

Medical Policy

| Spevigo® (spesolimab) | |
|---------------------------------------|--|
| MEDICAL POLICY NUMBER | MED_Clin_Ops_129 |
| CURRENT VERSION EFFECTIVE DATE | 01/01/2024 |
| APPLICABLE PRODUCT AND MARKET | Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL |

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Spevigo® (spesolimab) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage will be provided for two doses (900mg each) and may NOT be renewed.

Max Units (per dose and over time) [HCPCS Unit]:

- 900 mg (2 vials) on day 1 and 8

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1. Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
2. Patient does not have an active infection, including clinically important localized infections; **AND**
3. Patient will not receive live vaccines during therapy; **AND**
4. Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); **AND**
5. Patient is at least 18 years of age; **AND**
6. Patient does not have any of the following conditions:
 - a. Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome
 - b. Primary erythrodermic psoriasis vulgaris
 - c. Primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques
 - d. Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP); **AND**
7. Patient is experiencing an acute, moderate-to-severe intensity disease flare as defined by the following:
 - a. GPP-PGA total score of at least 3 (moderate) or greater; **AND**
 - b. Presence of fresh pustules (new appearance or worsening of pustules); **AND**
 - c. GPP-PGA pustulation sub score of at least 2 (mild); **AND**
 - d. At least 5% of body surface area (BSA) covered with erythema and the presence of pustules.; **AND**
8. Patient will not use concomitantly with systemic immunosuppressants (e.g., retinoids, cyclosporine, methotrexate, etc.) or other topical agents (e.g., corticosteroids, calcipotriene, tacrolimus, etc.).

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

CODING

| Applicable NDC Codes | |
|----------------------|--|
| 58468-0050 -01 | Spevigo 450 mg/7.5 mL (60 mg/mL) two-pack single-dose vial (SDV) |

| Applicable Procedure Code | |
|---------------------------|------------------------|
| J3590 | Unclassified biologics |

| Applicable ICD-10 Codes | |
|-------------------------|--------------------------------|
| L40.1 | Generalized pustular psoriasis |

EVIDENCE BASED REFERENCES

1. Spevigo [package insert]. Ridgefield, NJ; Boehringer Ingelheim Pharmaceuticals, Inc.; September 2022. Accessed October 2022.

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POLICY HISTORY

| Revision History | Month Day, Year | Updates |
|---------------------------|------------------|--|
| Original Effective Date | NOVEMBER 8, 2022 | |
| Revision | MARCH 1, 2023 | Adopted by MA UMC |
| P&T Committee Endorsement | NOVEMBER 8, 2022 | |
| Revision | JANUARY 1, 2024 | Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan |