Recommendation to the Nova Scotia Department of Health and Wellness from Nova Scotia Health Authority / Nova Scotia Cancer Care Program

Guidelines for the Role of Nivolumab for Adjuvant Melanoma

Approved Use:

Nivolumab:

For the adjuvant treatment of patients with cutaneous or mucosal melanoma with completely resected Stage IIIA (limited to lymph node metastases of \( \geq 1 \) mm) to Stage IV (8th edition of the American Joint Committee on Cancer [AJCC] melanoma staging system), regardless of BRAF status. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed. Patients should have a good performance status and brain metastases, if present, must be completely resected (or definitively treated with stereotactic radiation). Eligible patients should continue treatment until disease progression or a maximum of 1 year, whichever comes first.

Clinical Notes:

Patients are eligible to receive 12 months of adjuvant treatment with immunotherapy or BRAF targeted therapy. Patients who are unable to tolerate initial adjuvant therapy, within the first 3 months of treatment, may switch to alternate funded treatment, provided criteria are met.

Patients with ocular melanoma are not eligible for adjuvant treatment with nivolumab.

Patients who progress during adjuvant therapy with nivolumab or pembrolizumab, or within 6 months of completion of adjuvant therapy, ipilimumab monotherapy may be funded as a subsequent line of therapy in the metastatic setting.

Patients will be eligible for all immunotherapy options in the advanced or metastatic setting (including combination nivolumab with ipilimumab) only if there has been a 6 month progression-free interval between completion of adjuvant immunotherapy and confirmation of disease progression.

This policy recommendation represents an updated guideline document and a restriction of nivolumab for the adjuvant treatment of patients with cutaneous or mucosal melanoma.