

Proposed Project Scope

Blinatumomab for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse

Background and Rationale

CDA-AMC received a request from public drug programs for a Non-Sponsored Reimbursement Review of blinatumomab for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse.

Table I: Policy Questions

Item	Policy Question
1	Should blinatumomab be publicly reimbursed for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse?

Table II: Products Available in Canada

Product	Manufacturer
Blinatumomab	n/a

Project Description

Table III: Project Scope

Criteria	Description
Population	Pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor ALL (B-ALL) who are in first relapse, with or without extramedullary (EM) disease
Intervention(s)	Blinatumomab, followed by continuation chemotherapy intercalated with blinatumomab blocks , followed by maintenance chemotherapy (arm D of AALL1331 trial)
Comparators	Block 3 chemotherapy, followed by two continuation chemotherapy cycles , then maintenance chemotherapy (arm C of AALL1331 trial)
Outcomes	Disease-free survival, overall survival, and adverse events

Table IV: Research Questions

Item	Policy Question
1	What is the effectiveness of blinatumomab for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse?
2	What are the harms associated with blinatumomab for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse?
3	What is the expected cost of blinatumomab for pediatric patients with Philadelphia chromosome negative relapsed/refractory B precursor acute lymphoblastic leukemia (ALL) who are in first relapse. 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.