NYE METODER

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.

Utfylt 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)

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: 24.07.2026

1 Kontaktopplysninger	
1.1 Leverandør (innehaver/søker av markedsføringstillatelse i Norge)	Roche Norge AS
1.2 Navn kontaktperson	Charlotte Indre Lund // Fabienne Olivia Villars
1.3 Stilling kontaktperson	Nordic Access Manager // Medical Partner
1.4 Telefon	+47 408 389 78 // +47 918 63 020
1.5 E-post	charlotte_indre.lund@roche.com // fabienne_olivia.villars@roche.com
Ekstern representasjon - vedlegg fullmakt	
1.6 Navn/virksomhet	N/A
1.7 Telefon og e-post	N/A

2 Legemiddelinformasjon og indikasjon	
2.1 Hva gjelder anmodningen? *Kryss av for hva anmodningen gjelder*	Et nytt virkestoff ☐ En indikasjonsutvidelse / ny indikasjon ☒ En ny styrke eller formulering ☐
2.2 Hvilken indikasjon gjelder anmodningen?	Lupusnefritt (LN): I kombinasjon med mykofenolatmofetil (MMF) til behandling av voksne med

	aktiv LN av klasse III eller IV, med eller uten sammenfallende klasse V.
2.3 Handelsnavn	Gazyvaro
2.4 Generisk navn/virkestoff	Obinutuzumab
2.5 ATC-kode	L01FA03
2.6 Administrasjonsform og styrke	Administration: Intravenous infusion. Dosage: 1000 mg in combination with mycophenolate mofetil (MMF) at weeks 0, 2, 24, and 26 the first year, thereafter every 6 months. Evaluation of treatment duration from week 76.
2.7 Farmakoterapeutisk gruppe og virkningsmekanisme.	Humanized monoclonal antibody (Type II anti-CD20) causing direct B-cell death. Has a glycoengineered Fc region for higher binding affinity and increased antibody-dependent cellular cytotoxicity (ADCC).

3 Historikk – virkestoff og indikasjon

3.1 Har Nye metoder behandlet metoder med det aktuelle virkestoffet tidligere?	Yes ☒ No ☐ ID-nummer: Obinutuzumab is approved and reimbursed in Norway for the treatment of • ID2014_004 Chronic lymphocytic leukemia (CLL) • ID2016_2013 r/r follicular lymphoma (FL) • ID2017_004 1L follicular lymphoma (FL)
3.2 Er du kjent med om andre legemidler/virkestoff er vurdert i Nye metoder til samme indikasjon?	Yes ☒ No ☐ ID-nummer: • ID2020_088 Benlysta Belimumab received a positive reimbursement decision from the decision forum in August 2021 for treatment in combination with immunosuppressive treatment for the treatment of adult patients with active lupus nephritis; Benlysta underwent a simplified assessment for the most severe patient subgroup in LN. • ID2022_010 Voklosporin (Lupkynis): Kombinasjon med mykofenolatmofetil til behandling av aktiv lupusnefritt (LN) klasse III, IV eller V (inkl. blandede klasser III/V og IV/V).
3.3 Er du kjent med om det er gjennomført en metodevurdering i et annet land som kan være relevant i norsk sammenheng?	Yes ☒ No ☐

	Referanse: • The Danish Medicines Council (Medicinrådet) has evaluated and recommended obinutuzumab for the treatment of active lupus nephritis (recommendation dated June 24, 2026). • In Sweden Gazyvaro in LN is included in the tender without assessment. • In Finland, a formal national HTA process was bypassed. Instead, immediate access was secured because Gazyvaro's acquisition cost was already considered highly favorable, given that its primary oncological indications (CLL and FL) were already fully reimbursed. Consequently, the decision to adopt and fund the treatment for this new indication rested directly on the clinical and budgetary authority of the individual Heads of Clinics within the hospitals.

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: 2014
4.2 Markedsføres legemiddelet i Norge?	Ja ☒ Nei ☐
4.3 Har legemiddelet MT i Norge for anmodet indikasjon?	MT i Norge: Ja ☒ Nei ☐ Prosedyrenummer i EMA: EMA/VR/0000244907
	Hvis metoden ikke har MT: N/A
	Hvis metoden har MT: Dato for MT i Norge for den aktuelle indikasjonen: 04.12.2025
4.4 Har legemiddelet en betinget markedsføringstillatelse for anmodet indikasjon?	Ja ☐ Nei ☒
4.5 Har anmodet indikasjon vært i «accelerated assessment» hos EMA?	Ja ☐ Nei ☒

4.6 Har legemiddelet «orphan drug designation» i EMA?	Ja ☐ Nei ☒

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 ☒

6 Sammenlignbarhet og anbud

6.1 Finnes det andre legemidler med lignende virkningsmekanisme og /eller tilsvarende effekt til den aktuelle indikasjonen?	Ja ☐ Nei ☒
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?	Ja ☐ Nei ☒
6.3 Er det eksisterende anbud på terapiområdet som kan være aktuelt for legemiddelet?	Ja ☐ Nei ☒ Kommentar: Patient population is considered to be very small (10 patient/ year) and heterogenous- the available treatments are individualized and based on this it might not make sense to set up and manage a tender for such situation.

7 Nordisk samarbeid JNHB (Joint Nordic HTA-bodies)

7.1 Er anmodet indikasjon aktuell for utredning i det nordiske HTA-samarbeidet JNHB?	Ja ☐ Nei ☒ Begrunnelse: • Sweden and Finland extended access via regional or hospital tender processes without requiring a national HTA. • The Danish Medicines Council underwent an expedited HTA assessment. Based on the robust efficacy and safety data from the Phase III REGENCY study (specifically focusing on QALYs and life-years gained),

	Denmark granted conditional reimbursement for Gazyvaro in Lupus Nephritis. This initial approval is based on current evidence and covers a 1-year treatment course for a cohort of 17 patients, with a requirement to review long-term outcome data (when it becomes available) before extending treatment beyond the first year.

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)?	Ja ☐ Nei ☒ Dato for søknad til EMA: N/A

9 Helseøkonomisk dokumentasjon og forslag til helseøkonomisk analyse

9.1 Hvilken type helseøkonomisk analyse foreslår leverandøren?	We propose a simplified budget impact (BIM) analysis for the following reasons: • **Established precedent:** Gazyvaro shares a comparable situation with Benlysta (Nye metoder ID2020_088) in terms of patient population and size and B-cell target. Benlysta did previously qualify for a simplified assessment for severe LN. • **Resource efficiency:** The target population is exceptionally small (approximately 10 patients with the most severe LN). A simplified process ensures a proportionate use of assessment resources compared to a full national HTA. • **Clinical endorsement:**Clinicians that Roche has consulted express the wish and experience with use of G in addition to currently available drugs such as Belysta for certain LN patients, citing superior real-world efficacy, a deep B- cell depletion and superior patient compliance, aiming to prevent high-risk patients from progressing to chronic renal failure and long-term kidney damage. • **Patent expiry**: With biosimilars expected to enter the market in 2029, our BIM analysis will demonstrate that the long-term systemic

	cost for this treatment course will drop significantly. By introducing Gazyvaro now, the healthcare system can immediately protect a small, vulnerable patient population while avoiding the massive, lifelong healthcare costs associated with chronic dialysis and kidney transplants.
9.2 Pasientpopulasjonen som den helseøkonomiske analysen baseres på, herunder eventuelle undergrupper.	Same patients as the indication.
9.3 Hvilken dokumentasjon skal ligge til grunn? (H2H studie, ITC, konstruert komparatorarm etc.)	We suggest that all the relevant templates to budget impact analyses (Excel BI model, BIM section in the HTA dossier, and the submission checklist) are the most relevant for this assessment. Please refer to the reasons in section 9.1. **We are open for dialogue and would like to discuss this case before sending in any documentation.**
9.4 Forventet legemiddelbudsjett i det året med størst budsjettvirkning i de første fem år.	Budget Impact projection (2026–2030) The budget impact analysis is based on a stable cohort of 10 severe LN patients receiving treatment starting in 2026. This forecast assumes a constant current price (applied for three different indications) throughout the 5-year horizon, with no price reductions modeled for patent expiration from 2029 • Year 1 (2026): Due to the initial induction regimen outlined in the SmPC, the first-year treatment cost is 208 531 NOK per patient. For the cohort of 10 patients, the total Year 1 budget impact is 2 085 310 NOK. • Years 2 through 5 (2027–2030): Maintenance therapy requires 2 injections per patient per year. At the current constant price, the total 83 412,40 NOK per patient annually. For the 10-patient cohort, this results in a stable annual budget impact of 834 124 NOK per year. • Total cumulative impact: Over the standard 5-year assessment horizon, the maximum cumulative budget impact for this 10-patient cohort will be not more than 5 421 819 NOK prior to any negotiated tender discounts.

9.5 Forventet tidspunkt (måned og år) for levering av dokumentasjon til Direktoratet for medisinske produkter og/eller Sykehusinnkjøp HF.	To be discussed- see point 14.3

10 Sykdommen og eksisterende behandling

10.1 Sykdomsbeskrivelse for aktuell indikasjon	Lupus nephritis is a severe, chronic autoimmune complication of systemic lupus erythematosus (SLE) characterized by immune complex deposition in the kidney glomeruli and tubulointerstitium, leading to inflammation and fibrosis. The disease mostly affects young women is characterized by immune complex deposition in the kidney glomeruli and tubulointerstitium, leading to inflammation and fibrosis and for an estimated that 10-15% of LN patients kidney failure (Norby et al. 2010, Tidsskriftet). G is a new approved treatment for the most severe forms of LN.
10.2 Fagområde	Nephrology and Rheumatology
10.3 Kreftområde	Not applicable.
10.4 Dagens behandling	Current standard-of-care for active lupus nephritis consists of glucocorticoids in combination with immunosuppressive agents like mycophenolate mofetil (MMF) or cyclophosphamide (CYC) (References: ACR 2024, KDIGO 2024 guidelines). According to the Norwegian physician the current standard of care for the most severe LN patients in Norway is Benlysta as an add-on therapy to the MMF and glucocorticoids.
10.5 Prognose	Despite standard-of-care, up to ~20% of patients progress to end-stage kidney disease (ESKD) within 10 years. Chronic glucocorticoid use also leads to significant long-term toxicities, including infections and cardiovascular events.
10.6 Det nye legemiddelets innplassering i behandlingsalgoritmen	Gazyvaro is intended as an add-on therapy to standard-of-care (MMF and corticosteroids) for adult patients with active Class III or IV lupus nephritis.

10.7 Pasientgrunnlag	Lupus nephritis develops in approximately 40–50% of all SLE patients. The annual incidence in Norway is estimated to be 0.4–0.6 per 100,000 population. Total patient counts would correspond to the eligible adult population with active Class III or IV disease. According to Norwegian expert physicians a maximum of 10 patients per year present with this condition with about 50% being considered for treatment with Gazyvaro.

11 Studiekarakteristika for relevante kliniske studier

	Studie 1	Studie 2
11.1 Studie-ID	REGENCY (CA41705) - Phase III, randomized, double-blind, placebo-controlled, multicentre study. NCT04226523	NOBILITY (WA29748) - Phase II, randomized, double-blind, placebo-controlled, multicentre study. NCT02550525
11.2 Studietype og -design	Phase III, randomized, double-blind, placebo-controlled, multicentre study evaluating Gazyvaro in combination with standard-of-care.	Phase II, randomized, double-blind, placebo-controlled, parallel-group, multicentre study evaluating Gazyvaro in combination with standard-of-care.
11.3 Formål	To evaluate the efficacy and safety of Gazyvaro in combination with standard-of-care (MMF and corticosteroids) versus placebo plus standard-of-care in patients with active Class III or IV (± Class V) lupus nephritis.	To evaluate the safety and efficacy of Gazyvaro in combination with standard-of-care in patients with active Class III or IV (± Class V) lupus nephritis.
11.4 Populasjon	Adult patients (≥ 18 years) with biopsy-proven active, proliferative Class III/IV (± Class V) lupus nephritis at high risk of progression.	Adult patients (≥ 18 years) with SLE and active ISN/RPS 2003 Class III or IV (± Class V) lupus nephritis.
11.5 Intervensjon (n)	Gazyvaro 1000 mg IV (Weeks 0, 2, 24, 26, and every 6 months thereafter) in combination with standard-of-care (mycophenolate mofetil and glucocorticoids).	Gazyvaro 1000 mg IV (Day 0, Week 2, 24, 26) in combination with standard-of-care (mycophenolate mofetil/mycophenolic acid and glucocorticoids).
11.6 Komparator (n)	Placebo IV (dosed at Weeks 0, 2, 24, 26, and every 6 months	Placebo IV (dosed at Day 0, Week 2, 24, 26) in combination with

	thereafter) in combination with standard-of-care (mycophenolate mofetil and glucocorticoids).	standard-of-care (mycophenolate mofetil/mycophenolic acid and glucocorticoids).
11.7 Endepunkter	Primary: Complete Renal Response (CRR) at Week 76. Secondary: CRR with successful prednisone taper, proteinuric response, mean change in eGFR, and reduction in renal-related events through Week 76.	Primary: Complete Renal Response (CRR) at Week 52. Secondary: Overall Renal Response (ORR), modified CRR (mCRR), and partial renal response (PRR) at Weeks 52, 76, and 104.
11.8 Relevante subgruppeanalyser	N/A	N/A
11.9 Oppfølgingstid	Data available up to primary data at week 76	Data available for week 104
11.10 Tidsperspektiv resultater	Completed study. Primary data cut-off: 15 August 2024.	Completed study. Primary data cut-off: 2 August 2023.
11.11 Publikasjoner	Furie R, et al. Efficacy and safety of obinutuzumab in patients with active lupus nephritis: results from the Phase III REGENCY study. 2025. Search PubMed	Furie R, et al. Efficacy and safety of obinutuzumab in patients with active lupus nephritis: results from the Phase II NOBILITY study. 2025. Search PubMed

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?	Ja ☐ Nei ☒
12.2 Er det pågående eller planlagte studier for legemiddelet for andre indikasjoner?	Ja ☒ Nei ☐ • Study Number: NCT05039619 Study Title: A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Obinutuzumab in Adolescent Patients With Active Class III or IV Lupus Nephritis, Including an Evaluation of Open Label Safety and PK in a Cohort of Pediatric Patients (Aged 5 to < 12) ○ Link: https://clinicaltrials.gov/study/NCT05039619

	○ This trial specifically investigates the use of obinutuzumab (Gazyvaro) in both adolescent (12 to <18 years) and younger pediatric (5 to <12 years) patient cohorts with active Class III or IV lupus nephritis. ● Study Number: NCT04963296 Study Title: A Study to Evaluate the Efficacy and Safety of Obinutuzumab in Active Systemic Lupus Erythematosus (ALLEGORY) ○ Link: https://clinicaltrials.gov/study/NCT04963296 ○ This study specifically investigated the efficacy and safety of obinutuzumab compared with a placebo in patients with active systemic lupus erythematosus (SLE).

13 Diagnostikk

13.1 Vil bruk av legemiddelet til anmodet indikasjon kreve diagnostisk test for analyse av biomarkør?	Ja ☐ Nei ☒
13.2 Er testen etablert i klinisk praksis?	N/A
13.3 Hvis det er behov for en test som ikke er etablert i klinisk praksis, beskriv behovet inkludert antatte kostnader/ressursbruk	N/A

14 Andre relevante opplysninger

14.1 Har dere vært i kontakt med fagpersoner (for eksempel klinikere) ved norske helseforetak om dette legemiddelet/indikasjonen?	Ja ☒ Nei ☐ Norwegian expert physician contributed to the following insights: ● Comparative effectiveness: Real-world data indicates superior effectiveness of Gazyvaro compared to Benlysta in this clinical setting. ● Patient population: The severe LN patient cohort currently treated with Benlysta is highly restricted, consisting of approximately 10 individuals.

	• Treatment compliance: Gazyvaro provides a guaranteed compliance advantage for this specific sub-population, which represents a critical clinical differentiator. • Unmet need: There is a strong clinical need and a clear desire among physicians to expand the use of Gazyvaro for this severe patient subpopulation. Another independent KOL submitted a direct, unsolicited request to Roche to make Gazyvaro available for LN patients. This request was prompted by recent regulatory updates tightening the criteria for exemptions rule patients ("unntaksordning").
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?	Ja ☒ Nei ☐ Gazyvaro already has several indications in malignant hematology in addition to the now approved indication in LN. We expect use in treatment of severe LN patients which do not respond to standard treatment and the estimated number of lupus patients are very low and significantly smaller than the number of hematology patients Gazyvaro is reimbursed and approved in hematology, at current price. Because the LN patient population is significantly smaller compared to hematology patients, it is considered challenging to adapt the G price to a cost effective price for LN if rebate is necessary for the full volume of G (aka flat rebate).
14.3 Andre relevante opplysninger?	Roche decided to submit a "anmodning" after a request from a Norwegian physician. The physician experienced reduced access to Gazyvaro as a result of EMA marketing authorization approval as only drugs where "Anmodning" is submitted can be used via the so-called "Unntaksordning". Roche hereby asks and encourages dialogue and collaboration with NM and/or hospital procurement in order to find a sustainable and resource effective solution to provide LN patients equal access to Gazyvaro. As our initial assessments showed a low probability of success for access if Roche were to submit a full HTA. We therefore did not pursuite an "anmodning" as this likely would lead to unreasonable resource use with a negative outcome. However, based on feedback from

	clinicians we are open to a constructive dialog on finding a way forward for these patients.

Informasjon om Nye metoder finnes på nettsiden nyemetoder.no