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2 **Proposed Project Scope**

3 **Nivolumab and**
4 **Ipilimumab for Advanced**
5 **Melanoma When Patients**
6 **Progress During or Within**
7 **6 Months of Adjuvant PD-**
8 **1 Therapy**

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Date: October 2023

23 Background and Rationale

24 CADTH received a request from public drug programs for a Non-Sponsored Reimbursement Review of nivolumab
25 and ipilimumab for advanced melanoma when patients progress during or within 6 months of adjuvant PD-1 therapy.

26 Table I: Policy Questions

Item	Policy Question
1	Should nivolumab and ipilimumab be publicly reimbursed for advanced melanoma in patients who progress during or within 6 months of adjuvant PD-1 therapy?

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28 Table II: Products Available in Canada

Product	Manufacturer
Nivolumab and Ipilimumab	Bristol-Myers Squibb Canada

29 Project Description

30 Table III: Project Scope

Criteria	Description
Population	Patients with advanced (unresectable or metastatic) melanoma who progress during or within 6 months of adjuvant PD-1 therapy
Intervention(s)	Nivolumab and ipilimumab
Comparators	Pembrolizumab and ipilimumab; ipilimumab; BRAF-targeted therapy (dabrafenib-trametinib, cobimetinib-vemurafenib, encorafenib-binimetinib)
Outcomes	Objective response rate, progression-free survival, overall survival, and adverse events

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32 Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of nivolumab and ipilimumab for advanced melanoma when patients progress during or within 6 months of adjuvant PD-1 therapy?
2	What are the harms associated with nivolumab and ipilimumab for advanced melanoma when patients progress during or within 6 months of adjuvant PD-1 therapy?
3	What is the expected cost of nivolumab and ipilimumab for advanced melanoma when patients progress during or within 6 months of adjuvant PD-1 therapy?

33 Key Project and Protocol Components

34 This project will follow the [Procedures for Non-Sponsored Reimbursement Reviews](#).

35 Status of the Document

36 This proposed project scope is being posted for information.