

Anmodning om vurdering av legemiddel i Nye metoder

Skjema for leverandører

En leverandør som ønsker offentlig finansiering av et legemiddel/legemiddelindikasjon i den norske spesialisthelsetjenesten, skal anmode om vurdering i Nye metoder ved å fylle ut dette skjemaet.

Utfyllt anmodningsskjema sendes til Nye metoder: nyemetoder@helse-sorost.no

Leverandøren skal på anmodningstidspunktet både ha et forslag til type helseøkonomisk analyse og en plan for når de leverer dokumentasjonen. Merk at dokumentasjon i henhold til oppdraget fra Bestillerforum for nye metoder må leveres inn senest 12 måneder etter anmodningstidspunktet.

Hele anmodningsskjemaet skal fylles ut. Mer informasjon og veiledning finnes i artikkelen [For leverandører \(nyemetoder.no\)](https://nyemetoder.no)

Merk: Skjemaet vil bli publisert i sin helhet på nyemetoder.no.

Innsender er klar over at skjemaet vil bli publisert i sin helhet (må krysses av): ☒

Fyll ut dato for innsending av skjema: 30.09.2026

1 Kontaktopplysninger	
1.1 Leverandør (innehaver/søker av markedsføringstillatelse i Norge)	Falk Pharma Nordiska AB
1.2 Navn kontaktperson	Hanh Meszaros
1.3 Stilling kontaktperson	Head of Market Access, Nordics
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Ekstern representasjon - vedlegg fullmakt	
1.6 Navn/virksomhet	Klikk eller trykk her for å skrive inn tekst.
1.7 Telefon og e-post	Klikk eller trykk her for å skrive inn tekst.

2 Legemiddelinformasjon og indikasjon	
2.1 Hva gjelder anmodningen? <i>Kryss av for hva anmodningen gjelder</i>	Et nytt virkestoff ☐ En indikasjonsutvidelse / ny indikasjon ☐ En ny styrke eller formulering ☒
2.2 Hvilken indikasjon gjelder anmodningen?	Jorveza 0,2 mg/ml mikstur, suspensjon er indisert til behandling av eosinofil øsofagitt (EoE) hos pediatriske pasienter i alderen 2 til 17 år.

<i>Indikasjonen skal oppgis på norsk. Hvis prosess for godkjenning pågår, oppgi også indikasjon på engelsk.</i> <i>Merk: Leverandør skal anmode om vurdering av hele indikasjonen som de har fått godkjent eller søker om godkjenning for. Dersom leverandør foreslår en avgrensning til undergrupper, må dette begrunnes og leverandør må levere dokumentasjonen som trengs for å foreta en vurdering av undergruppen i tillegg til dokumentasjonen for hele indikasjonen.</i>	Falk Pharma Nordics propose the reimbursement to be restricted to a subpopulation of the EMA indication, for paediatric patients from age 2-11 years of age. The corticosteroid formulations currently available on the Norwegian market are used off label and not optimal for paediatric patients, especially those under 12 years of age. This highlights a significant medical need for a formulation tailored to address the unmet requirements in paediatric populations with EoE
2.3 Handelsnavn	Jorveza
2.4 Generisk navn/virkestoff	Budesonide
2.5 ATC-kode	A07EA06
2.6 Administrasjonsform og styrke <i>Oppgi også forventet dosering og behandlingstid</i> <i>Skriv kort</i>	0.2 mg/mL oral suspension <i>Induction of remission</i> The usual duration of induction treatment is 12 weeks. For patients who are not appropriately responding within 12 weeks, the treatment can be extended to up to 24 weeks. <i>Children 2 to 11 years of age</i> The recommended daily dose is 1 mg budesonide to be administered as two separate doses per day: one dose of 2.5 mL suspension (corresponding to 0.5 mg budesonide) in the morning and one dose of 2.5 mL suspension (corresponding to 0.5 mg budesonide) in the evening. <i>Maintenance of remission</i> The duration of maintenance therapy is determined by the treating physician. <i>Children 2 to 11 years of age</i> The recommended daily dose is 0.5 mg budesonide to be administered as one dose of 2.5 mL suspension (corresponding to 0.5 mg budesonide) in the morning, depending on the individual clinical requirement of the patient. A maintenance dose of 0.5 mg budesonide twice daily is recommended for patients with a long-standing disease

	history and/or high extent of oesophageal inflammation in their acute disease state.
2.7 Farmakoterapeutisk gruppe og virkningsmekanisme. <i>Skriv kort</i>	Pharmacotherapeutic group: Antidiarrheals, intestinal anti-inflammatory/anti-infective agents, corticosteroids acting locally. Mechanism of action: Budesonide (a locally acting corticosteroid) is a non-halogenated glucocorticosteroid, which acts primarily anti-inflammatory via binding to the glucocorticoid receptor. In the treatment of EoE with Jorveza, budesonide inhibits antigen-stimulated secretion of many pro-inflammatory signal molecules such as thymic stromal lymphopoeitin, interleukin-13 and eotaxin-3 in the oesophageal epithelium, which results in a significant reduction of the oesophageal eosinophilic inflammatory infiltrate. Budesonide offers a favourable benefit–risk profile because of its high first-pass hepatic metabolism and local action resulting in low systemic bioavailability and a reduced risk of corticosteroid-related adverse effects.

3 Historikk – virkestoff og indikasjon

3.1 Har Nye metoder behandlet metoder med det aktuelle virkestoffet tidligere? <i>Hvis ja, oppgi ID-nummer til metoden/metodene i Nye metoder</i>	Ja ☒ Nei ☐ ID-nummer: ID2019_011 ID2021_103
3.2 Er du kjent med om andre legemidler/virkestoff er vurdert i Nye metoder til samme indikasjon? <i>Hvis ja, oppgi ID-nummer til metoden/metodene i Nye metoder</i>	Ja ☐ Nei ☒ ID-nummer: Klikk eller trykk her for å skrive inn tekst.
3.3 Er du kjent med om det er gjennomført en metodevurdering i et annet land som kan være relevant i norsk sammenheng? <i>Hvis ja, oppgi referanse</i>	Ja ☐ Nei ☒ Referanse: Klikk eller trykk her for å skrive inn tekst.

4 Status for markedsføringstillatelse (MT) og markedsføring

4.1 Har legemiddelet MT i Norge for en eller flere indikasjoner?	Ja ☒ Nei ☐ Dato for MT for første indikasjon: 8. januar 2018
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Hvis ja - skriv inn dato for norsk MT for den første indikasjonen	
4.2 Markedsføres legemiddelet i Norge?	Ja ☐ Nei ☒
4.3 Har legemiddelet MT i Norge for anmodet indikasjon? <i>For alle metoder: Fyll ut prosedyrenummer i EMA (det europeiske legemiddelbyrået)</i> <i>Hvis metoden ikke har MT i Norge, fyll ut forventet tidspunkt (måned/år) for CHMP opinion i EMA.</i> <i>Hvis metoden har MT i Norge, fyll ut dato for MT</i>	MT i Norge: Ja ☒ Nei ☐ Prosedyrenummer i EMA: EMA/X/0000257468 Hvis metoden ikke har MT: Forventet tidspunkt for CHMP opinion i EMA (måned/år): Klikk eller trykk her for å skrive inn tekst. Forventet tidspunkt for markedsføringstillatelse (MT) for den aktuelle indikasjonen i Norge (måned/år): Klikk eller trykk her for å skrive inn tekst. Hvis metoden har MT: Dato for MT i Norge for den aktuelle indikasjonen: 27.09.2022; EU/1/17/1254/012
4.4 Har legemiddelet en betinget markedsføringstillatelse for anmodet indikasjon? <i>Hvis ja, fyll ut en beskrivelse av hva som skal leveres til EMA og når.</i>	Ja ☐ Nei ☒ Beskrivelse: Klikk eller trykk her for å skrive inn tekst.
4.5 Har anmodet indikasjon vært i «accelerated assessment» hos EMA?	Ja ☒ Nei ☐
4.6 Har legemiddelet «orphan drug designation» i EMA? <i>Hvis ja, fyll ut dato</i>	Ja ☒ Nei ☐ Dato for «orphan drug designation»: 05.08.2013

5 Ordning for forenklet vurdering av PD-(L)1-legemidler

5.1 Er legemiddelet registrert i Nye metoders ordning «Forenklet vurdering av PD-(L)1-legemidler»?	Ja ☐ Nei ☒
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6 Sammenlignbarhet og anbud

6.1 Finnes det andre legemidler med lignende virkningsmekanisme og /eller tilsvarende effekt til den aktuelle indikasjonen?	Ja ☐ Nei ☒ Kommentar: Klikk eller trykk her for å skrive inn tekst.
6.2 Vurderer leverandør at legemiddelet i anmodningen er sammenlignbart med et eller flere andre legemidler som Nye metoder har besluttet å innføre til den samme indikasjonen? <i>Hvis ja, hvilke(t)? Oppgi ID-nummer på metoden/metodene i Nye metoder</i>	Ja ☐ Nei ☒ Legemiddel og ID-nummer: Klikk eller trykk her for å skrive inn tekst.
6.3 Er det eksisterende anbud på terapiområdet som kan være aktuelt for legemiddelet?	Ja ☐ Nei ☒ Kommentar: Klikk eller trykk her for å skrive inn tekst.

7 Nordisk samarbeid JNHB (Joint Nordic HTA-bodies)

7.1 Er anmodet indikasjon aktuell for utredning i det nordiske HTA-samarbeidet JNHB? <i>Hvis nei, begrunn kort</i>	Ja ☐ Nei ☒ Begrunnelse: The product is a new pharmaceutical form associated with a new strength intended for a paediatric indication.
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8 Europeisk samarbeid om vurdering av relativ effekt og sikkerhet (HTAR)

8.1 Er anmodet legemiddel/indikasjon omfattet av regelverket for utredning av relativ effekt og sikkerhet i europeisk prosess (HTAR)? <i>Hvis ja, fyll ut dato for søknad om MT til EMA</i>	Ja ☐ Nei ☒ Dato for søknad til EMA: Klikk eller trykk for å skrive inn en dato.
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9 Helseøkonomisk dokumentasjon og forslag til helseøkonomisk analyse

9.1 Hvilken type helseøkonomisk analyse foreslår leverandøren?	Jorveza 0.2 mg/ml oral suspension (OS) serves as an extension to Jorveza oral dispersed tablets (ODT),
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<i>F.eks. kostnad-per-QALY analyse eller kostnadsminimeringsanalyse.</i> <i>Begrunn forslaget</i>	targeting the same disease but intended for a pediatric population. Falk Pharma Nordics propose simplified assessment (forenklet metodevurdering); instead of a full health economic analysis: consisting of estimation of the costs for treatment with Jorveza (budesonide) oral suspension and a simple budget impact analysis. This proposal aligns with the assessments conducted for Jorveza (budesonide) ODT (ID2021_103 and ID2019_011). Given the small patient population, minimal budget impact, and the substantial need for a child-appropriate formulation to improve quality of life for both children and their families, a streamlined assessment method is deemed most appropriate.
9.2 Pasientpopulasjonen som den helseøkonomiske analysen baseres på, herunder eventuelle undergrupper.	Falk Pharma Nordics propose restricted reimbursement to a subpopulation aged 2–11 years. The currently available formulations on the Norwegian market—both topical steroids as inhaled suspension or aerosol—are unsuitable for paediatric use, especially those under 12 years of age. This highlights a significant medical need for a formulation tailored to address the unmet requirements in paediatric populations with EoE.
9.3 Hvilken dokumentasjon skal ligge til grunn? (H2H studie, ITC, konstruert komparatorarm etc.) <i>Angi det som er relevant med tanke på hvilken type analyse som foreslås.</i>	H2H
9.4 Forventet legemiddelbudsjett i det året med størst budsjettvirkning i de første fem år.	For the subpopulation of 2-11 years old, the projection estimates to peak in year 5 with stabilization at approx. 3 million NOK per year (based on estimated maks AIP) For the ITT-population (<18years), the budget impact peak in year 5 is estimated to be around 6 million NOK per year (based on estimated maks AIP)
9.5 Forventet tidspunkt (måned og år) for levering av dokumentasjon til Direktoratet for medisinske produkter og/eller Sykehusinnkjøp HF. <i>Tidspunkt må oppgis</i>	Januari 2027

10 Sykdommen og eksisterende behandling

10.1 Sykdomsbeskrivelse for aktuell indikasjon

Kort beskrivelse av sykdommens patofysiologi og klinisk presentasjon / symptom bilde, eventuelt inkl. referanser

Eosinophilic oesophagitis (EoE) is a chronic, immune-mediated, antigen-triggered inflammatory disease of the oesophagus characterized by symptoms of oesophageal dysfunction and histologically by eosinophil-predominant inflammation (1).

EoE persists throughout life, requiring ongoing management to maintain remission. If left untreated, persistent eosinophilic inflammation can lead to progressive tissue remodelling, including subepithelial fibrosis and oesophageal strictures. The disease can transition from an inflammatory to a fibrostenotic phenotype over time and this can translate into recurrent bolus obstruction, emergency endoscopy and, in fibrostenotic disease, oesophageal dilatation. This progression underscores the importance of early and effective anti-inflammatory treatment to prevent long-term complications (1).

EoE significantly impacts quality of life. Children may experience failure to thrive, anxiety around eating, and social limitations due to dietary restrictions. Adolescents and adults report food impactions requiring emergency intervention and adapt their eating habits to cope with symptoms. Delayed diagnosis can further exacerbate emotional and physical burden due to the risk of complications and the chronic nature of the disease (1,2,3)

Symptoms

The clinical manifestations of EoE are age-dependent. The youngest children most often have symptoms reminiscent of gastroesophageal reflux—poor feeding and failure to thrive in infancy, followed by regurgitation, vomiting, and abdominal pain. In older children, the symptoms resemble those seen in adults. Adolescents typically present with dysphagia and food impaction. In adults, over 90% report dysphagia with solid foods, either intermittent or chronic, and up to 60% first seek medical care due to food becoming stuck in the esophagus. About one-fifth of adults also experience heartburn (1,2,3).

Reference:

	1. https://www.ema.europa.eu/en/documents/variation-report/jorveza-x-0000257468-epar-assessment-report_en.pdf 2. https://tidsskriftet.no/2011/12/oversiktsartikkel/eosinofil-osofagitt 3. https://www.helsebiblioteket.no/innhold/retningslinjer/pediatri/generell-veileder-i-pediatri/5.mage-tarm-lever-og-ernaering/5.16-eosinofil-osofagitt
10.2 Fagområde <i>Angi hvilket fagområde som best beskriver metoden</i>	Velg fagområde fra menyen: Mage- og tarmsykdommer
10.3 Kreftområde <i>Hvis metoden gjelder fagområdet Kreftsykdommer, angi hvilket kreftområde som er aktuelt</i>	Velg kreftområde fra menyen: Velg et element.
10.4 Dagens behandling <i>Nåværende standardbehandling i Norge, inkl. referanse</i>	Norwegian EoE treatment options for pediatrics include proton pump inhibitors (PPI), topically applied corticosteroids, elemental and empirical six-food elimination diets and endoscopic dilation. 1. Treatment with PPIs are recommended as first line treatment. 2. If remission is not achieved through PPI therapy, topical corticosteroids or elemental and empirical six-food diets are both effective and safe treatment. After completing treatment with topical steroids, many patients will experience a recurrence of symptoms. 3. In cases of significant esophageal stricture, esophageal dilation may be necessary. The treatment can provide symptom relief when the disease has led to significant narrowing of the esophagus despite adequate treatment. Reference: 1. https://www.helsebiblioteket.no/innhold/retningslinjer/pediatri/generell-veileder-i-pediatri/5.mage-tarm-lever-og-ernaering/5.16-eosinofil-osofagitt 2. https://tidsskriftet.no/2011/12/oversiktsartikkel/eosinofil-osofagitt

10.5 Prognose <i>Beskriv prognosen med nåværende behandlingstilbud, inkl. referanse</i>	Both reflux disease and EoE can coexist—the conditions are closely linked, and both have several characteristics that increase the likelihood of developing the other condition as well. An estimated proportion up to 50% of patients achieve symptomatic improvement with PPIs (1). Histological response with PPI observed in 30-68.6% of the children (EoE) (1,2). In cases of EoE, where PPIs have no effect, patients essentially have two options: topical steroids or diet. a. Current available topical steroid treatments in Norway are off-label for children, as their formulations are not specifically designed for paediatric use. Off-label oral corticosteroids in the form of compounded slurries or repurposed inhalers raise concerns about dosing errors and inconsistent treatment outcomes, palatability contributing to poor adherence and increased caregiver burden (3). Jorveza ODT is considered unsuitable for younger children due to the risk of swallowing and aspiration - the risk that the tablet enters the airway and lungs instead of the oesophagus during swallowing. A meta-analysis to evaluate the histologic and clinical effectiveness of the use of corticosteroids in pediatric patients with a diagnosis of EoE by Munoz-Osores et al, showed that histologic response was 49.25% in the corticosteroids group and 4.16% in the placebo group (risk ratio 11.05 [confidence interval 3.8-32.15]; $P < .0001$). Symptomatic response was 33.6% in the corticosteroids group and 21.8% in the control group (risk ratio 1.62 [confidence interval 0.94-2.79]; $P = 0.08$) (4). It is widely recognised that many patients with EoE experience symptom recurrence following the cessation of topical steroid therapy (1). Maintenance treatment sustains remission and may prevent progressive tissue remodelling, including subepithelial fibrosis and oesophageal strictures. b. Although food antigens play a role in the pathogenesis of EoE, the disease is not a food allergy and should not be conflated with IgE-
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	mediated food allergy (IgE-FA). EoE is a chronic, immune-mediated inflammatory disease of the oesophagus, driven predominantly by cell-mediated type 2 (Th2) immune responses, with delayed symptom onset and no reliable IgE-based diagnostic markers (5). Elemental and empirical six-food elimination diets are effective treatment option but are often difficult to maintain and associated with reduced quality of life for children and their caregivers. It has proven difficult to identify the specific foods that cause eosinophilic esophagitis. Mayerhofer C et al systematically assessed the efficacy of 4 major dietary treatment regimens in EoE. The overall rate of histologic remission was 53.8% (95% CI, 48.0%–59.6%), Diet regimen and patient age did not significantly affect rates of histologic remission. The overall rate of clinical response was 80.8% (95% CI, 72.3%–88.2%) (6). The efficacy results directly correlate with the type of diet (elemental, 6 food v, 4 food, 2 food vs. 1 food elimination diet). The stricter the approach the better efficacy but strict diet can be demanding for the patient and their caregivers and requires close follow-up with a registered dietitian to avoid malnutrition and ensure adequate caloric intake. Unmet Needs and Treatment Gaps: No medicinal product (topical corticosteroids) was authorized in the Norway specifically for pediatric EoE. Off-label use of inhaled corticosteroids in liquid or slurry form lacks regulatory oversight and standardization, raising concerns about safety, efficacy, and dosing accuracy (3). A recent (2024) web-based US survey has reported low adherence rates in adolescents of 11-17 years with EoE (37.1%) (7). There is a clear need for a pediatric formulation that ensures optimal esophageal delivery, is well tolerated, and offers predictable pharmacokinetics and therapeutic outcomes. Reference: 1. 5.16 Eosinofil øsofagitt - Helsebiblioteket: https://www.helsebiblioteket.no/innhold/retningslinjer/pediatri/generell-veileder-i-
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	pediatri/5.mage-tarm-lever-og-ernaering/5.16-eosinofil-osofagitt 2. Gutiérrez-Junquera C, F.-F. S. (2016). High Prevalence of Response to Proton-pump Inhibitor Treatment in Children With Esophageal Eosinophilia. <i>J Pediatr Gastroenterol Nutr</i>, 62(5):704-10. doi: 10.1097/MPG.0000000000001019. PMID: 26513622. 3. Amil-Dias, J et al. (2024). Diagnosis and management of eosinophilic esophagitis in children: An update from the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). <i>J Pediatr Gastroenterol Nutr</i> , 79, 394–437. https://doi.org/10.1002/jpn3.12188. 4. Munoz-Osores E, M.-C. I.-L. (2020). Corticosteroids for Eosinophilic Esophagitis in Children: A Meta-analysis. <i>Pediatrics.</i>, 146(5):e20200874. doi: 10.1542/peds.2020-0874. PMID: 33115796. 5. Burk, C.M., Shreffler, W.G., 2024. Triggers for eosinophilic esophagitis (EoE): The intersection of food allergy and EoE. <i>J Allergy Clin Immunol</i> 153, 1500–1509. https://doi.org/10.1016/j.jaci.2024.04.010 6. Mayerhofer C, K. A. (2023). Efficacy of Elimination Diets in Eosinophilic Esophagitis: A Systematic Review and Meta-analysis. <i>Clin Gastroenterol Hepatol.</i> , 21(9):2197-2210.e3. doi: 10.1016/j.cgh.2023.01.019. 7. Gold, B.D., Goodwin, B., Davis, K., Sweeney, C., Ziemiecki, R., Jiang, J., Fan, T., Boules, M., Chen, S.-T., Katzka, D.A., 2025. Satisfaction With and Adherence to Off-Label Corticosteroids in Adolescents and Adults With Eosinophilic Esophagitis: Results of a Web-Based Survey in the United States. <i>Journal of Clinical Gastroenterology</i> 59, 138. https://doi.org/10.1097/MCG.0000000000002006
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10.6 Det nye legemiddelets innplassering i behandlingsalgoritmen	Klikk eller trykk her for å skrive inn tekst.
10.7 Pasientgrunnlag <i>Beskrivelse, insidens og prevalens av pasienter omfattet av aktuell indikasjon* i Norge, inkl. referanse.</i> <i>Antall norske pasienter antatt aktuelle for behandling med legemiddelet til denne indikasjonen.</i> <i>* Hele pasientgruppen som omfattes av aktuell indikasjon skal beskrives</i>	The incidence appears to be between 0,1 and 0,5 per 100,000 in the pediatric population, but the figures vary widely (1). There are no available prevalence data for the pediatric population in Norway; however, based on figures from Sweden (2) and Denmark (3), the average prevalence is estimated at 35 per 100,000. Using this estimate, there are approximately 230 eligible patients aged 2–11 years, and around 430 eligible patients aged 2–18 years. Please note that only a small proportion of these patients are expected to actually receive treatment with Jorveza suspension (second line to PPIs). References: 1. https://www.helsebiblioteket.no/innhold/retningslinjer/pediatric/generell-veileder-i-pediatric/5.mage-tarm-lever-og-ernaering/5.16-eosinofil-osofagitt 2. Plate J, Söderbergh T, Bergqvist J, Lingblom C, Bergquist H, Larsson H. Eosinophilic esophagitis prevalence, incidence, and presenting features: a 22-year population-based observational study from southwest Sweden. Dis Esophagus. 2025 Jan 7;38(1):doae025. doi: 10.1093/dote/doae025. PMID: 38525937; PMCID: PMC11734667. 3. Allin KH, Poulsen G, Melgaard D, Frandsen LT, Jess T, Krarup AL. Eosinophilic oesophagitis in Denmark: Population-based incidence and prevalence in a nationwide study from 2008 to 2018. United European Gastroenterol J. 2022 Sep;10(7):640-650. doi: 10.1002/ueg2.12273. Epub 2022 Sep 15. PMID: 36106558; PMCID: PMC9486498.

11 Studiekarakteristika for relevante kliniske studier			
	Studie 1	Studie 2	Studie 3

11.1 Studie-ID <i>Studienavn, NCT-nummer, hyperlenke</i>	BUU-5/EEA (PEDEOS-1) EudraCT number: 2017-003737-29	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.
11.2 Studietype og -design	The PEDEOS-1 trial was a pivotal, Phase II/III, randomized 1:1:1 ratio to receive high-dose JOS (JOS-H), low-dose JOS (JOS-L), or matching placebo during the double-blind induction phase, placebo-controlled, multicentre study. Randomisation was stratified by age, reflecting clinically meaningful differences in symptom presentation and dosing requirements across the paediatric age spectrum. Patients were stratified into two predefined age groups at baseline: • Stratum I: children 2 to 11 years • Stratum II: adolescents 12 to <18 years Screening period: up to 4 weeks, including endoscopy with oesophageal biopsies and confirmation of active EoE by a central pathologist. Double-blind (DB) induction phase: 12 weeks of treatment with JOS or placebo Open-label induction (OLI) phase (optional):	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

	12 weeks of active JOS for all (JOS and placebo arms) eligible patients without adequate response during the DB phase. Open-label extension (OLE) phase (optional): 24 weeks of JOS in patients achieving histological and clinical response Tapering phase: 3 weeks of dose reduction Follow-up phase: 4 weeks post-treatment safety follow-up		
11.3 Formål	The primary objective of the study was to prove superior efficacy of JOS compared to placebo in children and adolescents with EoE. Secondary objectives were to further assess efficacy and to study safety and tolerability.	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.
11.4 Populasjon <i>Viktige inklusjons- og eksklusjonskriterier</i>	PEDEOS-1 enrolled children and adolescents aged ≥ 2 to <18 years with a confirmed clinico-pathological diagnosis of active EoE according to established diagnostic criteria	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

	(clinical symptoms, histology and endoscopic features). Key inclusion criteria additionally included clinically relevant symptoms, assessed using age-appropriate patient- or caregiver-reported instruments. Patients were required to have disease severity warranting treatment with a swallowed topical corticosteroid. Key exclusions were alternative causes of oesophageal eosinophilia, clinically significant oesophageal complications, recent use of systemic immunosuppressive therapies, and changes to background EoE management during the double-blind phase.		
11.5 Intervensjon (n) <i>Dosering, doseringsintervall, behandlingsvarighet</i>	During the double-blind induction phase, patients received one of the following regimens for 12 weeks: Age stratum I: children 2 to 11 years • High-dose JOS; 0,5mg budesonide (2,5 ml) in the morning and evening. • Low-dose JOS ; 0,5 mg budesonide (2,5ml) in the	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

	morning. Placebo in the evening (2,5ml). Age stratum II: Adolcents 12 to <18 years • High-dose JOS; 1 mg budesonide (5 ml) in the morning and evening. • Low-dose JOS ; 1 mg budesonide (5 ml) in the morning. Placebo in the evening (5ml). Dosing volumes and budesonide exposure were adapted according to age stratum, ensuring weight- and age-appropriate delivery while maintaining blinding across treatment arms.		
11.6 Komparator (n) <i>Dosering, doseringsintervall, behandlingsvarighet</i>	Placebo was selected as the comparator because no medicinal product was approved for paediatric EoE at the time of study initiation.	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

	Placebo oral suspension for 12 weeks. Dosing of 2,5ml in the morning and 2,5ml in the evening.		
11.7 Endepunkter <i>Primære, sekundære og eksplorative endepunkter, herunder definisjon, målemetode og ev. tidspunkt for måling</i>	Primary endpoint: The primary efficacy endpoint was assessed at Week 12 of the double-blind phase, combining histological remission and clinical response. Histological remission defined as a peak of <16 eos/mm² hpf at DB week 12 (Last Observation Carried Forward (LOCF)). Clinical response defined as $\geq 30\%$ reduction in the total score of PEES Version 2.0 For Stratum I: Age 2 to 11 years: parent-reported assessments For Stratum II: Age 12 to <18 years: patient-reported assessments Key secondary endpoint: 1. Rate of patients with histological remission: Defined as a peak of <16 eos/mm² hpf at DB week 12 (Last	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

	Observation Carried Forward [LOCF]) 2. Change in the peak eos/mm² hpf 3. Rate of patients with clinico-histological remission 4. Rate of patients with clinical remission 5. Rate of patients with clinical response at DB week 12 (LOCF) 6. Resolution of dysphagia symptoms		
11.8 Relevante subgruppeanalyser <i>Beskrivelse av ev. subgruppeanalyser</i>	Subgroup analysis for patients in age stratum 1 (Age 2 to 11 years)	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.
11.9 Oppfølgingstid <i>Hvis pågående studie, angi oppfølgingstid for data som forventes å være tilgjengelige for vurderingen hos Direktoratet for medisinske produkter samt den forventede/planlagte samlede oppfølgingstid for studien</i>	End of trial date 1 Aug 2023.	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

11.10 Tidsperspektiv resultater <i>Pågående eller avsluttet studie? Tilgjengelige og fremtidige datakutt</i>	Results published in EU Clinical trial register on the 5th April 2025.	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.
11.11 Publikasjoner <i>Tittel, forfatter, tidsskrift og årstall. Ev. forventet tidspunkt for publisasjon</i>	PEDEOS-1 (BUU-5/EEA) study: EU Clinical trial register, Aug 2023 (EU-CTR, 2025) EudraCT Number: 2017-003737-29 Dr. Falk Pharma GmbH, 2026. JOS SmPC.	Klikk eller trykk her for å skrive inn tekst.	Klikk eller trykk her for å skrive inn tekst.

12 Igangsatte og planlagte studier

12.1 Er det pågående eller planlagte studier for legemiddelet innenfor samme indikasjon som kan gi ytterligere informasjon i fremtiden? <i>Hvis ja, oppgi forventet tidspunkt</i>	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.
12.2 Er det pågående eller planlagte studier for legemiddelet for andre indikasjoner?	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.

13 Diagnostikk

13.1 Vil bruk av legemiddelet til anmodet indikasjon kreve diagnostisk test for analyse av biomarkør? <i>Hvis ja, fyll ut de neste spørsmålene</i>	Ja ☐ Nei ☒
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13.2 Er testen etablert i klinisk praksis? <i>Hvis ja, testes pasientene rutinemessig i dag?</i>	Ja ☐ Nei ☐ Hvis ja, testes pasientene rutinemessig i dag? Ja ☐ Nei ☐
13.3 Hvis det er behov for en test som ikke er etablert i klinisk praksis, beskriv behovet inkludert antatte kostnader/ressursbruk	Klikk eller trykk her for å skrive inn tekst.

14 Andre relevante opplysninger	
14.1 Har dere vært i kontakt med fagpersoner (for eksempel klinikere) ved norske helseforetak om dette legemiddelet/indikasjonen? <i>Hvis ja, hvem har dere vært i kontakt med og hva har de bidratt med?</i> <i>(Relevant informasjon i forbindelse med rekruttering av fageksperter i Nye metoder)</i>	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.
14.2 Anser leverandør at det kan være spesielle forhold ved dette legemiddelet som gjør at en innkjøpsavtale ikke kan basere seg på flat rabatt for at legemiddelet skal kunne oppfylle prioriteringskriteriene? <i>Hvis ja, begrunn kort.</i> <i>Hvis ja, skal eget skjema fylles ut og sendes til Sykehusinnkjøp HF samtidig med at dokumentasjon til metodevurdering sendes til Direktoratet for medisinske produkter.</i> Nærmere informasjon og skjema: Informasjon og opplæring - Sykehusinnkjøp HF	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.
14.3 Andre relevante opplysninger?	Falk Pharma Nordics would like to schedule a pre-submission meeting with DMP secretariat to discuss the clinical evidence package and align on the assessment process ahead of our planned reimbursement application in January 2027. For the proposed subpopulation of 2-11 years old, the projection estimates to peak at year 5 at appro. 3

	million NOK per year (based on estimated maks AIP). Given the small number of patients, minimal budget impact, and the high unmet need for a child-friendly formulation to improve the quality of life for children with EoE and their families, we believe that a streamlined assessment process is the most effective approach for assessing Jorveza 0.2mg/ml oral suspension (also consistent with previous assessment Jorveza ODT for adults) A meta-analysis by Muñoz-Osores et al. evaluating the histological and clinical effectiveness of corticosteroids in pediatric patients with EoE demonstrated a histological response rate of 49.3% in the corticosteroid-treated group compared with 4.2% in the placebo group (risk ratio 11.05; 95% CI 3.8-32.15; $p < 0.0001$). Jorveza ODT are only approved for adults, the formulation requires specific administration techniques to ensure adequate mucosal contact time in the esophagus. The tablet must be retained in the oral cavity and allowed to dissolve completely before swallowing. Premature swallowing may reduce esophageal exposure and consequently decrease treatment effectiveness. Although there may be clinical experience with Jorveza ODT in some pediatric patients, younger children, particularly those below 12 years of age, may have limited ability to comply with these administration requirements. The phase II/III BUU-5 study evaluating Jorveza Oral Suspension (JOS) versus placebo in children and adolescents with EoE demonstrated a histological response rate of 88.5% in the treatment group compared with 0% in the placebo group ($p < 0.0001$). In the key subgroup of children aged 2-11 years, the histological response rate was 91.7% versus 0% for placebo ($p < 0.0001$; 98.75% CI: 71.74-100.00). Considering the efficacy demonstrated in BUU-5, together with the need for an age-appropriate formulation, we believe that Jorveza oral suspension could provide a valuable addition to the Norwegian treatment arsenal for pediatric EoE. It has the potential to address a significant unmet medical need and expand treatment options for children and families affected by this chronic disease. We would appreciate the opportunity to discuss the proposed submission strategy and assessment
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	pathway with the DMP Secretariat and look forward to your guidance. 1. Munoz-Osores E, M.-C. I.-L. (2020). Corticosteroids for Eosinophilic Esophagitis in Children: A Meta-analysis. . Pediatrics., 146(5):e20200874. doi: 10.1542/peds.2020-0874. PMID: 33115796. 2. PEDEOS-1 (BUU-5/EEA) study: EU Clinical trial register, Aug 2023 (EU-CTR, 2025) EudraCT Number: 2017-003737-29
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