

Drug Implementation Advice: Proposed Scope

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

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

BACKGROUND

At the request of participating publicly-funded drug programs, an Implementation Advice Panel (IAP) is being convened to advise the drug programs on reimbursement criteria for icatibant for the treatment of acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH). Appendix 1 lists the drug reimbursement recommendations for icatibant. This document outlines a draft scope for to inform panel discussions, including which drugs are under consideration and questions to be addressed by the panel.

1. OBJECTIVES

The panel will be comprised of specialists in Canada with expertise in the diagnosis and management of patients with HAE. In addition to the clinical panelists and staff, representatives from public drug programs will be invited to participate in the discussion as well as provide input in advance of the meeting on discussion points for the panel. For more information on the implementation advice process, please refer to the [Procedures for Implementation Advice for Health Technologies](#).

The Formulary Working Group (FWG) are requesting implementation guidance on the following questions:

1. Which subpopulation of patients with normal C1-inhibitor (HAE nC1-INH) would benefit most from access to icatibant? What specific clinical criteria should they possess?
2. Should the treatment approach for acute attacks for patients with type III HAE be aligned with the treatment of acute attacks for patients with HAE types I/II?
3. Based on the currently available data regarding the efficacy and safety of berinert and icatibant, what factors should be considered when deciding between both drugs (irrespective of the mode of administration)?
 - a. If both berinert and icatibant are deemed standard treatment options for Type III HAE, is there a sub-group of patients who would benefit most from treatment with icatibant?
 - b. If a sub-group of patients can be identified, which patients (e.g. those with laryngeal vs. non-laryngeal symptoms) may benefit more from icatibant?

2. OPPORTUNITIES FOR STAKEHOLDER INPUT

We welcome input from patient and clinician groups as well as manufacturers whose product(s) may be impacted by the implementation advice. All external partners are invited to provide comments and/or complementary information using the [Input template for Implementation Advice](#). This input will be considered by the implementation advice panel in their deliberations.

3. OPPORTUNITIES FOR FEEDBACK ON DRAFT ADVICE

When ready, draft implementation advice will be posted for feedback on our website. At that time eligible external partners are welcome to provide feedback on the draft advice using the [Feedback on Draft Implementation Advice Report template](#).

4. DRUGS IN SCOPE FOR IMPLEMENTATION ADVICE

Table 1: Currently Marketed Icatibant Products and Approved Indications

Drug	Brand	Approved Indication
icatibant	Firazyr	<p>Icatibant Injection (icatibant acetate) is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults, adolescents and children aged 2 years and older with C1-esterase inhibitor deficiency.</p> <p>Icatibant Injection is supplied through a controlled distribution program that is accessed by patients and pharmacies. Patients or a caregiver should be trained in subcutaneous injection techniques under the guidance of a healthcare professional before they can administer Icatibant Injection (see DOSAGE AND ADMINISTRATION).</p> <p>Geriatrics (> 65 years of age): Limited information is available regarding the use of icatibant acetate in patients older than 65 years of age (see WARNINGS AND PRECAUTIONS and ACTION AND CLINICAL PHARMACOLOGY, Pharmacokinetics).</p> <p>Pediatrics (<18 years of age): Icatibant Injection is indicated for use in adolescents and children aged 2 years and older. Studies in children aged less than 2 years or weighing less than 12 kg have not been</p>

		<p>performed. No dosage regimen can be recommended in children aged less than two years or weighing less than 12 kg as the safety and efficacy have not been established.</p> <p>Please Note: use of icatibant for the treatment acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH) is considered off-label use</p>
C1 Esterase Inhibitor	Beriner® 500/Beriner® 1500	Beriner (C1 Esterase Inhibitor, Human) is indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema (HAE) of moderate to severe intensity* in pediatric and adult patients.
Generics products:	<ul style="list-style-type: none"> • ACCORD Healthcare Inc: Icatibant Injection • JUNO Pharmaceuticals Corp: Icatibant Injection • JAMP Pharma Corporation: Icatibant Injection • MINT Pharmaceuticals Inc: Mint-Icatibant • TEVA Canada Limited: Teva-Icatibant 	

Source: Drug Product Monograph, May 17, 2024; JAMP Pharma Corporation

5. APPENDICES

Appendix 1: CADTH Recommendations on icaltiban for the treatment of acute attacks of hereditary angioedema (HAE) with normal C1-inhibitor (HAE nC1-INH)

Drug	Brand	Indication	CDEC Recommendation	Final Rec. Date
icaltiban	Firazyr	HAE nC1-INH	No recommendations were issued	-
icaltiban	Firazyr	For routine prevention of attacks of hereditary angioedema (HAE) in adolescents and adult (Type I/II)	Reimburse with clinical criteria and/or conditions	November 19, 2019