BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/18/2021
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TAVNEOS™ (avacopan) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

TAVNEOS™ (avacopan) oral

Criteria:

- **Criteria for initial therapy:** Tavneos (avacopan) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Rheumatologist, Nephrologist, Pulmonologist, or Otolaryngologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA])

  4. Will be used in combination with standard therapy (cyclophosphamide, azathioprine or mycophenolate mofetil if azathioprine is contraindicated, or rituximab), including glucocorticoids

  5. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Hepatitis B (HBV) testing with Hepatitis B surface antigen (HBsAg) and Hepatitis B core antibody (anti-HBc)
     b. Positive test for anti-myeloperoxidase (MPO) or anti-proteinase 3 (PR3) antibodies

  6. Individual has an estimated glomerular filtration rate of at least 15 mL/min/1.73 m^2

  7. Individual does not have active, serious infection, including localized infection

  8. Individual does not have active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis

  9. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Tavneos (avacopan) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Rheumatologist, Nephrologist, Pulmonologist, or Otolaryngologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Achieved and maintains absence of any clinical manifestations from ongoing active vasculitis
        ii. Reduced number of relapses over baseline
        iii. No evidence of disease progression

iv. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Hepatotoxicity
        ii. Serious hypersensitivity reaction such as angioedema
        iii. Hepatitis B reactivation
        iv. Infection

5. Individual does not have active, serious infection, including localized infection

6. Individual does not have active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis

7. Individual has an estimated glomerular filtration rate of at least 15 mL/min/1.73 m^2

8. Individual does not have severe hepatic impairment (Child-Pugh Class C)

9. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of a Non-Cancer Medications**

    2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Tavneos (avacopan) is a complement 5a receptor (C5aR, also known as CD88) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos (avacopan) does not eliminate glucocorticoid use.

Avacopan inhibits the interaction between C5aR and the anaphylatoxin C5a. Avacopan blocks C5a-mediated neutrophil activation and migration and blocks the C5a-induced upregulation of CD11b (integrin alpha M) on

neutrophils. The precise mechanism by which avacopan exerts a therapeutic effect in patients with ANCA-associated vasculitis has not been definitively established.

ANCA–associated vasculitis is a serious and potentially life-threatening condition. The illness includes several related forms of small-vessel vasculitis: GPA (also known as Wegener's granulomatosis), MPA, renal-limited vasculitis, and eosinophilic granulomatosis with polyangiitis (known as Churg-Strauss). GPA and MPA have variable presentation in terms of organ manifestations and severity; however, the most commonly and severely affected organs include upper and lower respiratory tract and the kidneys.

Patients with both GPA and MPA typically present with nonspecific symptoms including fever, malaise, anorexia, weight loss, myalgias, and arthralgias. Specific organ involvement can include ear, nose, and throat; trachea and lungs; kidney; skin; ophthalmic and orbital; and neurologic. Other organ systems less commonly involved include the gastrointestinal tract, heart (pericarditis, myocarditis, conduction system abnormalities), lower genitourinary tract (including the ureters and prostate), parotid glands, thyroid, liver, or breast.

The diagnosis of GPA or MPA should be suspected in any patient who presents with constitutional symptoms and clinical evidence of glomerulonephritis or upper or lower respiratory tract involvement. The diagnosis is based upon the combination of characteristic clinical findings, laboratory tests, and imaging studies. A positive ANCA test strongly supports but does not confirm the diagnosis. Histologic examination of tissue obtained by biopsy of an affected organ (generally, kidney, skin, or lung) remains the most definitive method to establish a diagnosis and is still often required.

GPA and MPA are thought to be triggered by the production of circulating autoantibodies against the neutrophil-expressed antigens myeloperoxidase (MPO) or proteinase 3 (PR3). The current treatment for GPA and MPA includes induction of and maintenance of remission using glucocorticoids combined with either rituximab or cyclophosphamide followed by oral azathioprine, methotrexate, mycophenolate, or rituximab.

Resources:

Tavneos (avacopan) product information, revised by ChemoCentryx, Inc. 10-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 21, 2021.

Falk RJ, Merkel PA, King TE. Granulomatosis with polyangiitis and microscopic polyangiitis: Clinical manifestations and diagnosis. In: UpToDate, Glassock RJ, Appel GB, Lam AQ, Curtis MR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 26, 2021.

Merkel PA, Kaplan AA, Falk RJ. Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy. In: UpToDate, Appel GB, Fervenza FC, Lam AQ, Curtis MR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 26, 2021.

Falk RJ, Merkel PA, King TE. Granulomatosis with polyangiitis and microscopic polyangiitis: Management of relapsing disease. In: UpToDate, Glassock RJ, Appel GB, Lam AQ, Curtis MR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 26, 2021.

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Jayne DRW, Merkel PA, Schall TJ, Bekker P. Avacopan for the treatment of ANCA-associated vasculitis. NEJM 2021 Feb 18; 384 (7):599-609. Accessed October 25, 2021.