SPECTRUM ACCESS 4 ME®

Prior Authorization Checklist

Prior authorizations (PAs) are a required process where healthcare providers seek approval from insurance companies before certain medical services, procedures, or medications can be covered. This step is crucial in ensuring patients receive the necessary treatments without unexpected financial burdens. Prior authorizations involve submitting detailed information about the patient's medical condition, corresponding treatment plan, and the basis for the requested service or medication. Insurance companies review this information to determine if the requested treatment meets their coverage criteria.

The below checklist features information and items that may be required to acquire a PA decision from an insurer.

Completed PA Request Form

- ❑ If a PA is required for treatment with ROLVEDON® (eflapegrastim-xnst) injection, be sure to complete all the insurer's necessary fields on the PA request form to receive a timely response for the patient's treatment plan. This form can be found on the insurer's website, or by calling the insurer's customer service phone number.
- ❑ Before starting the PA process, verify that the patient's insurance has not changed since their last visit.
- ❑ Including a Letter of Medical Necessity can explain the rationale and clinical decision behind the choice of the specific therapy, this could include a summary statement of medical need and reasons for the medication being requested. See sample here
- ❑ Include the Indication for ROLVEDON, located on page one of the PI, first column here

Patient and Provider Information

- ❑ Full legal name
- ❑ Date of birth
- ❑ Insurance ID Number/Insurance Group Number
- ❑ Case ID Number (if available)
- ☑ Physician and facility/office information (provider ID/tax ID)

Patient Diagnosis and History

Summary of the patient's diagnosis:

- ❑ Patient medical records
- ❑ Diagnostic test results, pathology reports, imaging results, and allergies
- ❑ Severity of the patient's condition
- ❑ The clinical rationale for treatment, including trial data supporting the FDA approval, administration and dosing information for ROLVEDON. FDA Approval Letter here
- ❑ Additional information regarding the treatment decision: For example peer-reviewed journal articles or documentation referencing nationally recognized guidelines (eg, ASCO, NCCN)

Summary of the patient's history and treatments:

- ❑ Prior administered treatment(s)/procedure(s) and dates
- ❑ Response to the intervention(s)
- ❑ New symptoms
- ❑ Physician opinion of patient prognosis
- ❑ Relevant procedure and HCPCS codes for products/services to be provided/performed
- ❑ ROLVEDON NDC # 76961-101-01

As a reminder, make sure to keep all your records/documentation, including copies of what you send out and notes about any calls you make to the patient's health insurance company.

Indications and Usage

ROLVEDON is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

Limitations of Use

ROLVEDON is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Selected Safety Information

Contraindications

- ROLVEDON is contraindicated in patients with a history of serious allergic reactions to eflapegrastim, pegfilgrastim or filgrastim products. Reactions may include anaphylaxis.

Please see additional Important Safety Information on the next page and accompanying full Prescribing Information for ROLVEDON.

ROLVEDON®
(eflapegrastim-xnst) injection
13.2 mg/0.6 mL

Important Safety Information (Cont'd)
Warnings and Precautions

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of recombinant human granulocyte colony-stimulating factor (rhG-CSF) products. Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture.

Acute Respiratory Distress Syndrome (ARDS)

- ARDS can occur in patients receiving rhG-CSF products. Evaluate patients who develop fever, lung infiltrates, or respiratory distress. Discontinue ROLVEDON in patients with ARDS.

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving rhG-CSF products. Permanently discontinue ROLVEDON in patients who experience serious allergic reactions.

Sickle Cell Crisis in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving rhG-CSF products. Discontinue ROLVEDON if sickle cell crisis occurs.

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving rhG-CSF products. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation. Evaluate and consider dose reduction or interruption of ROLVEDON if causality is likely.

Leukocytosis

- White blood cell (WBC) counts of 100 x 10^9/L or greater have been observed in patients receiving rhG-CSF products. Monitor complete blood count (CBC) during ROLVEDON therapy. Discontinue ROLVEDON treatment if WBC count of 100 x 10^9/L or greater occurs.

Thrombocytopenia

- Thrombocytopenia has been reported in patients receiving rhG-CSF products. Monitor platelet counts.

Capillary Leak Syndrome

- Capillary leak syndrome has been reported after administration of rhG-CSF products and is characterized by hypotension, hypoalbuminemia, edema and hemoconcentration. Episodes vary in frequency and severity and may be life-threatening if treatment is delayed. If symptoms develop, closely monitor and give standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- The granulocyte colony-stimulating factor (G-CSF) receptor through which ROLVEDON acts has been found on tumor cell lines. The possibility that ROLVEDON acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which ROLVEDON is not approved, cannot be excluded.

Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML) in Patients with Breast and Lung Cancer

- MDS and AML have been associated with the use of rhG-CSF products in conjunction with chemotherapy and/or radiotherapy in patients with breast and lung cancer. Monitor patients for signs and symptoms of MDS/AML in these settings.

Aortitis

- Aortitis has been reported in patients receiving rhG-CSF products. It may occur as early as the first week after start of therapy. Consider aortitis in patients who develop generalized signs and symptoms such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c-reactive protein and white blood cell count) without known etiology. Discontinue ROLVEDON if aortitis is suspected.

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting bone imaging results.

Adverse Reactions

- The most common adverse reactions (≥20%) were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain.
- Permanent discontinuation due to an adverse reaction occurred in 4% of patients who received ROLVEDON. The adverse reaction requiring permanent discontinuation in 3 patients who received ROLVEDON was rash.

To report SUSPECTED ADVERSE REACTIONS, contact Spectrum Pharmaceuticals, Inc. at 1-888-713-0688 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for ROLVEDON.

SPECTRUM® PHARMACEUTICALS

PP-ROL-00-0590

ROLVEDON®
(eflapegrastim-xnst) injection
13.2 mg/0.6 mL