

| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
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| Original Development Date: Original Effective Date: Revision Date: | January 21, 2025 |

XolremdiTM (mavorixafor)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 12 years of age; **AND**
- Patient must have a diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome; AND
- Genotype-confirmed variant of CXC chemokine receptor 4 (CXCR4) consistent with WHIM syndrome; **AND**
- Confirmed absolute neutrophil count (ANC) ≤ 400 cells/µL (or total white blood cell [WBC] count ≤ 400 cells/µL if ANC is below lower limit of detection); **AND**
- Prescriber attestation to assess QTc at baseline and to monitor QTc periodically during treatment for patients with risk factors for QTc prolongation; AND
- Females of reproductive potential must have a confirmed negative pregnancy test prior to initiation AND must attest to use effective contraception during treatment and for 3 weeks after the last dose.

CONTINUATION OF THERAPY

- Patient met initial review criteria; AND
- Documentation of disease improvement (e.g., improvement in ANC and/or absolute lymphocyte counts [ALC], reduction in infections); **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., significant QTc prolongation);
 AND
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 100 mg capsules.
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

