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2021020886

Our reference
2021020886

Date 8 June 2021
Subject GVS advice Doptelet®

Dear Ms van Ark,

In your letter of 16 March 2021 (CIBG-21-01601), you requested the National Health Care Institute to carry out a substantive review of whether the medicinal product avatrombopag (Doptelet®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed its substantive assessment. The considerations are included in the GVS report attached to this letter.

Avatrombopag (Doptelet®) is indicated for the treatment of:
- primary chronic immune thrombocytopenia (ITP) in adult patients resistant to other treatments (e.g. corticosteroids, immunoglobulins)
- severe thrombocytopenia in adult patients with chronic liver disease scheduled for an invasive procedure. Avatrombopag is available as a film-coated tablet.

The outcome of the assessment
The National Health Care Institute has concluded that avatrombopag meets the established medical science and medical practice in the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are resistant to other treatments (e.g. corticosteroids, immunoglobulins). Avatrombopag has a therapeutic value comparable to eltrombopag.

Avatrombopag has an added therapeutic value to placebo in the treatment of serious thrombocytopenia in adult patients with chronic liver disease scheduled for an invasive procedure. No conclusion can be drawn on the relative effectiveness of avatrombopag in relation to prophylactic thrombocyte transfusion.

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Review of interchangeability
On the basis of the criteria for interchangeability, it can be concluded that avatrombopag is interchangeable with eltrombopag (Revolade®).

Advice
Based on the above, we recommend that you include avatrombopag (Doptelet®) with eltrombopag (Revolade®) in the newly formed cluster on List 1A of the GVS. 20 mg/day can be applied as the standard dose for avatrombopag. The standard dose for eltrombopag can be set at 50 mg per day.

Further conditions for eltrombopag and romiplostim
Currently, the following further conditions apply to eltrombopag:
Only for insured persons aged 18 and older with chronic immune (idiopathic) thrombocytopenic purpura (cITP) who:

a.
1. Have undergone a splenectomy and are refractory to other treatments, or
2. Have a contraindication for splenectomy and no longer respond sufficiently to other treatments, including at least corticosteroids, or

b. Persons aged 1 to 18 with chronic immune (idiopathic) thrombocytopenic purpura (cITP) who are refractory to other treatments, or

c. Patients 18 years and older with chronic infection with hepatitis C virus (HCV) for the treatment of thrombocytopenia, with the degree of thrombocytopenia being:
1. The main factor that prevents the start of an optimal treatment based on interferon, or
2. A limiting factor to the possibility of continuing this interferon treatment, or

d. Patients 18 years and older with acquired serious aplastic anaemia (SAA) who are refractory to previous immunosuppressive therapy, or have had intensive pre-treatment, and who are not eligible for haemopoietic stem cell transplantation.

In addition, the following further condition applies to romiplostim:
only for insured persons aged 18 and older with chronic immune (idiopathic) thrombocytopenic purpura (cITP) who:

a.
1. Have undergone a splenectomy and are refractory to other treatments, or
2. Have a contraindication for splenectomy and no longer respond sufficiently to other treatments, including at least corticosteroids, or

b. persons aged 1 to 18 with chronic immune (idiopathic) thrombocytopenic purpura (cITP) who are refractory to other treatments.

These additional conditions restrict the application prior to a splenectomy. In 2019, during the update of List 2, it was determined whether the further conditions for eltrombopag and romiplostim could be cancelled. It was then concluded that the place in the treatment had not yet been fully determined. Revised guidelines were published by the Netherlands Association for Haematology in September 2020. Partly on the basis of available scientific data from daily practice, a strong preference is expressed for TPO-RA over splenectomy.

On the basis of the attached assessment of avatrombopag and this recent update of the guidelines, the National Health Care Institute sees no reason to maintain

the current further conditions for eltrombopag (Revolade®) and romiplostim (Nplate®). These can now be cancelled.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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