



> Return address PO Box 320, 1 110 AH Diemen

Minister of Medical Care and Sports
PO Box 20350
2500 EJ THE HAGUE

2021014427

Date 25 May 2021
Subject Package advice isatuximab (Sarclisa®)

**National Health Care
Institute**

Care I
Oncology

Willem Dudokhof 1
1 1 12 ZA Diemen
PO Box 320
1 1 10 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact

Ms J.E. de Boer
T +31 (0)6 215 833 54

Our reference

2021014427

Dear Ms van Ark,

In this letter, the National Health Care Institute advises you about the use of isatuximab in combination with carfilzomib and dexamethasone for the treatment of adult patients with multiple myeloma (MM) who have had at least one earlier therapy. The reason for this advice was the placement of isatuximab (Sarclisa®) in the package lock for expensive medicinal products.

Isatuximab is a monoclonal antibody derived from IgG1 that binds to a specific extracellular epitope of the CD38 protein, a glycoprotein that is highly expressed on the surface of multiple myeloma tumour cells. It is available as a 20 mg/ml concentration for infusion solution.

Isatuximab has already been registered and is reimbursed for the treatment of patients with recurring and refractory MM who have received at least two previous therapies, including lenalidomide and a proteasome inhibitor, and who showed disease progression during the last treatment. In these cases, it is used in combination with pomalidomide and dexamethasone.

Preliminary package advice

Following the multiple myeloma package advice that we issued to you on 11 February this year, we recommend that you temporarily include isatuximab in combination with carfilzomib and dexamethasone, under conditions and after competitive price negotiations, in the health care package, pending a final approach and advice from the National Health Care Institute. This in the context of the pilot to work out an indication-wide assessment using a Multiple Myeloma task group. In our advice of 11 February this year, we explained in detail the background for the design of this pilot.

Explanation of preliminary package advice

The National Health Care Institute considers the effectiveness of isatuximab, used in different treatment combinations, sufficiently demonstrated, based on the well-founded (draft) guideline of the Myeloma Working Group and the underlying clinical studies. We will take into consideration the dynamics in the treatment landscape and we realise there are questions about which combination of

medicinal products is most effective for MM and about determining the (most effective) positioning of these combination therapies.

Isatuximab in combination with carfilzomib-dexamethasone is included in the draft guideline for MM as a secondary care treatment for patients who are refractory to lenalidomide. On the basis of the available literature, it was considered that isatuximab, in combination with carfilzomib-dexamethasone, is preferable to carfilzomib-dexamethasone, given the longer progression-free survival rate, especially in patients with clinically relevant disease symptoms. It is also indicated that the combination isatuximab-carfilzomib-dexamethasone is equivalent to the combination daratumumab-carfilzomib-dexamethasone, about which we have previously advised you in the context of the aforementioned MM pilot.

Conclusion

The National Health Care Institute advises you, as part of the pilot, to temporarily include the combination therapy isatuximab-carfilzomib-dexamethasone, under conditions and after keen price negotiations, in the health care package, pending a final approach and advice from the National Health Care Institute in cooperation with the Multiple Myeloma task group.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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