



Xpovio® (selinexor) – New indication

- On June 22, 2020, [Karyopharm Therapeutics announced](#) the FDA approval of [Xpovio \(selinexor\)](#), 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.
 - This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Xpovio is also approved in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma 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.
- The approval of Xpovio for the new indication was based on SADAL, a single-arm, open-label study of 134 adults with relapsed or refractory DLBCL, not otherwise specified, after 2 to 5 systemic regimens. Efficacy was based on overall response rate (ORR) and duration of response (DOR).
 - The ORR was 29%. Of the patients with a response, 38% (15/39) maintained a response at 6 months and 15% (6/39) maintained a response at 12 months.
- The most common adverse reactions ($\geq 20\%$) with Xpovio use in patients with DLBCL, excluding laboratory abnormalities, were fatigue, nausea, diarrhea, appetite decrease, weight decrease, constipation, vomiting, and pyrexia. Grade 3 to 4 laboratory abnormalities ($\geq 15\%$) were thrombocytopenia, lymphopenia, neutropenia, anemia, and hyponatremia.
- The recommended dose of Xpovio for the treatment of DLBCL is 60 mg taken orally on days 1 and 3 of each week until disease progression or unacceptable toxicity.
 - Refer to the Xpovio drug label for multiple myeloma dosing.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.