

Yervoy® (ipilimumab) – Expanded indication

- On May 23, 2021, the [FDA approved](#) Bristol Myers Squibb's [Yervoy \(ipilimumab\)](#), in combination with [Opdivo® \(nivolumab\)](#), for the treatment of unresectable or metastatic melanoma in adult patients.
 - Yervoy was previously approved as monotherapy for the treatment of unresectable or metastatic melanoma in adults and pediatric patients 12 years and older.
- Yervoy is also approved for adjuvant treatment of melanoma, advanced renal cell carcinoma, microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer, hepatocellular carcinoma, metastatic non-small cell lung cancer, and malignant pleural mesothelioma.
- The approval of Yervoy for the expanded indication was based on CHECKMATE-067, a randomized, double-blind study in 945 patients with previously untreated, unresectable or metastatic melanoma. Patients were randomized to Yervoy plus Opdivo, Opdivo, or Yervoy. The major efficacy outcome measures were progression-free survival (PFS) and overall survival (OS).
 - Patients randomized to either Opdivo-containing arm demonstrated statistically significant improvements in OS and PFS vs. Yervoy alone.

	Yervoy plus Opdivo (n = 314)	Opdivo (n = 316)	Yervoy (n = 315)
OS			
Deaths (%)	128 (41)	142 (45)	197 (63)
Hazard ratio (vs. Yervoy) (95% CI)	0.55 (0.44, 0.69)	0.63 (0.50, 0.78)	
p-value	< 0.0001	< 0.0001	
PFS			
Median (months)	11.5	6.9	2.9
Hazard ratio (vs. Yervoy) (95% CI)	0.42 (0.34, 0.51)	0.57 (0.47, 0.69)	
p-value	< 0.0001	< 0.0001	
Overall Response Rate (95% CI)	50% (44, 55)	40% (34, 46)	14% (10, 18)
p-value	< 0.0001	< 0.0001	
DOR			
Proportion ≥ 6 months in duration	76%	74%	63%
Range (months)	1.2+ to 15.8+	1.3+ to 14.6+	1.0+ to 13.8+

- The recommended dose of Yervoy for the treatment of melanoma is 3 mg/kg every 3 weeks (90-minute intravenous infusion) with Opdivo 1 mg/kg (30-minute intravenous infusion on the same day). Yervoy should be used in combination with Opdivo for a maximum of 4 doses or until unacceptable toxicity, whichever occurs earlier. After completing 4 doses of combination therapy, Opdivo should be administered as a single agent until disease progression or unacceptable toxicity.

- Refer to the Yervoy drug label for dosing for all its other indications.
- Refer to the Opdivo drug label for dosing after completing use in combination with Yervoy.



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