

Proposed Project Scope

Ibrutinib in combination with immunochemotherapy with or without autologous stem-cell transplantation (ASCT) for previously untreated transplant-eligible patients with mantle cell lymphoma (MCL)

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of ibrutinib in combination with immunochemotherapy with or without autologous stem-cell transplantation (ASCT) for previously untreated transplant-eligible patients with mantle cell lymphoma (MCL).

Table I: Policy Questions

Item	Policy Question
1	Should ibrutinib in combination with immunochemotherapy with or without ASCT be publicly reimbursed for previously untreated transplant-eligible patients with mantle cell lymphoma (MCL)?

Table II: Products Available in Canada

Product	Manufacturer
Ibrutinib	n/a

Project Description

Table III: Project Scope

Criteria	Description
Population	Untreated patients with mantle cell lymphoma who are eligible for autologous stem cell transplantation
Intervention(s)	Ibrutinib in combination with immunochemotherapy with or without autologous stem-cell transplantation (ASCT)
Comparators	<ul style="list-style-type: none">- Alternating R-CHOP/R-DHAP (rituximab/cyclophosphamide/vincristine/ doxorubicin/prednisone; rituximab/dexamethasone/ARA-C/cisplatin)- R-hyper CVAD (hyperfractionated intense-dose cyclophosphamide, vincristine, continuous doxorubicin, and dexamethasone)- R-maxi-CHOP-21/ARA-C- Bendamustine/rituximab
Outcomes	<ul style="list-style-type: none">- Failure-free survival- Overall survival- Progression-free survival- Duration of remission- Overall and complete remission rates- Conversion rate of partial remission to complete remission after end of induction- Adverse events, including serious adverse events- Cumulative incidence rates of secondary primary malignancies

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of ibrutinib in combination with immunochemotherapy with or without ASCT for untreated transplant-eligible MCL?

2	What are the harms associated with ibrutinib in combination with immunochemotherapy with or without ASCT for untreated transplant-eligible MCL?
3	What is the expected cost of ibrutinib in combination with immunochemotherapy with or without ASCT for untreated transplant-eligible MCL vs. other reimbursed regimes?

Key Project and Protocol Components

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

Status of the Document

This proposed project scope is being posted for information.