



## Yervoy<sup>®</sup> (ipilimumab) – Expanded indication

- On July 24, 2017, [Bristol-Myers Squibb announced](#) the FDA approval of [Yervoy \(ipilimumab\)](#), for the treatment of unresectable or metastatic melanoma in adults and pediatric patients (12 years and older).
  - Previously, Yervoy was only indicated for the treatment of unresectable or metastatic melanoma in adults.
- Yervoy is also indicated for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.
- The safety and effectiveness of Yervoy in pediatric patients 12 years and older is supported by evidence from adequate and well controlled studies of Yervoy in adults and population pharmacokinetic data demonstrating that the exposure at a dose of 3 mg/kg in the pediatric and adult populations is comparable.
  - In addition, the tumor biology and course of advanced melanoma is sufficiently similar in adults and pediatric patients 12 years and older to allow extrapolation of data from adults to pediatric patients.
- Yervoy carries a boxed warning for immune-mediated adverse reactions.
- The recommended dosage of Yervoy for the treatment of unresectable or metastatic melanoma in adults and pediatric patients > 12 years of age is 3 mg/kg administered intravenously over 90 minutes every 3 weeks for a maximum of 4 doses.
- For the adjuvant treatment of melanoma, the recommended dosage of Yervoy is 10 mg/kg administered intravenously over 90 minutes every 3 weeks for 4 doses followed by 10 mg/kg every 12 weeks for up to 3 years.



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

All Optum<sup>®</sup> 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<sup>®</sup> is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.