Bimekizumab-bkzx (BIMZELX) in Plaque Psoriasis
National Drug Monograph

November 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The purpose of VA PBM Services drug monographs is to provide a focused drug review for making formulary decisions. Updates will be made if new clinical data warrant additional formulary discussion. The Product Information or other resources should be consulted for detailed and most current drug information.

Abbreviations: ADA, adalimumab; BKZ, bimekizumab; bIMM, biologic immunomodulator; DLQI-0/1, Dermatology Life Quality Index total score of 0 or 1 (range, 0–30 with higher scores indicating a greater effect of PsO on daily life); IMG, immunogenicity; L, line (therapy); PBO, placebo; PK, pharmacokinetics; PsA, psoriatic arthritis; PPsO, plaque psoriasis; W, week(s)

FDA APPROVAL INFORMATION

Description / MOA	Bimekizumab-bkzx (BKZ) is a humanized interleukin-17A and F (IL-17A/F) antagonist. IL-17F is a proinflammatory cytokine that shares 50% homology with IL-17A and, like IL-17A, is elevated in psoriatic lesions.
Indication Under Review[1]	Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
Dosage Regimen	320 mg SC at Weeks 0, 4, 8, 12, and 16 then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider 320 mg every 4 weeks after Week 16.
Dosage Forms Under Review	Injection: 160 mg/mL in a single-dose prefilled syringe or single-dose prefilled autoinjector
Pretreatment Evaluations	Tuberculosis infection Liver enzymes, alkaline phosphatase, and bilirubin Update all age-appropriate vaccinations as per current guidelines

EFFICACY CONSIDERATIONS

Clinical Trials of BKZ in Moderate to Severe PPsO

Major Efficacy Trials

RCT	Design	BKZ (N)	Comparator (N)	PASI-90, %	DLQI-0/1, %	Time (W)
Phase 2a[2]	Phase 2a	320 mg SC at W0, W4, and W16 (17)	BKZ / PBO: BKZ 320 mg SC at W0, W4, then PBO at W16 (32)	64.7 vs 31.3	—	28
BE ABLE 1[3]	Phase 2b MN DB PC RCT 1st L or 2nd L after 1 bIMM	64, 160, 320/160, 320, or 480 mg SC Q4W	PBO	60 vs 0	—	12
BE ABLE 2[4]	Phase 2b extension	64/64 mg (15) 160/160 mg (55) 320 / 320 mg (33) 480/320 mg (30)	—	80–100	76.4–93.3	60
BE READY[5]	Phase 3b MC DB PC RCT 1st L or 2nd L after 1 bIMM	320 mg Q4W (349), W0–W16	PBO (86)	91 vs 1	75.6 vs 5.8	16
	randomized withdrawal	320 mg Q4W (106) or Q8W (100), W16–56	PBO (105)	89 vs 16	76–86 vs 19	56
BE SURE[6]	Phase 3 MN DB DD AC RCT 1st L or 2nd L after 1 bIMM	320 mg SC Q4W x 56W (158) 320 mg Q4W x 16W then Q8W from W16 to W56 (161)	ADA 80 mg SC at W0, 40 mg at W1 then Q2W x 24W then BKZ 320 mg Q4W to W56 (159)	86.2 (pooled) vs 47.2	—	16
				85.6 (pooled) vs 51.6	67.1 vs 47.8	24
				82.6–84.8 vs 81.8	74.1–78.9 vs 73.0	56
BE VIVID[7]	Phase 3b MN DB AC PC RCT 1st L or 2nd L after 1 bIMM	320 mg SC Q4W (321) Q4W could be switched to Q8W at W76 (W24 of BE BRIGHT) if PASI ≥ 90	UST 45 mg (≤ 100 kg) or 90 mg (> 100 kg) at	85 vs 50 vs 5	67 vs 42 vs 12	16

			W0, W4, then Q12W (163) PBO Q4W to W16 (83)			
BE RADIANT[8]	Phase 3b MN DB AC RCT 1st L or 2nd L after 1 bIMM with 16-W initial therapy, rerandomization 1:2 at W16, then 32-W maintenance	320 mg SC Q4W to W16 (373)	SEC 300 mg SC QW to W4 (370)	85.5 vs 74.3	—	16
		320 mg Q4W (147) or Q8W (215) from W16 to W48	SEC 300 mg Q4W from W4 to W16 then to W48 (354)	83.6 vs 70.5	78 vs 70	48

PASI90 Treatment Effects at Week 16 in Phase 3 Active-controlled Trials

Trial	BKZ Q4W, n/N (%)	Comparator, n/N (%)		RR (95% CI)	AAE (95% CI)	Q
BE SURE	136/158 (86)	ADA	75/159 (47)	1.8 (1.53, 2.18)	389 (295, 484)	M[α]
BE VIVID	273/321 (85)	UST	82/163 (50)	1.7 (1.44, 1.98)	347 (261, 434)	M[α]
BE RADIANT	319/373 (86)	SEC	275/370 (74)	1.2 (1.07, 1.24)	113 (58, 168)	M[α]

[α] Downgraded for indirectness (not a clinical outcome).
M, moderate; Q, GRADE quality

DLQI-0/1 Treatment Effects in Phase 3 Active-controlled Trials

Trial	Time, wk	BKZ Q4W, n/N (%)	Comparator, n/N (%)		RR (95% CI)	AAE (95% CI)	Q
BE SURE	24	108/161 (67)	ADA	76/159 (48)	1.4 (1.15, 1.71)	193 (87, 299)	M[α]
BE VIVID	16	215/321 (67)	UST	68/163 (42)	1.6 (1.32, 1.96)	253 (161, 344)	H
BE RADIANT	48	291/373 (78)	SEC	259/370 (70)	1.1 (1.02, 1.21)	80 (17, 143)	H

[α] Downgraded for imprecision (optimal information size not met)
H, high; M, moderate; Q, GRADE quality

Open-label Extensions (OLEs)

Effects in Switchers from adalimumab (BE SURE), ustekinumab (BE VIVID / BE BRIGHT), or secukinumab (BE RADIANT) to BKZ[9]

Design

Phase 3/3b; efficacy and safety of BKZ in switchers in BE SURE / BE BRIGHT OLE (ADA/BKZ), BE VIVID / BE BRIGHT OLE (UST/BKZ), and BE RADIANT / BE RADIANT OLE (SEC/BKZ)

- BE SURE / BE BRIGHT OLE: BKZ rerandomized 4:1 at W56. BKZ 320 mg Q4W if PASI < 90 or 320 mg Q8W if PASI ≥ 90. Q4W could be switched to Q8W at W80 (W24 of BE BRIGHT) if PASI ≥ 90.
- BE VIVID / BE BRIGHT OLE: rerandomized 1:1 at W52. BKZ 320 mg Q4W if PASI < 90 or 320 mg Q8W if PASI ≥ 90. Q4W could be switched to Q8W at W76 (W24 of BE BRIGHT) if PASI ≥ 90.
- BE RADIANT / BE RADIANT OLE: 96-W OLE; rerandomized 1:1 at W48. 320 mg Q4W if PASI < 90 or 320 mg Q8W if PASI ≥ 90. Q4W could be switched to Q8W at W64.

Results

Efficacy of BKZ in Switchers

Efficacy Measure	ADA/BKZ Q4W/BKZ	UST/BKZ	SEC/BKZ
PASI90 Nonresponders on ADA, UST, or SEC who switched to BKZ			
PASI90 at W4, n/N (%)	36/54 (67)	35/44 (79)	28/53 (53)
PASI90 at W48, n/N (%)	49/54 (91)	40/44 (90)	42/53 (79)
DLQI-0/1 at W0|24|48/56, % (n)	30|81|84 (54)	49|81|88 (44)	51|86|74 (53)
PASI90 Responders on ADA, UST, or SEC who switched to BKZ			
PASI90 at W48, n/N (%)	72/75 (96)	92/92 (100)	243/256 (95)
DLQI-0/1 at W0|24|48/56, % (n)	69|87|89 (75)	86|87|89 (92)	88|88|84 (256)

Network Meta-analysis (NMA)

Systemic pharmacologic treatment for chronic plaque psoriasis: a network meta-analysis (living review)[10]

Design

NMA of RCTs of systemic treatments compared with PBO or another active agent

Population	Adults > 18 y; moderate to severe PPsO at any stage of treatment
Results	Only biologic and targeted therapies are presented here. The agents ranked best in the table below were all based on high-certainty evidence.

Outcome Measure	Ranked Best	Ranked Worst	BKZ Better Than	BKZ Similar To	BKZ Worse Than
PASI90 at 8–24W	Infliximab Bimekizumab Ixekizumab Risankizumab	Cyclosporine	Secukinumab Brodalumab Guselkumab Ustekinumab 3 TNFIs (ADA, CER, ETA) Deucravacitinib Apremilast	Infliximab Ixekizumab Risankizumab	—

Indirect comparative effects between BKZ and drugs worse than BKZ in PASI90 response

Drug Worse Than BKZ	RR (95% CI), BKZ vs Other
Secukinumab	1.15 (1.08, 1.23)
Brodalumab	1.26 (1.12, 1.41)
Guselkumab	1.26 (1.16, 1.37)
Ustekinumab	1.61 (1.49, 1.74)
Adalimumab	1.73 (1.58, 1.89)
Certolizumab	2.29 (1.7, 3.09)
Etanercept	2.88 (2.55, 3.26)
Deucravacitinib	2.0 (1.46, 2.73)
Apremilast	2.88 (2.55, 3.26)

Duration of an Adequate Trial	16 weeks based on PASI90 response
Other Trials of Interest	Bimekizumab has been shown to be efficacious and has been FDA-approved for **PsA**[11,12,13,14,15,16] and **axial spondyloarthritis** (ankylosing spondylitis and **nonradiographic axial spondyloarthritis**),[17,18] and to be promising in hidradenitis suppurativa (phase 2 RCT).[19]
Evidence Gaps	Efficacy of BKZ for scalp, nail, and palmoplantar involvement has been reported only in an abstract.[20]

SAFETY CONSIDERATIONS

Boxed Warnings	None
Contraindications	None
Other Warnings	Suicidal ideation and behavior, infections, tuberculosis, liver biochemical abnormalities, inflammatory bowel disease, immunizations
Top 5 AEs	Upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections
Drug Interactions	CYP450 substrates, particularly those with a narrow therapeutic index. Consider monitoring for effect (e.g., warfarin) or drug concentration (e.g., cyclosporine), and dosage modification of the substrate.
NMA[10]	There were no significant differences between BKZ and other biologics, targeted small-molecule immunomodulators, and conventional immunomodulators used for PPsO in the risk of serious adverse events.

PLACE IN THERAPY

DRUG	On VANF	Restrictions / Clinical Guidance	FDA	JOINT AAD / NPF GUIDELINES (2019, 2020)
IL-17A/F Antagonist				
Bimekizumab-bkzx	TBD	TBD	Treatment of moderate to severe PPsO in adults who are candidates for systemic therapy or phototherapy	Not mentioned (guideline preceded drug approval).
Dihydrofolate Reductase Inhibitor				
Methotrexate	Yes	Methotrexate Contraindications and Risk Factors for Serious Adverse Events in Inflammatory Disorders_508.pdf	Treatment of severe PPsO Treatment of recalcitrant or disabling PPsO inadequately responsive to other forms of therapy	Recommended for treatment of moderate to severe PPsO in adults. Less effective than adalimumab and infliximab for cutaneous psoriasis. Efficacious for treatment of PsA (peripheral arthritis, but not for axial involvement). Less effective than TNFIs in PsA.
Calcineurin Inhibitor				
Cyclosporine, modified (oral capsules and solution, and injection)	Yes	None	Treatment of severe or recalcitrant PPsO in nonimmune-compromised adults unresponsive or intolerant to ≥ 1 systemic therapy	Recommended for severe, recalcitrant psoriasis. Can be recommended for erythrodermic, generalized pustular, and/or palmoplantar psoriasis. Can be recommended as short-term interventional therapy for flares while on pre-existing systemic therapy.
Retinoids				
Acitretin	Yes	None	Treatment of severe PPsO. For women of reproductive potential, limit use to nonpregnant patients unresponsive to other therapies.	Can be recommended as monotherapy for PPsO. Can be recommended for erythrodermic, pustular, and palmar-plantar psoriasis.
Phosphodiesterase-4 Enzyme Inhibitor				
Apremilast	Yes	PA-F, with Apremilast in Psoriasis Criteria Rev. Oct 2022.pdf Moderate to Severe PPsO: 4th line after 1 conventional immunomodulator and 2 classes of targeted immunomodulators	Treatment of PPsO in adults who are candidates for systemic therapy or phototherapy	Recommended for moderate to severe psoriasis in adults.
Tumor Necrosis Factor Inhibitors				
Adalimumab / Biosimilars	Yes	PA-F, restricted to providers appropriate for prescribing TNF inhibitors	Treatment of moderate to severe chronic PPsO in adults who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate	Recommended as a monotherapy treatment option for moderate to severe plaque psoriasis in adults.

[redacted]	Certolizumab	Yes	PA-F, restricted to providers appropriate for prescribing TNF inhibitors	Same as BKZ	Based on extrapolated data from other TNFIs, certolizumab is likely to have class characteristics (combination treatment, efficacy in difficult-to-treat areas, and possibly immunogenicity) similar to those of other TNFIs.
	Etanercept	Yes	PA-F, restricted to providers appropriate for prescribing TNF inhibitors	Same as BKZ	Recommended as a monotherapy treatment option for moderate to severe plaque psoriasis including scalp, nails, and pustular or erythrodermic subtypes. Recommended as a monotherapy treatment option for plaque psoriasis of any severity when associated with significant PsA.
	Infliximab / Biosimilars	Yes	PA-F, restricted to providers appropriate for prescribing TNF inhibitors Infliximab-abda is the preferred product.	Treatment of chronic severe (i.e., extensive and/or disabling) PPsO in adults who are candidates for systemic therapy and when other systemic therapies are medically less appropriate	Recommended as a monotherapy treatment option for moderate to severe plaque psoriasis including plaque-type palmoplantar psoriasis, scalp, nails, and pustular or erythrodermic subtypes. Recommended as a monotherapy treatment option for plaque psoriasis of any severity when associated with significant PsA. Can inhibit radiographic progression.
	IL-17A Antagonists				
	Ixekizumab	No	Ixekizumab (TALTZ) Criteria for Use (Rev. Feb 2022)_508.pdf Preferred IL-17A agent in new starts. 3rd–4th line after methotrexate, phototherapy (if available and feasible), and TNFI	Treatment of moderate to severe PPsO in patients ≥ 6 years of age who are candidates for systemic therapy or phototherapy	Recommended as a monotherapy treatment option for moderate to severe PPsO. Can be recommended as a monotherapy treatment option for moderate to severe plaque psoriasis affecting the scalp or nails, for erythrodermic psoriasis, and for generalized pustular psoriasis. Recommended as a monotherapy treatment option for adults with plaque psoriasis when associated with PsA.

Secukinumab	No	Secukinumab (COSENTYX) Criteria for Use (Rev. Feb 2022)_508.pdf 3rd–4th line after methotrexate, phototherapy (if available and feasible), and TNFI	Same as ixekizumab	Recommended as a monotherapy treatment option for moderate to severe plaque psoriasis in adults including disease affecting the nails or palms and soles. Can be recommended as a monotherapy treatment option for moderate to severe plaque psoriasis affecting the head and neck, including the scalp, and for moderate to severe palmoplantar pustulosis. Can be used as monotherapy for erythrodermic psoriasis. May be used as monotherapy for adults with plaque psoriasis when associated with PsA.
IL-17 Receptor Antagonist				
Brodalumab	No	Brodalumab (SILIQ) Criteria for Use (Rev. Feb 2022)_508.pdf 6th–7th line therapy after methotrexate, phototherapy (if available and feasible), TNFIs, IL-17AI, IL-23I, and ustekinumab	Treatment of moderate to severe PPsO in adults who are candidates for systemic therapy or phototherapy and have failed or lost response to other systemic therapies	Recommended as a monotherapy treatment option for moderate to severe PPsO in adults. Can be used as monotherapy for generalized pustular psoriasis in adults.
IL-23p19 Antagonists				
Guselkumab	No	Guselkumab TREMFYA in Psoriasis Criteria Oct 2022.pdf 3rd–4th line therapy after methotrexate, phototherapy (if available and feasible), and TNFIs	Same as BKZ	Recommended as a monotherapy treatment option for moderate to severe PPsO in adults and for scalp, nail, and plaque-type palmoplantar psoriasis.
Risankizumab-rzaa	No	Risankizumab-rzaa (SKYRIZI) in Psoriasis Criteria for Use (Rev. Feb 2022)_508.pdf 3rd–4th line therapy after methotrexate, phototherapy (if available and feasible), and TNFIs	Same as BKZ	Guideline preceded drug approval. Can be used as monotherapy for moderate to severe PPsO in adults.
Tildrakizumab-asmn	No	Tildrakizumab-asmn (ILUMYA) Criteria for Use (Rev. Feb 2022)_508.pdf 3rd–4th line therapy after methotrexate, phototherapy (if available and feasible), and TNFIs	Same as BKZ	Recommended as a monotherapy treatment option for moderate to severe PPsO in adults.
IL-12/23 Antagonist				

	Ustekinumab / Biosimilars	No	Ustekinumab (STELARA) Criteria for Use (Rev. Dec 2021)_508.pdf 4th–5th line therapy after methotrexate, phototherapy (if available and feasible), a TNFI, and an IL-17AI.	Same as BKZ	Recommended as a monotherapy treatment option for moderate to severe PPsO in adults and for PPsO when associated with PsA. Can be recommended as a monotherapy treatment option for moderate to severe PPsO affecting the nails in adults. Can be used as monotherapy for moderate to severe plaque-type palmoplantar psoriasis, for moderate to severe PPsO affecting the scalp, palmoplantar, pustular or erythrodermic subtypes of moderate to severe PPsO.
	Tyrosine Kinase 2 Inhibitor				
	Deucravacitinib	No	Deucravacitinib SOTYKTU in Plaque Psoriasis Criteria Apr 2023.pdf 5th–6th line therapy after methotrexate, phototherapy (if available and feasible), and 3 targeted systemic antipsoriatic drugs (≥ 1 drug per class)	Same as BKZ	Not mentioned (guideline preceded drug approval)
	T-cell Modulator				
	Alefacept	No	None	Same as BKZ	Not mentioned (reason not provided)

VHA PLACE IN THERAPY	**Potential Use in VHA**	1. There were three head-to-head trials to inform the place in therapy of bimekizumab-bkzx in the treatment of PPsO. In patients who received bimekizumab-bkzx as a 1st-line or 2nd-line therapy after a biologic immunomodulator, bimekizumab-bkzx showed small to moderate Week-16 PASI-90 induction benefits over adalimumab (BE SURE trial) and ustekinumab (BE VIVID trial), and small, if any, benefits over secukinumab (BE RADIANT). Rates of remission maintenance with bimekizumab-bkzx were similar to those for adalimumab at Week 56 and secukinumab at Week 48. Bimekizumab-bkzx showed additional efficacy at Week 48 in up to 91%, 90%, and 79% of PASI90 nonresponders to adalimumab, ustekinumab, or secukinumab, respectively. Therefore, the main benefits with bimekizumab-bkzx were seen with induction rather than maintenance therapy and in nonresponders to prior adalimumab, ustekinumab, and secukinumab. In a network meta-analysis, bimekizumab-bkzx was similar to infliximab, ixekizumab, and risankizumab in PASI90 efficacy at Weeks 8–24. 2. The proposed place in therapy of bimekizumab-bkzx is as a 5th–6th-line systemic therapy for moderate to severe PPsO after methotrexate, phototherapy (if available and feasible), a TNFI, and less-costly IL-17Ais and IL-23is. Bimekizumab-bkzx may be preferred over ustekinumab 90 mg because of greater efficacy and lower cost; however, bimekizumab-bkzx is higher in cost than ustekinumab 45 mg. 3. For *severe* PPsO, an IL-17A antagonist (preferably ixekizumab) rather than a TNFI can be considered on a case-by-case basis. Severe PPsO can be described as psoriasis that affects >10% body surface area, impairs work or biopsychosocial function, affects hands, feet, nails, scalp, face, or genital area, or causes intractable pruritus, pain or bleeding. An IL-17A/F antagonist (e.g., BKZ) or IL-23 antagonist (e.g., risankizumab) may be considered for severe PPsO as an alternative to a TNFI (e.g., infliximab / biosimilar) if an IL-17A antagonist is medically inadvisable.

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