

Clinical Oversight Review Board (CORB) Criteria for Prescribing Spesolimab-sbzo IV (Spevigo IV)

Notes:

- Quantity Limits: N/A – infusion medication
- ^ Adequate trial is defined as the following:
 - Systemic non-biologics– 6 weeks
 - Biologics – 12 weeks
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- **If criteria met, spesolimab-sbzo IV will be approved for up to two infusions. Second infusion to be given one week after the first if flare symptoms have not resolved. Max of two infusion per flare.

Non-Formulary **spesolimab-sbzo IV (Spevigo IV)** requires a clinical review.
Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

- Patient has a diagnosis of generalized pustular psoriasis (GPP)
- Prescriber is a dermatologist
- Patient is at least 12 years of age and weighs at least 40 kilograms
- Patient is currently experiencing a moderate to severe GPP flare based on at least one of the following:
 - Presence of fresh pustules (new appearance or worsening pustules)
 - At least 5% body surface area (BSA) covering with erythema and the presence of pustules
 - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate)
 - GPPPGA pustulation sub-score of at least 2 (mild)
- Patient has failed an adequate trial[^], or patient has an allergy or intolerance* to, at least 1 of the following (or contraindication to all):
 - Methotrexate
 - Acitretin
 - Cyclosporine
- Patient has failed an adequate trial[^], or patient has an allergy or intolerance* to 2 of the following:
 - Infliximab product
 - Adalimumab product (criteria based)
 - Secukinumab (criteria based)
- Patient has not received an infusion of spesolimab-sbzo previously for the same GPP flare**

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