

Proposed Project Scope

Icatibant (Firazyr) for the treatment of acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH)

Date: March 2024

Background and Rationale

CADTH received a request from public drug programs for a Non-Sponsored Reimbursement Review of icatibant (Firazyr) for treatment of acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH).

Table I: Policy Questions

Item	Policy Question
1	Should icatibant (Firazyr) be publicly reimbursed for the treatment of acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH)?

HAE nC1-INH = hereditary angioedema with normal C1-inhibitor

Table II: Products Available in Canada

Product	Manufacturer
Icatibant (Firazyr)	Takeda Pharmaceuticals Accord Healthcare Inc Juno Pharmaceuticals Corp Mint Pharmaceuticals Inc Teva Canada Limited

Project Description

Table III: Project Scope

Criteria	Description
Population	Patients with HAE nC1-INH Subpopulations: Pediatric patients (<18 years of age) Adult patients (≥18 years of age)
Intervention(s)	Icatibant (Firazyr)
Comparators	placebo; no comparator; C1 esterase inhibitors; Berinert - subcutaneous administration (patient administered) Berinert - IV administration; steroids; berotralstat; tranexamic acid; antihistamines
Outcomes	Efficacy, harms and safety; rate of abdominal attacks, rate of laryngeal attacks, time to resolution of attack, time to onset of symptom relief, time to objective symptom relief, frequency of attacks, severity of attacks, duration of attacks, symptom relief, time to onset of symptom relief, time to objective symptom relief, reduction in the need for tracheotomy, intubation, hospital admissions, resolution of acute attacks, harms associated with the use of icatibant, adverse events, related patient outcomes and quality of life; consequences of delayed therapy especially as it applies for patients in rural settings; risk factors for treatment delay and related outcomes

HAE nC1-INH = hereditary angioedema with normal C1-inhibitor; IV = intravenous

Table IV: Research Questions

CADTH PROPOSED PROJECT SCOPE Icatibant for HAE nC1-INH

Item	Policy Question
1	What is the effectiveness of icatibant (Firazyr) in the treatment of acute attacks of HAE nC1-INH?
2	What are the harms associated with icatibant (Firazyr) in the treatment of acute attacks of HAE nC1-INH?
3	What is the expected cost of icatibant (Firazyr) for HAE nC1-INH vs. other reimbursed regimes?

HAE nC1-INH = hereditary angioedema with normal C1-inhibitor

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.