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Reimbursement Recommendation

Efgartigimod Alfa Injection (Vyvgart SC)

Indication: As monotherapy for adult patients with active chronic inflammatory demyelinating polyneuropathy

Sponsor: argenx Canada Inc.

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Vyvgart SC?

Canada's Drug Agency (CDA-AMC) recommends that Vyvgart SC be reimbursed by public drug plans as monotherapy for adult patients with active chronic inflammatory demyelinating polyneuropathy (CIDP), if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) determined that it is uncertain whether Vyvgart SC demonstrates acceptable clinical value versus immunoglobulin (Ig) treatments in adult patients with active CIDP. Evidence from 1 study showed that, compared to placebo, Vyvgart SC lowered the chance of CIDP symptoms getting worse. Indirect comparisons suggest possible improvement in daily function versus subcutaneous Ig, with little difference in other measures. There is no direct or indirect evidence against IV Ig or other standard therapies, leaving its relative benefit unclear.

CIDP is a chronic, disabling condition requiring lifelong treatment. Current options such as Ig treatments, corticosteroids, immunosuppressants, and plasma exchange are not effective for all patients and can cause side effects. Vyvgart SC offers a new mechanism of action for those who do not experience a response to or cannot tolerate existing therapies, but its benefit compared to standard therapies remains uncertain.

Existing treatments often involve lengthy infusions and frequent hospital visits, creating a burden for patients and caregivers, especially in rural areas. Vyvgart SC, administered as a weekly subcutaneous injection at home, may reduce treatment burden and reliance on blood products.

Which Patients Are Eligible for Coverage?

Vyvgart SC should only be covered for adults with CIDP confirmed by electrodiagnostic testing, or for adults with possible CIDP based on clinical features and at least 2 supportive criteria consistent with current guidelines. Supportive criteria may include objective response to treatment, imaging, cerebrospinal fluid analysis, or nerve biopsy. Vyvgart SC should not be covered for adults with a history of myelopathy, evidence of central demyelination, another disease that better explains symptoms, polyneuropathy of other causes, pure sensory CIDP as per clinician judgment, or anti-MAG peripheral neuropathy.

Summary

What Are the Conditions for Reimbursement?

Vyvgart SC should be prescribed by, or in consultation with, a neurologist or neuromuscular specialist. After the first 6 months of treatment, Vyvgart SC will only be covered if there is clinical stability in symptoms using at least 1 approved assessment tool and if the total cost of Vyvgart SC does not exceed the total cost of Ig treatment. Treatment can continue if the patient's condition remains stable after those 6 months, and it should be reviewed every 12 months thereafter.

Important budget impact considerations must be addressed for health systems to be able to adopt Vyvgart SC.

Review Background

- **Disease background**: CIDP is a rare, progressive, autoimmune neuropathy that leads to muscle weakness, sensory disturbances, fatigue, pain, and significant disability, often impairing mobility and daily functioning. Diagnosis is challenging due to its typical and variant forms and clinical heterogeneity, contributing to underrecognition and a substantial burden on patients' health-related quality of life (HRQoL). Prevalence is estimated at 8.9 cases per 100,000 in the US (2021), with a global annual incidence of 1 to 2 cases per 100,000; however, accurate Canadian data are lacking due to diagnostic complexities.
- **Indication and reimbursement request:** Efgartigimod alfa injection (Vyvgart SC) has been approved by Health Canada as monotherapy for the treatment of adult patients with CIDP (Notice of Compliance (NOC): November 3, 2025). The sponsor is seeking reimbursement for this patient population. The application was submitted by the sponsor before receiving a Notice of Compliance from Health Canada, and the CDA-AMC review reflects the anticipated indication for efgartigimod alfa injection at the time the review was conducted, which was for the treatment of adult patients with CIDP. The final NOC is aligned with the anticipated NOC and the CDA-AMC review.
- **Drug under review:** Efgartigimod alfa is an FcRn antagonist and immunomodulatory drug. It is available as a 1,000 mg/5 mL (200 mg/mL) solution in a single-dose prefilled syringe for subcutaneous use and the dosage recommended in the product monograph is 1,000 mg once weekly.
- **Treatment costs:** At the submitted price of $19,750.00 per 5 mL single-dose prefilled syringe, the annual cost of efgartigimod alfa injection is expected to be $1,030,527 per patient, based on the Health Canada–recommended dosage.

Highlights of Input From Interested Parties

The patient group (Muscular Dystrophy Canada) noted the following regarding impacts of the disease, unmet needs, and important outcomes:

- Based on patient input submitted to CDA-AMC, CIDP causes loss of physical function, fatigue, chronic pain, neuropathic symptoms, and emotional distress, which interfere with daily tasks, reduce independence, increase fall risk, and contribute to employment disruption, economic hardship, and social withdrawal.
- Treatments often involve frequent hospital visits, rigid infusion schedules, and side effects (e.g., weight gain, mood changes, insomnia), placing significant strain on patients and caregivers.
- The burden of care and logistical challenges are heightened for those in rural or low-income settings.

The clinician group (the Neuromuscular Disease Network for Canada [NMD4C]) and the clinical experts consulted by CDA-AMC noted the following regarding unmet needs arising from the disease and place in therapy for the drug under review:

- Clinicians identified limited response or tolerance to first-line therapies and the absence of disease-modifying treatments that halt or reverse CIDP progression. There is a need for more convenient, safer, and targeted therapies that reduce reliance on Ig therapy or corticosteroids and improve long-term management, especially for patients requiring maintenance therapy or facing access barriers.
- The clinician group and the clinical experts anticipate that efgartigimod alfa injection may shift the CIDP treatment paradigm due to its targeted FcRn inhibition, rapid onset, and favourable safety profile, with potential use as monotherapy or in combination, either early in treatment or for patients with refractory disease.

The participating public drug programs raised potential implementation issues related to considerations for initiation, renewal, and prescribing of therapy, as well as systemic and economic issues.

Recommendation

With a vote of 12 in favour versus 1 against, CDEC recommends that efgartigimod alfa injection be reimbursed for adult patients with CIDP, only if the conditions listed in Table 1 are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Patients should meet the following criteria: 1.1. age ≥ 18 years 1.2. diagnosis of CIDP confirmed by electrodiagnostic testing (consistent with current clinical practice guidelines) **or** 1.3. diagnosis of possible CIDP based on clinical features along with at least 2 supportive criteria (consistent with current clinical practice guidelines) 1.3.1. supportive criteria may include but are not limited to objective response to treatment, imaging, CSF, or nerve biopsy.	The results from the multicentre, pivotal, two-treatment stage, randomized withdrawal, double-blinded, placebo-controlled trial (the ADHERE trial) demonstrated that compared to placebo, treatment with efgartigimod alfa injection resulted in added clinical benefit in adult patients with CIDP. The clinical experts noted that those with possible CIDP on NCS based on the EAN and PNS guideline should have ancillary testing (e.g., imaging, CSF analysis, response to other therapy).	—

Reimbursement condition	Reason	Implementation guidance
2. Efgartigimod alfa injection should not be initiated in adult patients with CIDP who have: 2.1. history of myelopathy, evidence of central demyelination, or any other disease that could better explain the patient's signs and symptoms 2.2. polyneuropathy of other causes 2.3. pure sensory CIDP as per clinician judgment 2.4. anti-MAG peripheral neuropathy.	These patients were not included in the ADHERE trial. The efficacy and harms of efgartigimod alfa injection in these patients are unknown.	—
3. The maximum duration of initial authorization is 6 months.	In stage A of the ADHERE trial, ECI was noted in 66.5% of patients by 12 weeks. The initial approval period for IVIg treatment for CIDP, is 6 months.	The clinical experts noted that response to treatment in patients with CIDP who are treatment-naive is generally observed over several weeks (e.g., 4 to 12 weeks) but could be longer for some patients. Therefore, assessment of treatment response initially at 3-month to 6-month intervals would be reasonable.
Renewal		
4. Reimbursement of treatment with efgartigimod alfa injection should be continued if, after the initial 6 months of treatment, there is evidence of clinical stability based on at least 1 validated assessment tool.	In the ADHERE trial, efgartigimod alfa injection resulted in a clinically important reduction in clinical deterioration compared with placebo at the last assessment of the randomized withdrawal phase.	The clinical experts noted that, in clinical practice, neuromuscular clinicians do not regularly use formal outcome scales used in clinical trials (such as the INCAT or CDAS). Typically, clinicians use improvement in bedside manual motor testing (MRC sum score), with or without electrodiagnostic study improvements, to determine whether there has been a response to therapy. If a formal scale is used, the INCAT scale is generally the simplest to administer and most time effective. In clinical practice, the assessment of response may include subjective patient-reported outcomes, which correlate better with quality of life. Results from any validated functional scale assessment (e.g., aINCAT score, I-RODS score, MRC sum score, CDAS score) should be submitted at the time of initiation and renewal to assess change from baseline and confirm ongoing clinical benefit (stability or improvement).

Reimbursement condition	Reason	Implementation guidance
5. Reimbursement of treatment with efgartigimod alfa injection should be continued if, after 6 months of treatment, there is evidence of clinical stability. Reassessment should occur every 12 months thereafter.	This is to allow sufficient time for patients and clinicians to assess response.	The clinical experts indicated that, for patients stable on therapy, reassessment at 6-month to 12-month periods would be reasonable.
Prescribing		
6. Efgartigimod alfa injection should be prescribed by or in consultation with a neurologist or neuromuscular specialist.	Accurate diagnosis and follow-up of patients with CIDP is important to ensure that efgartigimod alfa injection is prescribed to appropriate patients.	The clinical experts noted to CDEC that supportive treatments such as steroids may be used concurrently with efgartigimod alfa injection.
Pricing		
7. The total cost of efgartigimod alfa injection should be negotiated so that it does not exceed the total cost of treatment with Ig.	Based on the committee's assessment of the evidence, indirect evidence submitted by the sponsor suggests that there may be little to no clinically meaningful difference in efficacy between efgartigimod alfa injection and Ig among patients with CIDP. Therefore, the total cost of efgartigimod alfa injection should be no more than Ig.	—
Feasibility of adoption		
8. The economic feasibility of adoption of efgartigimod alfa injection must be addressed.	At the submitted price, the incremental budget impact of efgartigimod alfa injection is expected to be greater than $40 million in years 1, 2, and 3, and the magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and the CDA-AMC estimate.	—

aINCAT = adjusted Inflammatory Neuropathy Cause and Treatment; CDAS = CIDP Disease Activity Scale; CIDP = chronic inflammatory demyelinating polyneuropathy; CSF = cerebrospinal fluid; EAN = European Academy of Neurology; HRQoL = health-related quality of life; Ig = immunoglobulin; INCAT = Inflammatory Neuropathy Cause and Treatment; I-RODS = Inflammatory Rasch-built Overall Disability Scale; MRC = Medical Research Council; NCS = nerve conduction study; PNS = Peripheral Nerve Society.

Rationale for the Recommendation

Clinical Value

Evidence from 1 multicentre, phase II study (the ADHERE study) that used a multistage, randomized withdrawal, double-blind, placebo-controlled design showed that efgartigimod alfa injection led to a reduction in the risk of clinical deterioration (CIDP relapse) with a hazard ratio (HR) of 0.39 (95% confidence interval [CI], 0.25 to 0.61). The estimated percentage of clinical deterioration at week 24 was 26% in the efgartigimod alfa injection group and 54% in the placebo group (−28.1% difference); at week 48, the rates were 34% and 60% (−25.8% difference), respectively. Benefit appeared maintained in the open-label extension (OLE) (the

ADHERE+ study), and those who had received placebo during the randomized withdrawal stage B and then switched to efgartigimod alfa injection for the OLE showed greater improvements. Adherence was high in the ADHERE+ study (mean compliance = 98.5%).

The sponsor conducted an indirect treatment comparison (ITC) comparing efgartigimod alfa injection with subcutaneous immunoglobulin injection (SCIg) treatments. Overall, the results suggested that efgartigimod alfa injection likely results in a clinically meaningful improvement in Inflammatory Rasch-built Overall Disability Scale (I-RODS) score, and little to no clinically meaningful difference in adjusted Inflammatory Neuropathy Cause and Treatment (aINCAT) score and Medical Research Council (MRC) sum score up to 32 weeks, when compared with SCIg treatments. However, the ITC did not include any comparisons to other comparators, notably IV immunoglobulin (IVIg) injection. Consequently, the relative efficacy and safety of efgartigimod alfa injection versus comparators other than SCIg remain uncertain.

CDEC concluded that efgartigimod alfa injection demonstrates uncertain clinical value versus appropriate comparators in adult patients with CIDP.

Further information on the committee's discussion around clinical value is provided in the Summary of Deliberation section.

Considering Significant Unmet Clinical Need

CIDP is a rare, immune-mediated neuropathy with significant clinical burden. Despite the availability of first-line therapies, many patients experience suboptimal responses or treatment-related side effects underscoring the need for alternative treatment options. Despite current treatments, there are patients who are refractory to current therapies and require other treatments including corticosteroids that may be associated with significant side effects with long-term use, and off-label immunosuppressives that are associated with increased risk of infection and supported by limited clinical evidence. CDEC determined that efgartigimod alfa injection potentially meets a significant unmet clinical need for an additional treatment option with a different mechanism of action and efficacy and safety profile for patients who show inadequate response or lack of tolerability to current treatment options. However, there is uncertainty in how well the drug addresses the unmet clinical need due to the absence of direct or indirect comparisons of its efficacy and safety relative to relevant comparators.

Further information on the committee's discussion around unmet clinical need is provided in the Summary of Deliberation section.

Considering Significant Unmet Nonclinical Need or Health Inequity

Patient and clinician groups stated a need for timely, equitable, and flexible access to therapies. A treatment with an easier administration may help patients regain or maintain independence and maintain employment and social participation. Current treatment options include IVIg induction (and maintenance, in some patients), which requires expertise in its administration and multiple hospital visits, and SCIg, which requires infusions using a specialized pump. CDEC noted that efgartigimod alfa injection meets a significant unmet nonclinical need for a flexible, home-based treatment option to reduce hospital visits, long infusions, and rigid

administration treatments. It may further reduce strain on caregivers and family members and reduce out-of-pocket costs associated with some current treatments. Importantly, as it is not a blood-derived product, it also provides an option for patients who prefer to avoid blood products.

Developing the Recommendation

Due to the uncertainty in clinical value, CDEC could not recommend whether to reimburse efgartigimod alfa injection based on clinical value alone. Therefore, the committee also considered whether efgartigimod alfa injection addressed a significant unmet clinical or nonclinical need, or health inequity. CDEC noted that efgartigimod alfa injection addresses both a significant unmet clinical need and a significant unmet nonclinical need. The committee concluded that the clinical value and its level of certainty were acceptable when considering the significant unmet clinical and nonclinical need, and recommended that efgartigimod alfa injection be reimbursed.

The unmet needs addressed include the subcutaneous administration via a prefilled syringe, which facilitates home-based treatment and eliminates the need for travel to a hospital or infusion centre as required for IVIg, and eliminates the need for at-home use of specialized infusion pumps, as required by SCIg. Given that a large proportion of patients receive immunoglobulin therapy for long-term management of CIDP, efgartigimod alfa injection is expected to present a less burdensome treatment alternative than IVIg and SCIg. Importantly, as it is not a blood-derived product, it also provides an option for patients who prefer to avoid blood products. Additionally, reducing reliance on blood products may help safeguard treatment access during periods of supply shortages. Based on all the preceding considerations, CDEC recommended that efgartigimod alfa injection be reimbursed.

Because CDEC recommended that efgartigimod alfa injection be reimbursed, the committee also deliberated on whether reimbursement conditions should be added to address important economic considerations, health system impacts, or social and ethical considerations, or to ensure clinical value is realized. The resulting reimbursement conditions, with accompanying reasons and implementation guidance, are stated in Table 1.

Summary of Deliberation

CDEC considered all domains of value of the deliberative framework (clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems) before developing its recommendation. For further information on the domains of value, refer to Expert Committee Deliberation at Canada's Drug Agency.

The committee considered the following key discussion points, organized by the 5 domains of value.

Clinical Value

- **Appropriate comparators:** Ig treatments (either IVIg or SCIg), corticosteroids, immunosuppressives, and plasma exchange (PLEX) were considered appropriate comparators for the drug under review. Igs are the most relevant treatment option, as the anticipated place in therapy for efgartigimod alfa injection is the current standard of care.
- **Efficacy versus placebo:** One phase II, multistage trial (the ADHERE trial; N during the double-blind, randomized withdrawal, placebo-controlled study period = 221) suggested that in adults with CIDP, efgartigimod alfa injection resulted in a clinically meaningful reduction in the risk of clinical deterioration compared to placebo over the 48-week treatment period, with an HR of 0.39 (95% CI, 0.25 to 0.61). The median time to clinical deterioration could not be calculated for the efgartigimod alfa injection group because less than 50% of the patients had clinically deteriorated. The median time to clinical deterioration in the placebo group was 140 days (95% CI, 75 days to not calculated [NC]). The estimated percentage of clinical deterioration at week 24 was 26% (95% CI, 19% to 36%) in the efgartigimod alfa injection group and 54% (95% CI, 45% to 64%) in the placebo group (difference between groups = −28.1%; 95% CI, −40.7% to −14.3%). At week 48, the rates were 34% (95% CI, 25% to 45%) and 60% (95% CI, 50% to 70%), respectively, with a difference between groups of −25.8% (95% CI, −39.4% to −10.9%). At the last assessment in stage B, the observed clinical deterioration rate was lower in the efgartigimod alfa injection group (28%; 95% CI, 20% to 36%) compared to the placebo group (54%; 95% CI, 44% to 63%), with a between-group risk difference of −26% (95% CI, −38% to 11%). At the last assessment of the randomized withdrawal phase, efgartigimod alfa injection was likely associated with an improvement in disability and functional impairment, based on aINCAT score (difference between groups = −0.8 points; 95% CI, −1.2 to −0.3), I-RODS score (difference = 7.8 points; 95% CI, 3.5 to 12.1), and MRC sum score (difference = 2.7 points; 95% CI, 0.9 to 4.6). Patients' quality of life as measured by EQ-5D-5L visual analogue scale (VAS) may have improved with efgartigimod alfa injection treatment, with between-group differences of [redacted] in a total of 118 patients. Patient satisfaction with the treatment remained unchanged. These beneficial effects were likely maintained or preserved over the long-term extension phase. No notable safety concerns were identified with efgartigimod alfa injection during the study period. There was a reduction in the risk of clinical deterioration (CIDP relapse). The beneficial effects observed in the placebo-controlled period were likely maintained or preserved over the long-term extension phase, based on aINCAT score, I-RODS score, MRC sum score, and EQ-5D-5L VAS score.
- **Efficacy versus Ig therapy**: Comparisons to Ig products were limited to indirect evidence that was assessed as evidence of low certainty. CDEC reviewed evidence from the matching-adjusted indirect comparisons (MAICs) using individual patient data from the ADHERE trial and aggregate data from 3 other comparator trials. CDEC concluded that the MAICs suggested that, when compared with subcutaneous Igs, efgartigimod alfa injection likely results in a clinically meaningful improvement in I-RODS score, and little to no clinically meaningful difference in aINCAT score and MRC sum score, up to 32 weeks. CDEC noted that the certainty of this evidence was low due to

methodological limitations related to residual confounding and heterogeneity across studies, and limited generalizability to the CIDP treatment-naive populations, lack of HRQoL outcome, and lack of statistical analysis of harms.

- **Harms:** No notable safety concerns were identified with efgartigimod alfa injection during the study period of the ADHERE and ADHERE+ studies.
- **Clinical importance of treatment effects**: Patient input indicated that individuals with CIDP value treatments that improve mobility and support independence and quality of life, while also emphasizing the importance of fewer relapses, minimal side effects, and consistent symptom control. The clinical experts considered the minimal important difference (MID) values identified in the literature to be reasonable and appropriate for comparing efgartigimod alfa injection with placebo or Ig therapy. These included a change of 1 point or more for aINCAT score, 4 points or more for the I-RODS, and 4 points or more in centile score for the MRC sum score. For clinical deterioration rate and EQ-5D-5L VAS score, no MID could be identified for patients with CIDP. Using these MIDs, results from the ADHERE randomized withdrawal period demonstrated clinically meaningful benefits in clinical deterioration, I-RODS score, and EQ-5D-5L VAS score. Additionally, MAIC analyses showed clinically meaningful improvements in I-RODS score with efgartigimod alfa injection compared to SCIg. CDEC concluded that the availability of an additional treatment option for CIDP is important to patients, with demonstrated benefits over placebo and improvements in I-RODS score compared to SCIg.
- **Certainty of the evidence:** The assessment of time to clinical deterioration, I-RODS score, and EQ-5D-5L VAS score at the last assessment during the randomized withdrawal study period was rated as high-certainty evidence (compared to placebo) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. The assessments of aINCAT score and MRC sum score, as well as serious adverse events, were rated as moderate-certainty evidence due to serious imprecision.

Unmet Clinical Need

- **Severity of the disease**: CDEC acknowledged that CIDP is a chronic, relapsing condition that can lead to disability and reduced quality of life with a need for lifelong treatment. The patient group input reflected that individuals with CIDP often lose responsiveness to treatments over time and highlighted the need for better-tolerated therapies with fewer side effects.
- **Limitations of current treatments**: The clinician group and clinical experts indicated patients with CIDP may have disease that is refractory to Igs or may be intolerant or nonresponsive to corticosteroids. The clinician group and clinical experts indicated that patients with CIDP receiving IVIg commonly experience infusion-related adverse events, such as headache, fatigue, fever, chills, nausea, and infusion site reactions. In some cases, more serious adverse events, such as thromboembolic events, may occur. Therefore, patients receiving IVIg require monitoring in a clinic setting.

Unmet Nonclinical Need or Health Inequity

- **Input on unmet nonclinical need**: CDEC acknowledged that CIDP is a chronic, relapsing condition that can lead to disability and reduced quality of life. A large proportion of patients are treated with Ig including IVIg in hospital or infusion centres. Frequent hospital visits and lengthy infusions were reported to disrupt daily life and place emotional and financial strain on caregivers, especially those with lower incomes. Furthermore, patients treated with SCIg require lengthy infusions through a subcutaneous pump, which requires hands-on set-up and management.
- **Advantages of efgartigimod alfa injection compared to current treatment options**: Patients and clinicians identified a need for more flexible, home-based therapies with fewer side effects and improved tolerability. They noted that current treatments often involve burdensome infusions and the need for monitoring. Access challenges, especially in rural areas, highlight the need for more accessible treatment options and that could also provide patients with less burdensome administration. CDEC noted that efgartigimod alfa injection may help address these needs through its subcutaneous formulation via prefilled syringes, enabling home-based administration and the potential to reduce treatment and financial burden including travel and hospital stays. Efgartigimod alfa injection would also be a treatment option for patients who prefer to avoid blood products, and additionally may help to reduce reliance on blood products.

Distinct Social and Ethical Considerations

- **Input on unmet nonclinical need:** CDEC acknowledged the patient group input on nonclinical need, which includes a need for fewer infusions or hospital visits, equitable diagnosis and drug access, and promoting equitable improvements in disability outcomes and quality of life, particularly in rural or underserved regions.
- **Equity considerations:** The clinical experts noted that while CIDP does not disproportionately affect systemically marginalized populations (which may include Indigenous Peoples, people who have recently immigrated to Canada, and people with low incomes), patients in remote or nonurban areas may face challenges accessing timely diagnosis and treatment due to limited availability of neuromuscular specialists, which contribute to a delayed diagnosis of disease and poorer health outcomes.
- **Significant unmet nonclinical need or health inequity:** CDEC noted that efgartigimod alfa injection offers a more convenient alternative to existing therapies, administered as a weekly subcutaneous injection that may be self-administered at home, potentially reducing nonclinical treatment burden on patients and caregivers that were reflected in the patient and clinician groups input. Its short administration time may further contribute to reducing this burden.

Economic Considerations

- **Health impacts of efgartigimod alfa injection versus relevant comparators:** Based on the CDA-AMC reanalysis of the submitted economic analysis, efgartigimod alfa injection is predicted

to be associated with no life-year gain compared to Ig and may result in a gain of 3.42 quality-adjusted life-years (QALYs) compared to Ig. Approximately 87% of the predicted incremental benefit was accrued on the basis of extrapolation. QALY gains are therefore contingent on long-term treatment efficacy and no treatment waning over time. However, the committee noted that there was uncertainty regarding the clinical benefit of efgartigimod alfa injection relative to Ig that informed the economic analysis. Therefore, the committee noted that the predicted QALY benefit associated with efgartigimod alfa injection was uncertain.

- **Cost of efgartigimod alfa injection versus relevant comparators:** Efgartigimod alfa injection is predicted to be associated with higher costs to the health care system than Ig (incremental costs = $6,405,231 per patient), primarily driven by increased costs associated with drug acquisition.
- **Key findings of the economic evaluation:** Based on the submitted evidence using the sponsor's cost-utility analysis, the CDA-AMC base-case analysis estimated that the incremental cost-effectiveness ratio (ICER) for efgartigimod alfa injection in CIDP was $1,872,111 per QALY gained when compared with Ig. However, the committee noted the indirect evidence informing this analysis limited the reliability of this finding.
- **Certainty of the evidence:** There was uncertainty in the analysis associated with a lack of head-to-head evidence versus comparators, limitations with the model structure, and the unknown price of Ig that could not be resolved by CDA-AMC. The cost-effectiveness of efgartigimod alfa injection versus off-label comparators such as corticosteroids, PLEX, immunosuppressives, and rituximab remains unknown. As such, the committee noted that there was insufficient evidence to indicate that the total cost of efgartigimod alfa injection to the health system should exceed that of Ig.

Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that by year 3 of reimbursement, 2,525 patients would be eligible for treatment with efgartigimod alfa injection, of whom 379 would be expected to receive efgartigimod alfa injection. The estimated incremental budget impact of reimbursing efgartigimod alfa injection is predicted to be approximately $691 million over the first 3 years, with an expected expenditure of $692 million on efgartigimod alfa injection. CDEC noted that, at the submitted price, the incremental budget impact of reimbursing efgartigimod alfa injection is predicted to be greater than $40 million in years 1, 2, and 3, and the economic feasibility of adoption must be addressed. Additionally, the magnitude of uncertainty in the budget impact must be addressed to ensure the feasibility of adoption, given the difference between the sponsor's estimate and the CDA-AMC drug plan perspective estimate. The actual budget impact will depend on the perspective applied (drug costs only or broader health care system) and the public reimbursement rate of certain treatments.
- **Organizational implications:** Reducing reliance on blood products may help safeguard treatment access during periods of supply shortages.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information (links to the full documents for the review can be found on the project webpage):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor, as well as relevant ethical issues related to Vyvgart SC (refer the Main Report and Supplemental Material document)
- the sponsor's comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 1 patient group, Muscular Dystrophy Canada (refer to the Patient and Clinician Group Input document)
- input from 1 clinician group, NMD4C (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Supplemental Material document)
- input from 2 clinical experts with expertise in the management of CIDP consulted by CDA-AMC.

CDEC Information

Members of the Committee

Dr. Peter Jamieson (Chair), Dr. Kerry Mansell (Vice-Chair), Sally Bean, Daryl Bell, Dan Dunsky, Dr. Ran Goldman, Dr. Trudy Huyghebaert, Dr. Dennis Ko, Dr. Christine Leong, Dr. Alicia McCallum, Dr. Srinivas Murthy, Dr. Nicholas Myers, Dr. Krishnan Ramanathan, Dr. Marco Solmi, Carla Velastegui, Dr. Edward Xie, and Dr. Peter Zed

Meeting date: October 22, 2025

Regrets: Two expert committee members did not attend.

Conflicts of interest: None

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Questions or requests for information about this report can be directed to Requests@cda-amc.ca.