

Stakeholder Input

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Industry Input

Bayer Inc

Does the proposed project scope accurately reflect the treatment landscape?

Yes, the proposed population and outcomes included in the project scope accurately reflect the treatment landscape for the treatment of venous thromboembolic events (VTE) and prevention of VTE recurrence in in term neonates, infants and toddlers, children and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment. For comparators, low molecular weight heparin (dalteparin, enoxaparin, tinzaparin), unfractionated heparin, and warfarin are appropriate comparators. Dabigatran is not an appropriate comparator based on the following considerations:

- Dabigatran does not currently have an approved pediatric indication from Health Canada for the treatment of VTE and prevention of VTE recurrence. (1)
- Clinical guidelines do not currently recommend the use of dabigatran for the treatment of VTE and prevention of VTE recurrence in the pediatric population. (2)
- Based on the Canadian treatment landscape, dabigatran is not a commonly used medication for the treatment of VTE and prevention of VTE recurrence in the pediatric population.

Are you aware of relevant published studies that you would like considered in the clinical review?

XARELTO is the first anticoagulant to be approved by Health Canada for use in children with VTE. This approval was based on findings from the EINSTEIN Junior phase III study, the first completed trial of a NOAC in children, and at publication, the largest trial of anticoagulant treatment performed in children. The results showed that compared with standard anticoagulants, XARELTO treatment led to similarly low risk of recurrent VTE and reduced thrombotic burden without increased bleeding. (3)

Do you have additional comments that you feel are pertinent to this review?

No.

Reference

1. Boehringer Ingelheim Canada Ltd. Pradaxa (dabigatran etexilate capsules) Product Monograph. March 23, 2022.
2. Monagle P, Chan AKC, Goldenberg NA, Ichord RN, Journeycake JM, Nowak-Gottl U, et al. Antithrombotic therapy in neonates and children: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):e737S-e801S.
3. Male C, Lensing AWA, Palumbo JS, Kumar R, Nurmeev I, Hege K, et al. Rivaroxaban compared with standard anticoagulants for the treatment of acute venous thromboembolism in children: a randomised, controlled, phase 3 trial. The Lancet Haematology. 2020;7(1):e18-e27.