Effective Date 02/01/2025
Reviewed: 11/2024
Scope: Medicaid

XOLREMDI (mavorixafor)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Xolremdi is indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis)
Authorization of 6 months may be granted for treatment of WHIM syndrome when all of the following criteria are met:

A. Member is 12 years of age or older
B. The medication is prescribed by or in consultation with a prescriber who specializes in WHIM syndrome (e.g., immunologist, hematologist).
C. Documentation that the member has a genotype-confirmed variant of *CXCR4* gene consistent with WHIM syndrome
D. Documentation that the member has a baseline absolute neutrophil count (ANC) ≤400 cells/μL
E. Documentation of baseline absolute lymphocyte count (ALC) and number of infections experienced within the last year
F. Documentation that the member exhibits at least one other clinical manifestation of disease at baseline (i.e., warts, hypogammaglobulinemia, infections, myelokathexis, lymphopenia, monocytopenia)
G. Member will not be taking Xolremdi concomitantly with plerixafor (Mozobil).
H. Documentation of member's current weight
I. Dose does not exceed either of the following:
    1. 300 mg (3 capsules) per day for members weighing ≤50 kg
    2. 400 mg (4 capsules) per day for patients weighing >50 kg

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members (including new members) requesting continuation of therapy when all of the following criteria are met:

A. Member continues to meet all initial criteria
B. Member is experiencing benefit from therapy as evidenced by updated laboratory results, chart notes and/or medical record documentation that include both of the following:
    1. An ANC ≥ 500 cells/μL within the last 3-6 months
    2. One of the following (i or ii):

i. An ALC ≥ 1,000 cells/μL within the last 3-6 months
ii. Reduction from baseline in infections

IV. QUANTITY LIMIT

Xolremdi has a quantity limit of 4 capsules per day.

V. REFERENCES

1. Xolremdi [package insert]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.
2. National Organization for Rare Disorders (NORD). WHIM syndrome. Rare Disease Database. https://rarediseases.org. Published 2013. Last updated January 16, 2024. Accessed May 9, 2024.
3. Badolato R, Donadieu J, WHIM Research Group. How I treat warts, hypogammaglobulinemia, infections, and myelokathexis syndrome. *Blood.* 2017;130(23):2491-2498. doi: 10.1182/blood-2017-02-708552