Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

**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

**Contact**
P. Bloemen
M +31 (0)6 42 40 33 82
warcg@zinl.nl

*TBD*

**Our reference**
TBD

Date 19 December 2025
Subject GVS advice olezarsen (Tryngolza®) for familial chylomicronemia syndrome

Dear Mr Bruijn,

The National Health Care Institute advises you on the inclusion of olezarsen (Tryngolza®) for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS) in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 10 November 2025 (CIBG-25-08921).

Clinical picture
Familial Chylomicronemia Syndrome (FCS) is a very rare hereditary disorder in which the body has problems breaking down fat from food. As a result, high levels of fat particles (triglycerides) and the corresponding transport particles of this fat form in the blood; these are called chylomicrons. FCS often presents itself in childhood with pancreatitis and associated severe abdominal pain. Acute pancreatitis can be fatal or lead to permanent damage, making the pancreas no longer able to help digest food and control blood sugar. Patients therefore need to follow a strict low-fat diet, which is perceived to be very stressful. In addition, there are often psychosocial symptoms. According to the professional association, an estimated 50-60 patients are being treated for FCS in expertise centres. 80% of these patients are genetically confirmed. In Dutch practice, the medicine volanesorsen is currently being prescribed as a subcutaneous injection for this condition if the triglyceride reduction is not sufficiently achieved with dietary restrictions. Olezarsen, also administered by subcutaneous injection, lowers the level of blood triglycerides, as does volanesorsen.

Licensed indication
Olezarsen is indicated for adult patients as an addition to a diet for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS). It is available in a pre-filled syringe containing 80 mg olezarsen in 0.8 ml solution. One pack contains 1 pre-filled syringe.

Claim by the marketing authorisation holder
Olezarsen has a similar value to volanesorsen in adult patients with genetically confirmed familial FCS.

The marketing authorisation holder is requesting inclusion in List 1A of the Health Insurance Regulation in a newly formed cluster for familial chylomicronemia

syndrome together with volanesorsen

**National Health Care Institute**
Care
Medicinal Products

**Date**
19 December 2025

**Our reference**
TBD

**Advisory report**
The National Health Care Institute has concluded that olezarsen has an equivalent value to volanesorsen. The National Health Care Institute therefore advises you to include olezarsen (Tryngolza®) for genetically confirmed FCS on List 1A of the GVS in a newly formed cluster with volanesorsen.

In addition, we advise you to place olezarsen (Tryngolza®) on List 2 with the following additional condition, which is also required for volanesorsen:

Condition for olezarsen
*Only for an insured person aged 18 years or older as an addition to the diet for the treatment of genetically confirmed familial chylomicronemia syndrome (FCS) for people with a high risk of pancreatitis who have an inadequate response to diet and triglyceride-lowering treatment.*

We explain the preparation of this advice below.

Substantive assessment

*Assessment of interchangeability*
Based on the criteria for interchangeability, the National Health Care Institute has concluded that olezarsen is interchangeable with volanesorsen, listed in List 1B of the Health Insurance Regulation. The standard dose of olezarsen is set at 2.6 mg per day and for volanesorsen at 20 mg per day.

*Therapeutic value*

The National Health Care Institute has concluded that olezarsen for this indication meets the established medical science and medical practice and has an equivalent value to standard treatment with volanesorsen. Due to the lack of a direct comparative study between the products, an indirect comparison of the BALANCE study (olezarsen) and the APPROACH study (volanesorsen) has been assumed. No clinically relevant differences were found between olezarsen and volanesorsen on the crucial outcome measure reduction of episodes of pancreatitis and the triglyceride values. When comparing the results of the studies for adverse effects, a potential benefit for olezarsen might be suggested. However, this benefit is not sufficiently substantiated by the differences between the studies and the uncertainty resulting from the indirect nature of the comparison to speak of a clinically relevant difference and a demonstrated added value. Therefore, the National Health Care Institute concludes that there is an equal value. When olezarsen is reimbursed in practice, the professional association expects to treat all patients with this product because of the ease of use and the expected benefit for patient safety.

Market registration of plozasiran, a new medicinal product for the treatment of both clinically and genetically confirmed FCS, is also expected soon.

Should you need any further information, please do not hesitate to contact us.
The assessment report is attached (interchangeability test, PT report).

Yours sincerely,

M.J. Janssen
*Chairperson of the Executive Board*

**National Health Care Institute**
Care
Medicinal Products

**Date**
19 December 2025

**Our reference**
TBD