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To the Minister of Medical Care and Sports
PO Box 20350
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2020004213

Date 3 February 2020
Subject GVS advice opicapone (Ongentys®)

**National Health Care
Institute**

Care II
Birth Care & Gynaecology

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Our reference

2020004213

Dear Mr Bruins,

In your letter of 11 November 2019 (CIBG-19-09084), you requested the National Health Care Institute to carry out a substantive review of whether opicapone (Ongentys®) is interchangeable with a product that is included in the medication reimbursement system (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter.

Opicapone (Ongentys®) is indicated as adjunctive therapy for levodopa/DOPA decarboxylase inhibitor (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations.

The manufacturer of opicapone (Ongentys®) states that opicapone is interchangeable with entacapone, a COMT inhibitor, and can therefore be placed on Annex 1A of the Health Insurance Regulations (Rzv), in the existing cluster 0N04BXAO V, together with entacapone.

Assessment outcome

The National Health Care Institute has reached the final conclusion that in the treatment of Parkinson's disease and end-of-dose motor fluctuations, opicapone (Ongentys®) as an 'add on' for levodopa/dopa decarboxylase inhibitor has an equal value compared to entacapone.

Review of interchangeability

On the basis of the criteria for interchangeability, it can be concluded that opicapone (Ongentys®) is interchangeable with the other COMT inhibitor entacapone in the GVS cluster 0N04BXAO V.

Advice

On this basis, we recommend that you include opicapone (Ongentys®) in the GVS cluster 0N04BXAO V on List 1A of the GVS. 50 mg/day can be used as the standard dose.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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