

BIMZELX
(bimekizumab-bkzx)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
 - a. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
 - i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Patients < 120 kg weight: 320 mg every 8 weeks
 - ii. Patients ≥ 120 kg weight: 320 mg every 4 weeks
 - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Active psoriatic arthritis (PsA)
 - a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
 - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
3. Active non-radiographic axial spondyloarthritis (nr-axSpA)
 - a. Patient has objective signs of inflammation

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- b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
 - c. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
 - d. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 4. Active ankylosing spondylitis (AS)
 - a. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
 - c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
- 5. Moderate to severe hidradenitis suppurativa (HS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 320 mg every 4 weeks

AND ALL of the following for **ALL** diagnoses:

- a. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
- b. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
- d. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO) Weight < 120 kg	160 mg/mL	20 injections (injection at Weeks 0, 4, 8, 12, 16, then every 8 weeks)
	320 mg/2 mL	10 injections (injection at Weeks 0, 4, 8, 12, 16, then every 8 weeks)

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		8 weeks)
Plaque psoriasis (PsO) Weight ≥ 120 kg	160 mg/mL	28 injections (injection at Weeks 0, 4, 8, 12, 16, then every 4 weeks)
	320 mg/2 mL	14 injections (injection at Weeks 0, 4, 8, 12, 16, then every 4 weeks)
Psoriatic arthritis (PsA)	160 mg/mL	13 injections (injection every 4 weeks)
Non-radiographic axial spondyloarthritis (nr-axSpA)	160 mg/mL	13 injections (injection every 4 weeks)
Ankylosing spondylitis (AS)	160 mg/mL	13 injections (injection every 4 weeks)
Hidradenitis suppurativa (HS)	160 mg/mL	36 injections (injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, 16, then every 4 weeks)
	320 mg/2 mL	18 injections (injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, 16, then every 4 weeks)

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Patients < 120 kg weight: 320 mg every 8 weeks
 - ii. Patients ≥ 120 kg weight: 320 mg every 4 weeks
 - b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Psoriatic arthritis (PsA)

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- a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
- b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
3. Non-radiographic axial spondyloarthritis (nr-axSpA)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
 - b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. Ankylosing spondylitis (AS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
 - b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
5. Hidradenitis suppurativa (HS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 320 mg every 4 weeks

AND ALL of the following for **ALL** diagnoses:

- a. Condition has shown improvement or stabilization
- b. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
- d. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	160 mg/mL	2 injections per 56 days
Weight < 120 kg	320 mg/2 mL	1 injection per 56 days
Plaque psoriasis (PsO)	160 mg/mL	4 injections per 56 days
Weight ≥ 120 kg	320 mg/2 mL	2 injections per 56 days
Psoriatic arthritis (PsA)	160 mg/mL	2 injections per 56 days
Non-radiographic axial	160 mg/mL	2 injections per 56 days

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spondyloarthritis (nr-axSpA)		
Ankylosing spondylitis (AS)	160 mg/mL	2 injections per 56 days
Hidradenitis suppurativa (HS)	160 mg/mL	4 injections per 56 days
	320 mg/2 mL	2 injections per 56 days

Duration 18 months

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytosan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)*

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
Bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo

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tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)*

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

*Refer to respective drug policy for biosimilars

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Plaque Psoriasis (PsO) Age 18+	*must try TWO preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try ONE preferred product: Enbrel Humira**
Psoriatic arthritis (PsA) Age 18+	*must try TWO preferred products: Enbrel Humira** Otezla Rinvoq Skyrizi Stelara (SC) Taltz Tremfya Xeljanz/XR	*must try ONE preferred product: Enbrel Humira**
Non-radiographic axial spondyloarthritis (nr-axSpA)	*must try TWO preferred products: Cimzia Rinvoq Taltz	No preferred products
Ankylosing spondylitis (AS)	*must try TWO preferred products: Enbrel Humira** Rinvoq Taltz	*must try ONE preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)