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National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

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Our reference
2025023976

Date 9 October 2025
Re: GVS advice odevixibat (Kayfanda®) for cholestatic pruritus

Dear Mr Bruijn,

National Health Care Institute advises you on the inclusion of odevixibat (Kayfanda®) for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 15 July 2025 (CIBG-25-08443). Odevixibat for Progressive Familial Intrahepatic Cholestasis (PFIC) is already included on List 1A under the brand name Bylvay®. The National Health Care Institute advises you to now also include odevixibat for ALGS under the brand name Kayfanda® on List 1A and to amend and merge the additional condition on List 2 with the additional condition for maralixibat.

ALGS is a hereditary disorder that can affect multiple organs, including the liver, heart, kidneys, eyes and the skeleton. Children can also have growth problems and developmental delays. The disease cannot be cured. One in 40,000 children is born with this syndrome. The treatment is aimed at reducing the symptoms of the disease. The symptoms mentioned are caused by the liver not properly draining the bile to the intestine. Therefore, the intestines cannot digest fats properly, leading to fatty diarrhoea. Because too much bile remains in the liver, the liver does not work properly. The build-up of bile acid causes itching, also called cholestatic pruritus. The pruritus may be so severe that it is the main reason for a liver transplant.
The National Health Care Institute has already given a positive advice on maralixibat for cholestatic pruritus due to ALGS syndrome.[1] Odevixibat, like maralixibat, reduces the accumulation of bile acids in the body, thereby relieving itching.

Therapeutic indication(s)
Odevixibat (Kayfanda®) is indicated for the treatment of cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older.

In addition, odevixibat (Bylvay®) is indicated and already included in the GVS on List 1A for the treatment of PFIC in patients aged 6 months or older. For this indication, odevixibat is clustered with maralixibat.

[1] https://www.zorginstituutnederland.nl/publicaties/adviezen/2024/09/20/gvs-advies-maralixibat-livmarli-bij-het-syndroom-van-alagille-algs

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Current condition odevixibat:
Only for an insured person aged six months and older

a. *With genetically confirmed PFIC (except PFIC2 subtype BSEP3);*
b. *Who is being treated at a centre of expertise;*
c. *For whom other non-invasive, symptomatic treatment has not yet been initiated, or has not resulted in a sustained, satisfactory therapeutic outcome.*

Treatment should be discontinued if no clinically detectable symptomatic treatment benefit can be established after up to nine months of continuous treatment.

Claim by the marketing authorisation holder
For the registered indication ALGS, odevixibat (Kayfanda®) has an equal value compared to maralixibat.

The marketing authorisation holder therefore requests inclusion on List 1A of the Health Insurance Act for the indication ALGS.

Advisory report
The National Health Care Institute advises you to expand the additional condition for odevixibat (Kayfanda®) with the indication ALGS in the GVS cluster 0A05AXAOV.

When this advice is adopted, odevixibat and maralixibat will be registered and reimbursed for the same two indications (ALGS and PFIC). The proposal is therefore to merge the two existing additional conditions for the products into common conditions for both medicinal products.

New condition odevixibat and maralixibat:

1. *Only for an insured person*
   a. *With genetically confirmed PFIC (except subtype BSEP3 of PFIC 2); and*
   b. *Who is being treated at a centre of expertise; OR*

2. *Only for an insured person*
   a. *With severe pruritus due to ALGS*
   b. *Who is being treated at a centre of expertise; and*
   c. *Who is not experiencing therapeutically sufficient effect from other non-invasive, symptomatic treatment; AND*

3. The treatment for PFIC and ALGS must be evaluated during the first months. If no clinically detectable symptomatic treatment benefit can be established after up to 6 months, treatment should be discontinued.

We have explained below how we reached this advice.

Substantive assessment
Assessment of interchangeability
On the basis of the criteria for interchangeability, the National Health Care Institute has concluded that odevixibat (Kayfanda®) is interchangeable with

maralixibat for ALGS. Both medicinal products are already listed on List 1A of the Health Insurance Act in the 0A05AXAOV cluster. Clustering can be maintained, with the additional condition for odevixibat (Bylvay®) to be extended with ALGS.

Interchangeability testing was performed in the assessment for the inclusion of maralixibat (Livmarli®) for ALGS in the GVS.[1] This assessment took into account both indications (PFIC and ALGS) for both odevixibat and maralixibat. Based on an indirect comparison of the clinical studies of these medicinal products (ASSERT study for odevixibat and ICONIC study for maralixibat), there is no evidence of a difference in beneficial and adverse effects in the treatment of cholestatic pruritus due to ALGS. The data provided by the marketing authorisation holder for the current reimbursement request has already been used in the GVS report for maralixibat.

The World Health Organisation WHO has not established a DDD for maralixibat and odevixibat. Based on the prevalence rates, no main indication can be identified. For standard doses, refer to the maralixibat package recommendation for ALGS.[1]

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

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