Medical Policy Bulletin
Title:
Spesolimab--sbzo (Spevigo®)
Policy #:
MA08.155b

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

Spesolimab-sbzo (Spevigo) is considered medically necessary and, therefore, covered as a single-dose intravenous infusion for the treatment of individuals ages 12 years or older with a generalized pustular psoriasis (GPP) flare when all of the following criteria are met:

- The individual has been diagnosed with generalized pustular psoriasis (GPP) and is currently experiencing a flare with both of the following:
    - The individual has at least 5% of body surface area (BSA) covered with erythema and the presence of pustules (new appearance or worsening of pustules)
    - The individual has a flare of GPP of moderate-to-severe intensity, as defined by the Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 (moderate) to 4 (severe) [the total GPPPGA score ranges from 0 (clear) to 4 (severe)]
- Prescribed by or in consultation with a dermatologist
- The individual does not have any of the following:
    - Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome.
    - Primary erythrodermic psoriasis vulgaris.
    - Primary plaque psoriasis vulgaris without the presence of pustules or with pustules that are restricted to psoriatic plaques.
    - Drug-triggered Acute Generalized Exanthematous Pustulosis (AGEP).
    - An immediate life-threatening flare of GPP or requiring intensive care treatment (e.g., cardiovascular/cytokine-driven shock, pulmonary distress syndrome, or renal failure)
    - Severe, progressive, or uncontrolled hepatic disease, defined as >3- fold Upper Limit of Normal (ULN) elevation in AST or ALT or alkaline phosphatase, or >2-fold ULN elevation in total bilirubin.

NOTE: If flare symptoms persist, may administer an additional intravenous 900 mg dose one week after the initial dose.

EXPERIMENTAL/INVESTIGATIONAL

All other uses of Spesolimab-sbzo (Spevigo) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

Guidelines

There is no Medicare coverage determination addressing spesolimab-sbzo (Spevigo) for intravenous use; therefore, the Company policy is applicable.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, spesolimab-sbzo (Spevigo) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria listed in this medical policy are met.

Spesolimab-sbzo (Spevigo) may be available under the member's medical benefits through the Direct Ship Injectables Program.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

U.S. Food and Drug Administration approved Spevigo on September 1, 2022, for the treatment of generalized pustular psoriasis (GPP) flares in adults. Spevigo is a selective antibody that blocks activation of the interleukin-36 receptor (IL-36R), a key part of a signaling pathway that shown to be involved in the cause of GPP.

ADMINISTRATION

According to U.S. FDA labeling, dosing for generalized pustular psoriasis flare spesolimab-sbzo (Spevigo) dosing is a one-time dose of 900 mg (2x 450 mg/7.5ml vials). If flare symptoms persist, may administer an additional intravenous 900 mg dose one week after the initial dose.

PEDIATRIC USE

The safety and effectiveness of spesolimab-sbzo (Spevigo) in pediatric individuals for the treatment of generalized pustular psoriasis (GPP) flares have not been evaluated.

Description

GENERALIZED PUSTULAR PSORIASIS (GPP)

Generalized Pustular Psoriasis (GPP) is a rare, lifelong skin disease, which may be life-threatening if left untreated. It is characterized by flares that appear suddenly in the form of painful, pus-filled blisters over large areas of the body. It may be accompanied by more general symptoms, such as fever, headache, extreme tiredness, or a burning sensation on the skin. GPP can present as more common plaque psoriasis, but they are different diseases. In the United States, it is estimated that 1 out of every 10,000 people has GPP.

US FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL OF SPESOLIMAB (SPEVIGO)

Spesolimab (Spevigo) for intravenous infusion received US Food and Drug Administration (FDA) approval on September 1, 2022, for the treatment of generalized pustular psoriasis (GPP) flares in adult individuals (18 years or older).

Spesolimab (Spevigo) is a novel antibody that blocks the activation of the interleukin 36 receptor (IL-36R). The interleukin 36 signaling pathway, of the immune system, has been shown to be involved in causing GPP flares.

PEER-REVIEWED LITERATURE

SUMMARY
FDA approval was based on a global, Phase II, placebo-controlled study that evaluated the efficacy, safety, and tolerability of spesolimab (Spevigo) in individuals presenting with an acute GPP flare. Individuals with an acute GPP flare were randomized 2:1 to receive a single 900 mg intravenous dose of spesolimab (Spevigo) or placebo and followed for up to 28 weeks. Individuals in both groups could receive an open-label dose of spesolimab on day 8, an open-label dose of spesolimab (Spevigo) as a rescue medication after day 8, and were followed to week 12. The primary endpoint was a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of 0 (range, 0 [no visible pustules] to 4 [severe pustulation]) at the end of week 1. The key secondary endpoint was a GPPGA total score of 0 or 1 (clear or almost clear skin) at the end of week 1; scores range from 0 to 4, with higher scores indicating greater disease severity. Safety was assessed over the study duration by the occurrence of treatment-emergent adverse events. Blood and skin biopsies were collected to assess biomarkers. The superiority of spesolimab (Spevigo) over placebo in the proportion of individuals achieving the primary and key secondary endpoints was evaluated.

The safety and effectiveness of Spevigo for the treatment of GPP have been established in multicentre, randomised, placebo-controlled, Phase IIb trial in pediatric individuals ages 12 years and older and weighing at least 40 kilograms. Use of Spevigo for GPP was supported by data from a randomized, placebo-controlled study which included six pediatric individuals ages 14 to 17 years with a history of GPP treated with subcutaneous Spevigo (Study Effisayil-2) and evidence from the study of intravenous Spevigo in adult individuals with GPP (Study Effisayil-1). Additional pharmacokinetic analyses showed similar drug exposure levels in adult and pediatric individuals ages 12 years and older and weighing 40 kg or more.

This study investigated whether long-term treatment with the antibody spesolimab helps prevent skin flares in individuals with generalized pustular psoriasis (GPP) . Participants were between ages 12 and 75 years with a documented history of GPP as per the European Rare and Severe Psoriasis Expert Network criteria, with a history of at least two past GPP flares, and a GPP Physician Global Assessment (PGA) score of 0 or 1 at screening and random assignment. Individuals were randomly assigned (1:1:1:1) to receive subcutaneous placebo, subcutaneous low-dose spesolimab (300 mg loading dose followed by 150 mg every 12 weeks), subcutaneous medium-dose spesolimab (600 mg loading dose followed by 300 mg every 12 weeks), or subcutaneous high-dose spesolimab (600 mg loading dose followed by 300 mg every 4 weeks) over 48 weeks. The primary objective was to demonstrate a non-flat dose-response curve on the primary endpoint, time to first GPP flare.

The Physician Global Assessment (PGA), also known as the Physician's or Investigator's Global Assessment, provides a single estimate of an individual's overall disease severity determined by the physician or investigator. This is a seven-point scale from clear (PGA = 0) to severe (PGA = 6).

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to the evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

References

Elsevier's Clinical Pharmacology Compendium. Spesolimab-sbzo. 09/03/2022. [Clinical Key Web site]. Available at: https://www.clinicalkey.com/pharmacology/ [via subscription only]. Accessed September 10, 2022.

Lexi-Drugs Compendium. Spesolimab -sbzo . 09/13/22. [Lexicomp Online Web site]. Available at: http://online.lexi.com/lco/action/home [via subscription only]. Accessed September 16, 2022.

Truven Health Analytics. Micromedex® DrugDex® Compendium. Spesolimab-sbzo. 07/13/22. Greenwood Village, CO. [Micromedex® Solutions Web site]. Available at: http://www.micromedexsolutions.com/micromedex2/librarian [via subscription only]. Accessed September 10, 2022.

US Food and Drug Administration (FDA). Spesolimab-sbzo [prescribing information]. [FDA Web site]. 09/22/2022. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed September 10, 2022.

Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. Spesolimab -sbzo (Spevigo). labeling.09/2022. Available at:https://docs.boehringer-ingelheim.com/Prescribing

Information/PIs/Spevigo/Spevigo.pdf?DMW_FORMAT=pdf. Accessed September 10, 2022.

ClinicalTrials.gov. Effisayil™ 1: A Study to Test Spesolimab (BI 655130) in Patients With a Flare-up of a Skin Disease

Called Generalized Pustular Psoriasis.ClinicalTrials.gov Identifier: NCT03782792.First Posted: December 20, 2018; Last Update Posted: March 9, 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03782792. Accessed September 4, 2022.

ClinicalTrials.gov.International Rare And Severe Psoriasis Expert Network. ClinicalTrials.gov Identifier: NCT04359394. First Posted: April 24, 2020; Last Update Posted: July 6, 2022. Available at: International Rare And Severe Psoriasis Expert Network - Full Text View - ClinicalTrials.gov. Accessed September 4, 2022.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
L40.1 Generalized pustular psoriasis

HCPCS Level II Code Number(s)
J1747 Injection, spesolimab-sbzo, 1 mg

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.155b:

09/16/2024	This version of the policy will become effective 09/16/2024. This policy has been updated to communicate the Company's coverage criteria for spesolimab -sbzo (Spevigo) for intravenous use for pediatric individuals who are ages 12 years and older and weigh 40 kg or more.

MA08.155a

05/07/24	The following new policy has been developed to communicate the Company's coverage criteria for Spesolimab -sbzo (Spevigo) for intravenous use.

Version Effective Date:
09/16/2024
Version Issued Date:
09/16/2024
Version Reissued Date:
N/A