

ONCORIX (rivolumab)

Approved Product Messages

For use by field medical and commercial teams only

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Approved Indication

ONCORIX is indicated for the treatment of adult patients with unresectable or metastatic melanoma.

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Efficacy

Claim 1 (Overall Survival): In the MERIDIAN-301 trial, ONCORIX demonstrated a statistically significant improvement in overall survival (OS) vs standard of care (median OS 24.1 months vs 13.6 months; HR 0.68; 95% CI: 0.53–0.87; $p=0.002$).

Claim 2 (Response Rate): The objective response rate (ORR) was 42.3% (95% CI: 35.1–49.8) in the ONCORIX arm compared to 16.2% in the control arm.

Claim 3 (Progression-Free Survival): Median progression-free survival (PFS) was 11.2 months (95% CI: 8.9–14.1) with ONCORIX vs 5.4 months with standard of care.

Claim 4 (Durability): Durable responses were observed: 78% of responders maintained response at 12 months.

Claim 5 (Subgroups): Subgroup analyses showed consistent OS benefit across pre-specified subgroups including PD-L1 expression level, ECOG status, and prior therapy.

Safety

Claim 6 (Common AEs): The most common adverse reactions ($\geq 20\%$) were fatigue (38%), rash (27%), diarrhoea (24%), and nausea (21%).

Claim 7 (Immune-Mediated AEs): Immune-mediated adverse events occurred in 31% of patients. Most were Grade 1-2 and manageable with established protocols.

Claim 8 (Grade 3-4 AEs): Grade 3-4 treatment-related adverse events occurred in 18% of patients in the ONCORIX arm vs 12% in the control arm.

Claim 9 (Discontinuation): Treatment discontinuation due to adverse events occurred in 9% of patients.

Claim 10 (Long-Term Safety): No new safety signals were identified in the 24-month follow-up analysis.

Dosing & Administration

Claim 11 (Recommended Dose): The recommended dose of ONCORIX is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks.

Claim 12 (Hepatic Impairment): No dose adjustment is required for patients with mild hepatic impairment (bilirubin $\leq$ ULN and AST $>$ ULN, or bilirubin 1–1.5 $\times$ ULN).

Claim 13 (Duration): Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Approved Talking Points

1. When discussing ONCORIX with oncologists, focus on the significant OS benefit demonstrated in MERIDIAN-301 and the manageable safety profile.
2. Always present efficacy and safety data together to ensure fair balance.
3. Refer HCPs to the full prescribing information for complete safety data.

End of Approved Product Messages. APM-2026-001.