AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Xolremdi	Page:	1 of 2
Effective Date:	1/13/2025	Last Review Date:	11/25/2024
Applies to:	☒ Illinois ☒ Maryland	☒ Florida Kids ☒ Pennsylvania Kids	☒ New Jersey ☐ Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xolremdi under the patient's prescription drug benefit.

Description:

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 Indication
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.

Applicable Drug List:

Xolremdi

Policy/Guideline:

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   i. Genetic testing results confirming a diagnosis of WHIM syndrome.
   ii. Laboratory results of neutrophil count.
   iii. Chart notes or medical record documentation of at least one clinical manifestation of disease.
B. Continuation requests: Chart notes or medical record documentation of benefit from therapy.

Prescriber Specialty:
This medication must be prescribed by or in consultation with an immunologist, pediatrician, hematologist, or dermatologist.

Criteria for Initial Approval:
Pulmonary arterial hypertension (PAH)
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:

1. Member has a genotype-confirmed variant of *CXCR4* gene consistent with WHIM syndrome.
2. Member has a confirmed low neutrophil count based on the reference laboratory range or current practice guidelines.
3. Member exhibits at least one other clinical manifestation of disease (i.e., warts, hypogammaglobulinemia, infections, myelokathexis, lymphopenia, monocytopenia).
4. Member is 12 years of age or older.

Continuation of Therapy:
Authorization of 12 months may be granted for all members (including new members) requesting continuation of therapy when the member is experiencing benefit from therapy (e.g., improvement in absolute neutrophil count [ANC], improvement in absolute lymphocyte count [ALC], reduction in infections).

Approval Duration and Quantity Restrictions:

Approval:

- Initial approval: 6 months
- Renewal: 12 months

Quantity limit: 120 capsules per 30 days

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