SKYRIZI® (risankizumab-rzaa) Medicaid Clinical Summary

Plaque psoriasis (Ps) is an immune-mediated disease that causes raised, red, scaly patches to appear on the skin. These patches or plaques most often show up on the scalp, knees, elbows and lower back with a silvery white buildup of dead skin cells. They are often itchy and painful, and they can crack and bleed.[1] The primary goal of treatment is to achieve and maintain high levels of skin clearance.[1]

Despite available treatment options, the majority of patients from a large US Claims Database were either diagnosed but untreated or had experienced a lapse in treatment.[2]

SKYRIZI (risankizumab-rzaa) INDICATIONS AND USAGE[3]

SKYRIZI (risankizumab-rzaa) is an interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

DOSAGE FORMS AND STRENGTHS[3]

Injection: 150mg/ml in each single-dose prefilled syringe or single-dose prefilled pen.

DOSAGE AND ADMINISTRATION[3]

150 mg administered by subcutaneous injection at week 0, week 4, and every 12 weeks thereafter.

SKYRIZI (risankizumab-rzaa) Clinical Program[4-7]

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Active Comparator	Ustekinumab*	Ustekinumab*	Adalimumab	None	Secukinumab
Treatment Arms	• Risankizumab: 150 mg • Ustekinumab: 45/90 mg (weight-based) • Placebo	• Risankizumab: 150 mg • Ustekinumab: 45/90 mg (weight-based) • Placebo	• Risankizumab: 150 mg • Adalimumab: 80 mg week 0, 40 mg week 1, and then Q2W	• Risankizumab: 150 mg • Placebo	• Risankizumab: 150 mg • Secukinumab: 300 mg
Study Duration	52 weeks	52 weeks	48 weeks	104 weeks	52 weeks
Sample Size	506	491	605	507	327
Type of Data	• Short-term superiority vs placebo • Short (16 weeks) and medium (52 weeks) superiority vs ustekinumab		• Short-term (16 weeks) efficacy vs adalimumab • Efficacy in incomplete responders to adalimumab (PASI 50- <PASI 90)	Impact of treatment withdrawal/retreatment	• Short-term (16 weeks) noninferiority vs secukinumab • Medium-term (52 weeks) superiority vs secukinumab

Adult patients with moderate to severe plaque Ps (involved body surface area [BSA] ≥ 10%, Psoriasis Area and Severity Index [PASI] ≥ 12, and static Physician Global Assessment [sPGA ≥ 3]) at screening and baseline were eligible to enter the studies. Patients in this Phase 3 program bear similarities to patients seen in clinical practice with ~30% of patients >100kg & ~30% of patients had either diagnosed (~10%) or suspected (~20%) psoriatic arthritis. A unique feature of this Phase 3 program was that it had a high proportion of patients with prior biologic use ranging from 30-57% across the trials.

The SKYRIZI (risankizumab-rzaa) psoriasis phase 3 clinical program was conducted in 5 trials with over 2,000 patients: UltIMMa 1 & 2 are two replicate studies evaluating superiority of risankizumab (RZB) to EU-sourced ustekinumab and placebo (over 16 & 52 weeks. IMMvent evaluated the superiority of RZB to adalimumab (ADA) at 16 weeks and the superiority of incomplete responders to ADA (PASI 50 - < PASI 90) that switched to RZB. IMMhance evaluated the impact of withdrawal and retreatment with RZB. IMMerge evaluated the noninferiority of RZB to secukinumab at 16 weeks, and the superiority of RZB to secukinumab at 52 weeks.

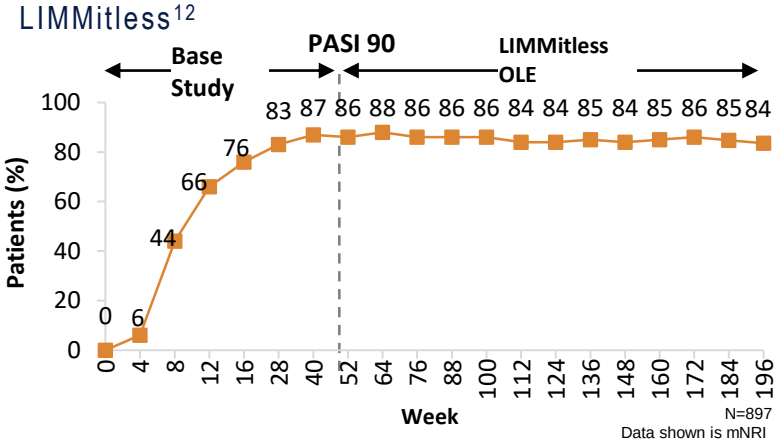
WARNINGS AND PRECAUTIONS[3]

- Infections: SKYRIZI may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer SKYRIZI until the infection resolves.
- Tuberculosis (TB): Evaluate for TB prior to initiating treatment with SKYRIZI.
- Administration of vaccines: Avoid use of live vaccines.

ADVERSE REACTIONS[3]

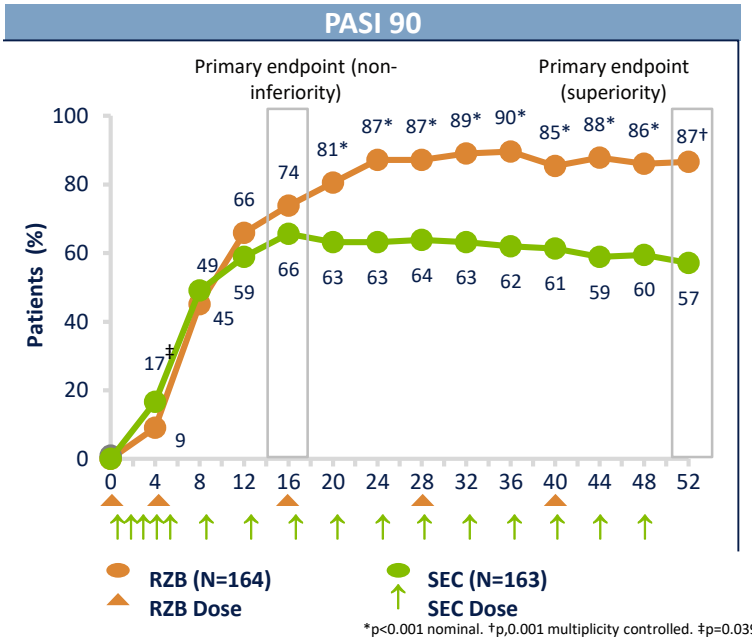
- Most common adverse reactions (≥ 1%) are upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

LIMMitless[12]



Results shown above are from the long-term open label extension study, LIMMitless, at week 196. Data is consistent with week 16 and week 52 efficacy data from both UltIMMa trials, IMMvent, IMMhance and IMMerge showing consistent efficacy of RZB treatment at PASI 90.

IMMerge[7]



*p<0.001 nominal. †p,0.001 multiplicity controlled. ‡p=0.039.
SEC=secukinumab.

In IMMerge, a randomized, open-label, blinded assessor, head-to-head study of RZB vs secukinumab (SEC), Risankizumab was noninferior to secukinumab in proportion of patients achieving PASI 90 at week 16 [73·8% vs. 65·6%; difference of 8·2% (within 12% noninferiority margin], and superior to secukinumab at week 52 [86·6% vs. 57·1%; P<0·001]. All other secondary endpoints were met (superiority of RZB vs. SEC at week 52 for sPGA 0/1, PASI 75 and PASI 100). No new safety signals were observed in the study.[6]

RZB met all primary and secondary endpoints in all 5 trials.

RZB demonstrated superiority of PASI 90 and 100 response vs. UST (EU-sourced) at weeks 16 and 52 in two trials.[4] Mean PASI improvement from baseline to week 52 by body mass index and body weight (last observation carried forward) was statistically higher for patients treated with RZB vs UST (EU-sourced).[9]

In the LIMMitless integrated analysis, the RZB PASI 90 and 100 response was maintained in the open-label extension period from week 52 through 196.[12]

In the IMMvent trial, RZB showed statistically significantly higher PASI 90 response rates vs. ADA at week 16, and significantly higher PASI 90 rates for those who were intermediate responders to ADA (PASI 50-<90) and switched to RZB, vs. those that remained on ADA.[5]

LONG-TERM INTEGRATED SAFETY (LIMMitless – 70.4 MONTHS)[12]

- Adverse events were low in LIMMitless and remained comparable with the rates observed in the primary psoriasis safety pool

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