



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xpovio (selinexor) is a nuclear export inhibitor. Xpovio reversibly inhibits nuclear export of tumor suppressor proteins (TSPs), growth regulators, and mRNAs of oncogenic proteins by blocking exportin 1 (XPO1). XPO1 inhibition by Xpovio leads to accumulation of TSPs in the nucleus, reductions in several oncoproteins, such as c-myc and cyclin D1, cell cycle arrest, and apoptosis of cancer cells (1).

Regulatory Status

FDA approved indications: Xpovio is a nuclear export inhibitor indicated: (1)

1. In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy
2. In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
3. For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

Low platelet counts are common with Xpovio and can lead to bleeding which can be severe and can sometimes cause death. Monitor for low platelet counts and manage promptly. Low white blood cell counts are common with Xpovio and can sometimes be severe leading to increased risk of infection which can sometimes cause death. Monitor for low white blood cell counts and manage promptly. It is important for patients to drink enough fluids to help prevent dehydration and to eat enough calories to help prevent weight loss during treatment with Xpovio. Patients should be monitored for weight loss (1).

Xpovio also contains warnings for: thrombocytopenia, neutropenia, hyponatremia, gastrointestinal toxicity, neurological toxicity, embryo-fetal toxicity, cataract and serious infections (1).

Females of reproductive potential should be advised to avoid becoming pregnant while being



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XPOVIO (selinexor)

treated, as Xpovio has been shown to cause fetal harm. Females of reproductive potential and males with a partner of reproductive potential should be advised to use effective contraception during treatment with Xpovio and for 1 week after the last dose (1).

The safety and effectiveness of Xpovio in patients less than 18 years of age have not been established (1).

Summary

Xpovio (selinexor) is a nuclear export inhibitor. Xpovio reversibly inhibits nuclear export of tumor suppressor proteins (TSPs), growth regulators, and mRNAs of oncogenic proteins by blocking exportin 1 (XPO1). XPO1 inhibition by Xpovio leads to accumulation of TSPs in the nucleus, reductions in several oncoproteins, such as c-myc and cyclin D1, cell cycle arrest, and apoptosis of cancer cells. The safety and effectiveness of Xpovio in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Xpovio while maintaining optimal therapeutic outcomes.

References

1. Xpovio [package insert]. Newton, MA: Karyopharm Therapeutics Inc.; March 2025.
2. NCCN Drugs & Biologics Compendium® Selinexor 2024. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2024.