COMMUNICATION

COM-2024-034

7
May
2024

PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and disease prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

First Therapy for WHIM Syndrome

The U.S. Food and Drug Administration (FDA) has approved Xolremdi™ (mavorixafor) capsules to treat patients of 12 years of age and older with warts, hypogammaglobulinemia, infections, and myelokathexis, (WHIM) syndrome; to increase the number of circulating mature neutrophils and lymphocytes.

Background

WHIM syndrome, which affects about 1,000 people in the United States, is an ultra-rare, combined primary immunodeficiency disease caused by genetic variations to the CXCR4 receptor. This receptor is a key regulator of the mobilization of white blood cells from the bone marrow. Almost all patients with this condition have neutropenia, thus are more susceptible to life-threatening bacterial infections and to human papillomavirus (HPV) infections. Typical treatment for WHIM syndrome has historically included the use of granulocyte-colony stimulating factor (G-CSF) and intravenous immunoglobulin (IVIG).

Xolremdi's Approval

Xolremdi is a selective CXC chemokine receptor 4 (CXCR4) antagonist and the first FDA-approved treatment specifically indicated in patients with WHIM syndrome.

The FDA approval was based on results of the Phase 3 4WHIM clinical trial, a randomized, double-blind, placebo-controlled, 52-week multicenter study that evaluated the efficacy and safety of Xolremdi in 31 participants 12 years of age and older diagnosed with WHIM syndrome. The efficacy was determined by improvement in absolute neutrophil counts, improvement in absolute lymphocyte counts, and a reduction in infections. Over a 52-week period, Xolremdi treatment demonstrated improvement in both absolute neutrophil count and absolute lymphocyte count compared with placebo. Both counts are used to check for infection and inflammation. Treatment with Xolremdi also resulted in a 60% reduction in the annualized infection rate compared with placebo-treated patients.

The most common adverse reactions in the trial were: thrombocytopenia, pityriasis, rash, rhinitis, epistaxis, vomiting, and dizziness. There was no serious treatment-related adverse events and no discontinuations because of adverse events.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext 219. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

pharmpix
POWERED BY ONEARK

REFERENCES:

1. Myshko, D. (2024, April 29). FDA Approves Xolremdi for Ultra Rare Immune Disorder. Formulary Watch. https://www.formularywatch.com/view/fda-approves-xolremdi-for-ultra-rare-immune-disorder
2. Brian Park, P. (2024, May 3). Xolremdi approved for patients with WHIM syndrome. MPR. https://www.empr.com/home/news/xolremdi-approved-for-patients-with-whim-syndrome/
3. Xolremdi (mavorixafor) dosing, indications, interactions, adverse effects, and more. (2024, April 29). https://reference.medscape.com/drug/xolremdi-mavorixafor-4000425

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000130-001

CLINICAL PEARLS BY PHARMPIX