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*2022014191*

**National Health Care Institute**
Care
Medicinal Products

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**Our reference**
2022014191

Date 20 April 2022
Subject GVS advice on avacopan (Tavneos®)

Dear Dr Kuipers,

In a letter dated 5 January 2022 (reference CIBG-21-03111), the Minister of Medical Care and Sport asked the National Health Care Institute to carry out a substantive assessment of whether the medicinal product avacopan (Tavneos®) is interchangeable with another medicinal product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has now completed this assessment.

Avacopan (Tavneos®), in combination with a rituximab regimen or cyclophosphamide regimen, is indicated for the treatment of adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

The National Health Care Institute advises you not to include avacopan (Tavneos®) in the GVS.

**Assessment of interchangeability**
To determine the place of a medicinal product in the GVS, its interchangeability with medicinal products already included in the GVS must first be assessed.

No other medicinal product has been included in the GVS that is specifically registered for the indication 'severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)'. The Dutch guideline shows that the following medicinal products can be used for GPA and MPA: prednisone, methylprednisolone, azathioprine, methotrexate, mycophenolate mofetil, cyclophosphamide, and rituximab.
Rituximab and cyclophosphamide are inpatient medicines and are not included in the GVS. As a result, these medicinal products are not eligible for an assessment of interchangeability with avacopan. Nor are the other medicinal products mentioned above eligible for any further assessment of interchangeability, as they do not have a similar therapeutic area.

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Based on the above, avacopan (Tavneos®) cannot be placed on List 1A. A review should be carried out to determine whether avacopan is eligible for inclusion on List 1B.

**Therapeutic value**
The National Health Care Institute has concluded that avacopan (Tavneos®), in combination with a rituximab regimen or cyclophosphamide regimen, complies with established medical science and medical practice for the treatment of adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA). In relapse prevention, avacopan has a clinically relevant effect that is superior to the prednisone tapering schedule. Treatment with avacopan makes it possible to use fewer glucocorticoids or lower doses thereof. This reduced use of glucocorticoids in the assessment has not yet been reflected by reduced glucocorticoid-related toxicity. Furthermore, it is very uncertain whether the use of avacopan results in fewer drop-outs due to undesirable effects. Nevertheless, it can be concluded that avacopan has added value compared to glucocorticoids.

**Budget impact analysis**
Avacopan costs €60,549 per one-year induction treatment (with 86.4% patient compliance). It is assumed that 1254 to 1391 patients per year will be eligible for avacopan. Based on a market penetration of 15% in year 1, rising to 45% in year 3, 1022 patients will eventually use avacopan in year 3. In addition, a small subgroup has been identified that is assumed to have a chronic need for avacopan. This involves 40 patients in year 3, assuming a market penetration of 100%. The total budget impact in year 3 is expected to be €33.1 million.

**Pharmacoeconomic analysis**
The cost-effectiveness analysis provided by the marketing authorisation holder is of insufficient quality, despite the fact that the market authorisation holder has been given – and has made use of – the opportunity to improve it. The National Health Care Institute is particularly aware of bias in the assumptions and of a lack of evidence to substantiate the assumptions made in the pharmacoeconomic analysis. As a result, the National Health Care Institute cannot provide a methodologically reliable estimate of cost-effectiveness. Nor can it give you an indication of the price reduction required to get close to an acceptable level of cost-effectiveness.

Unfortunately, this means that the National Health Care Institute cannot advise you regarding any price negotiations you might conduct. This is essential for you and for the National Health Care Institute, because the reimbursement of avacopan at the marketing authorisation holder’s current asking price would lead to a very substantial, socially unjustifiable budget impact.

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Thus, the National Health Care Institute recommends that you should not include avacopan (Tavneos®) in the GVS. The National Health Care Institute is aware that the outcome of the National Health Care Institute's assessment will be disappointing both for patients and practitioners. The National Health Care Institute, therefore, invites the marketing authorisation holder to modify and better substantiate the pharmacoeconomic analysis.

Yours sincerely,

Sjaak Wijma
*Chairperson of the Executive Board*