

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
PO Box 20350
2500 EJ The Hague

2022047346

**National Health Care
Institute**

Care
Medicinal Products

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Date 24 November 2022
Subject GVS advice baloxavir marboxil (Xofluza®)

Our reference
2022047346

Dear Mr Kuipers,

In your letter of 1 September 2022 (CIBG-22-04340), you requested the National Health Care Institute to carry out a substantive assessment of whether baloxavir marboxil (Xofluza®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the pharmacotherapeutic report attached to this letter.

Baloxavir marboxil is indicated for the treatment of uncomplicated influenza in patients aged 12 years and above and for the post-exposure prophylaxis of influenza in individuals aged 12 and above.

The marketing authorization holder requests the inclusion of baloxavir marboxil in List 1B of the Health Insurance Regulation for the treatment of uncomplicated influenza in patients aged 12 years and above who are eligible for annual flu vaccination.

Outcome of the substantive assessment

Therapeutic value conclusion

For baloxavir marboxil in the treatment of uncomplicated influenza in patients aged 12 years and above who are eligible for annual flu vaccination, no significant added value has been demonstrated above normal care (paracetamol, antibiotics) or oseltamivir. No clinically relevant benefit of baloxavir marboxil has been demonstrated on the crucial outcome parameters of survival, hospitalisation and complications (defined as pneumonia, myocarditis and pericarditis). Baloxavir marboxil has not been sufficiently investigated for its efficacy and effectiveness in persons belonging to a very high risk group.

The National Health Care Institute concludes, advised by the Scientific Advisory Board (WAR), that baloxavir marboxil does not meet the established medical science and medical practice for the treatment of uncomplicated influenza in patients aged 12 years and above who are eligible for annual flu vaccination. The available data, although sufficient for market registration, does not permit a positive assessment for inclusion in the insured package.

Advice on inclusion in the GVS

On the basis of the considerations mentioned above, the National Health Care Institute recommends that baloxavir marboxil should not be included in the GVS.

**National Health Care
Institute**
Care
Medicinal Products

Future developments

The National Health Care Institute is of course prepared to reconsider the package eligibility of baloxavir marboxil if additional research data not previously assessed by the National Health Care Institute leads to scientific publications.

Date
24 November 2022

Our reference
2022047346

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board