

STANDARD MEDICARE PART B MANAGEMENT

SPEVIGO (spesolimab-sbzo)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

For the treatment of generalized pustular psoriasis (GPP) flares in adults.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

Chart notes or medical record documentation of affected area(s) must be available, upon request, for all submissions.

III. CRITERIA FOR INITIAL APPROVAL

Generalized pustular psoriasis (GPP) flare

Authorization of 1 month may be granted for treatment of generalized pustular psoriasis flares in adult members when all of the following criteria are met:

- A. Member has a known documented history of GPP (either relapsing [greater than 1 episode] or persistent [greater than 3 months]).
- B. Member is presenting with primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques).
- C. At least 5% body surface area (BSA) is covered with erythema and the presence of pustules.

IV. CONTINUATION OF THERAPY

All adult members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. SUMMARY OF EVIDENCE

Reference number(s)
5582-A

The contents of this policy were created after examining the following resources:

1. The prescribing information for Spevigo.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology
3. European consensus statement on phenotypes of pustular psoriasis

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Spevigo are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Spevigo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022.
2. Bachelez H, Choon SE, Marrakchi S, et al. Trial of Spesolimab for Generalized Pustular Psoriasis. *N Engl J Med*. 2021;385(26):2431-2440.
3. Navarini AA, Burden AD, Capon F, et al. European consensus statement on phenotypes of pustular psoriasis. *J Eur Acad Dermatol Venereol*. 2017;31(11):1792-1799.