override criteria were added to approve 2 mL every 28 days at retail or 6 mL per 84 days at home delivery if the patient weighs ≥ 120 kg and requires a dose of 320 mg once every 4 weeks. • New override criteria were added to approve 8 mL per 56 days for a total of 112 days at retail or home delivery, if the patient is initiating treatment with Bimzelx for hidradenitis suppurativa or requires additional induction dosing for hidradenitis suppurativa. • New override criteria were added to approve 2 mL per 28 days at retail or 6 mL per 84 days at home delivery, if the patient is treating hidradenitis suppurativa.	
Annual Revision	No criteria changes.	11/05/2025
Selected Revision	**Bimzelx 160 mg/1 mL and 320 mg/2 mL auto-injectors and prefilled syringes:** Override criteria for a patient who requires initiation/induction dosing for plaque psoriasis was updated to approve a one-time override for 8 mL for 112 days at retail or home delivery. Previously, this override approved a quantity of 4 mL per 56 days for a total of 112 days at retail or home delivery. Override criteria for a patient who requires initiation/induction dosing for hidradenitis suppurativa was updated to approve a one-time override for 16 mL for 112 days at retail or home delivery. Previously, this override approved a quantity of 8 mL per 56 days for a total of 112 days at retail or home delivery.	11/19/2025