Canadian Journal of Health Technologies

Canada's Drug Agency
L'Agence des médicaments du Canada

September 2026 Volume 6 Issue 9

Drugs Health Technologies Health Systems

Reimbursement Recommendation

Inebilizumab (Uplizna)

Indication: As an add-on to standard therapy for the treatment of gMG in adult patients who are AChR or MuSK antibody positive

Sponsor: Amgen Canada Inc.

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Uplizna?

Canada's Drug Agency (CDA-AMC) recommends that Uplizna (inebilizumab) be reimbursed by public drug plans as an add-on therapy for adult patients with generalized myasthenia gravis (gMG) that is AChR or MuSK antibody positive and whose symptoms persist despite conventional therapy with AChE inhibitors, corticosteroids, and/or nonsteroidal immunosuppressive therapies (NSISTs), only if certain conditions are met.

Why Did CDA-AMC Recommend Reimbursement?

The Canadian Drug Expert Committee (CDEC) determined that Uplizna demonstrates acceptable clinical value versus conventional therapy (e.g., AChE inhibitors, corticosteroids, and/or NSISTs). This determination was enough for CDEC to recommend that Uplizna be reimbursed. Given that Uplizna is expected to be an additive treatment to conventional therapy, *acceptable clinical value* refers to added value versus conventional therapy.

Evidence from 1 pivotal phase III randomized, double-blind, placebo-controlled trial demonstrated that treatment with Uplizna over 26 weeks likely results in improvements in daily function and disease severity compared to placebo in the overall population of patients with gMG. CDEC discussed that Uplizna offers a different mechanism of action as a Health Canada–approved B-cell–depleting therapy compared with other available funded advanced biologics, and it may address significant unmet clinical needs. There is added clinical value for patients with gMG, particularly for the subpopulation with MuSK antibody–positive gMG that has limited treatment options and for patients whose disease remains refractory despite available treatment.

Which Patients Are Eligible for Coverage?

Uplizna should only be reimbursed for adult patients with gMG who meet all the following conditions: positive serologic test results for anti-AChR or anti-MuSK antibodies, Myasthenia Gravis Activities of Daily Living (MG-ADL) scores at baseline of 6 or higher (measured by the treating physician), Myasthenia Gravis Foundation of America class II to IV disease, and persistent symptoms despite stable doses of conventional therapy with AChE inhibitors, corticosteroids, and/or NSISTs.

What Are the Conditions for Reimbursement?

Reimbursement of Uplizna should be continued if there is documented improvement in disease symptoms, indicated by a reduction in MG-ADL

Summary

score of 2 points or more following an initial 12 months of treatment or if there is proof of no worsening in MG-ADL score provided annually for subsequent renewals. Uplizna should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG. The drug program cost of inebilizumab should be negotiated so that it does not exceed the drug program cost of treatment with the least costly advanced treatment reimbursed for the treatment of gMG.

Review Background

- **Disease background:**
  - gMG is a rare, chronic autoimmune disorder characterized by fluctuating skeletal muscle weakness. It most commonly affects the ocular, bulbar, limb, and respiratory muscles, leading to symptoms such as ptosis, diplopia, dysphagia, dysarthria, and exertional fatigue. In severe cases, gMG can result in myasthenic crisis requiring ventilatory support. gMG markedly reduces quality of life, independence, and functional capacity, often necessitating long-term immunosuppressive therapy.
  - As of 2026, it was estimated that there were 1,078 adult patients living with gMG (including both AChR and MuSK antibody–positive gMG) in Canada (excluding Quebec) whose symptoms persist despite conventional therapy.
- **Indication and reimbursement request:** Inebilizumab (Uplizna) has been approved by Health Canada "as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive." The sponsor is seeking reimbursement for it "as add-on therapy for adult patients with gMG who are AChR or MuSK antibody positive" and whose symptoms persist despite conventional therapy with AChE inhibitors, corticosteroids, and/or NSISTs.
- **Drug under review:** Inebilizumab is a CD19-directed cytolytic antibody. It is available as 100 mg per 10 mL solution per vial. The recommended dosage in the product monograph is 2 initial 300 mg IV infusions (2 weeks apart) and subsequent doses (starting 6 months from the first infusion) of single 300 mg IV infusions every 6 months.
- **Treatment costs:** At the submitted price of $25,623.00 per 100 mg vial, the annual cost of inebilizumab is expected to be $230,607 per patient in the first year of treatment and $153,738 per patient in subsequent years, based on the Health Canada–recommended dosage.

Highlights of Input From Interested Parties

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

- Patients experience unpredictable, fluctuating muscle weakness that can impair breathing, speech, swallowing, vision, and mobility. In severe cases, mechanical ventilation and admission to hospital are required. Patients' physical, psychological, and social health are significantly impaired.
- Patient groups indicated that despite several treatments being available for MG, adequate disease control is often not achieved. Many patients also experience treatment-related side effects that affect their quality of life. There is a need for treatments that achieve disease stability, restore physical function, reduce symptom burden, prevent respiratory crises, reduce reliance on corticosteroids and long-term immunosuppressants, and improve health-related quality of life (HRQoL).

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

- NSISTs do not work quickly to produce meaningful clinical benefit, and the use of corticosteroids is associated with significant long-term side effects and complications. Despite the availability of current standard therapies, as many as 15% of patients with gMG continue to have refractory disease. In addition, inequitable access to new targeted therapies is observed across Canada. The clinicians suggested that having multiple treatment options with different mechanisms of action is crucial for gMG, especially for patients with MuSK antibody–positive gMG, who have more limited treatment options compared with those who have AChR antibody–positive gMG.
- Clinicians noted that patients would benefit from the infrequent administration of inebilizumab compared to treatment with conventional nonsteroidal therapies and newer biologic drugs.
- Inebilizumab is expected to cause a shift in the current treatment paradigm due to its unique mechanism of action (i.e., it is the first CD19-directed B-cell–depleting therapy for antibody-positive gMG). The clinical experts indicated that patients with gMG should have completed a trial of combination conventional therapies first before inebilizumab is offered, which is similar to other existing targeted therapies.
- The participating public drug programs provided input regarding considerations for initiation, renewal, and prescribing of therapy and provided input on relevant comparators for this review.

Recommendation

With a vote of 14 in favour to 0 against, CDEC recommends that inebilizumab be reimbursed as add-on therapy for adult patients with gMG that is AChR or MuSK antibody positive and whose symptoms persist despite conventional therapy with AChE inhibitors, corticosteroids, and/or NSISTs, only if the conditions listed in Table 1 are met.

Table 1: Reimbursement Conditions and Reasons

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Treatment with inebilizumab should be reimbursed for adult patients with gMG who meet all the following conditions: 1.1. positive serologic test results for anti-AChR or anti-MuSK antibodies 1.2. an MG-ADL score at baseline of 6 or higher; the MG-ADL score should be	Evidence from 1 phase III, randomized, double-blind, placebo-controlled trial in adults with antibody-positive gMG whose disease responded inadequately to conventional therapies demonstrated that inebilizumab, when added to conventional therapies such as AChE inhibitors, corticosteroids, and/or NSISTs, likely results in improvements in daily function and disease severity at week 26 compared to placebo. The effect size in the subpopulation with AChR antibody–positive gMG was larger	Condition 1.4: Stable doses from the MINT trial are defined as 1 of the following: • corticosteroids only, with no dose increase within 4 weeks before randomization • NSIST, with continuous use for ≥ 6 months prior and no dose increase within 4 months before randomization

Reimbursement condition	Reason	Implementation guidance
measured and provided by the treating physician 1.3. MGFA class II to IV disease 1.4. persistent symptoms despite stable doses of conventional therapy with AChE inhibitors, corticosteroids, and/or NSISTs.	than that in the subpopulation with MuSK antibody–positive gMG.	• NSIST alone, or in combination with corticosteroids with continued use for ≥ 6 months prior (a combination of the 2 preceding definitions). Note that patients with MuSK antibody–positive gMG may not be clinically suitable to receive AChE inhibitors. CDEC noted that rituximab may be available in some jurisdictions; however, CDEC heard from the clinical experts that access to rituximab remains a barrier for some patients.
2. Treatment with inebilizumab should not be initiated in either of the following cases: 2.1. for patients during gMG exacerbation or crisis 2.2. for patients who have had thymectomy within 12 months.	The MINT trial excluded patients who had thymectomy within 12 months, and there is no evidence regarding the efficacy and safety of treatment with inebilizumab in patients with gMG exacerbation or crisis at baseline.	—
Renewal		
3. Reimbursement of treatment with inebilizumab for gMG should be continued if 1 of the following conditions is met: 3.1. following an initial 12 months of treatment, there is documented improvement in disease symptoms, indicated by a reduction in the MG-ADL score of ≥ 2 points 3.2. for subsequent renewals, there is proof of no worsening of the MG-ADL score provided annually.	There is no evidence that inebilizumab should be held to a different standard than other Health Canada–approved targeted biologics currently reimbursed when considering renewal. Inebilizumab should be renewed in a manner similar to those that apply to other targeted biologics for gMG.	Health Canada–approved biologics for gMG include FcRn antagonists (e.g., rozanolixizumab and efgartigimod alfa) and complement inhibitors (e.g., eculizumab, zilucoplan, and ravulizumab). Note that the initial renewal at 12 months should be conducted following the completion of 3 doses of inebilizumab (2 initial doses of 300 mg administered 2 weeks apart, with the third dose given 6 months after the first infusion). The initial renewal at 12 months is to determine the eligibility for the fourth dose at 12 months.
Prescribing		
4. Inebilizumab should be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.	Accurate diagnosis and follow-up of patients with gMG are important to ensure inebilizumab is appropriately prescribed for patients with gMG.	—
5. Inebilizumab should not be used concomitantly with rituximab, FcRn antagonists, and/or complement inhibitors.	The MINT trial did not assess such combinations, and the efficacy and safety of combination use with other advanced therapies	Inebilizumab should not be used concomitantly with rituximab. The efficacy and safety of inebilizumab used concomitantly with FcRn

Reimbursement condition	Reason	Implementation guidance
	based on the submitted evidence are currently unknown.	antagonists or complement inhibitors are currently uncertain and require further research.
Pricing		
6. The drug program cost of inebilizumab should be negotiated so that it does not exceed the drug program cost of treatment with the least costly advanced treatment reimbursed for the treatment of gMG.	Based on the committee's assessment of the evidence, inebilizumab is expected to have similar clinical benefits and harms compared with relevant comparators. Therefore, the drug program cost of inebilizumab should be no more than the least costly advanced treatment reimbursed for gMG.	—

CDEC = Canadian Drug Expert Committee; gMG = generalized myasthenia gravis; MG = myasthenia gravis; MG-ADL = Myasthenia Gravis Activities of Daily Living; MGFA = Myasthenia Gravis Foundation of America; NSIST = nonsteroidal immunosuppressive therapy.

Rationale for the Recommendation

Clinical Value

Based on the totality of the presented clinical evidence, CDEC concluded that inebilizumab demonstrates acceptable clinical value compared with appropriate comparators, including conventional therapy (e.g., AChE inhibitors, corticosteroids, and NSISTs) and advanced targeted biologics (e.g., rituximab, complement inhibitors, and FcRn antagonists), in patients with gMG. Given that inebilizumab is expected to be an additive treatment to conventional therapy, *acceptable clinical value* refers to added value versus conventional therapy.

Evidence from 1 pivotal phase III randomized, double-blind, placebo-controlled trial (MINT) comparing inebilizumab to placebo in adults with antibody-positive gMG demonstrated that 26 weeks of treatment with inebilizumab likely results in improvements in daily function and disease severity compared to placebo. At week 26 in the overall population, the least square (LS) mean change from baseline in MG-ADL score was −4.2 in the inebilizumab group and −2.2 in the placebo group. The adjusted between-group difference was −1.9 (95% confidence interval [CI], −2.9 to −1.0; $P < 0.0001$). While the effect size in the subpopulation with AChR antibody–positive gMG was larger than that in the subpopulation with MuSK antibody–positive gMG, CDEC discussed that inebilizumab offers a different mechanism of action as a Health Canada–approved B-cell–depleting therapy compared with other reimbursed biologics, which are either complement inhibitors or FcRn antagonists. This offers important clinical value for patients with gMG, particularly for the subpopulation with MuSK antibody–positive gMG, which has limited treatment options, and for patients whose disease remains refractory despite available treatments.

Evidence from 1 network meta-analysis (NMA) suggested that inebilizumab is similar to other comparator treatments for gMG in terms of efficacy, as assessed by changes from baseline in MG-ADL and Quantitative Myasthenia Gravis (QMG) test scores. The ability to draw firm conclusions from the NMA was limited by

differences in patient characteristics, uncertainty in the distribution of some effect modifiers, sparse evidence networks, and the inability to assess the consistency assumption.

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

Developing the Recommendation

The determination of acceptable clinical value was sufficient for CDEC to recommend reimbursement of inebilizumab. As part of the deliberation on whether to recommend reimbursement or not, the committee also considered unmet clinical need, unmet nonclinical need, and health inequity. Information on this discussion is provided in the Unmet Clinical Need and Distinct Social and Ethical Considerations domains in the Summary of Deliberation section.

Because CDEC recommended that inebilizumab 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 before developing its recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. 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:** CDEC noted that the current standard of care (SOC) includes conventional therapy that encompasses treatment with AChE inhibitors (e.g., pyridostigmine), systemic corticosteroids (e.g., prednisone), and NSISTs (e.g., azathioprine, mycophenolate mofetil, cyclosporine, and tacrolimus). Inebilizumab was evaluated in the MINT trial against placebo in addition to standard conventional therapy and a protocol-mandated steroid taper. CDEC noted that this is a reasonable comparator for addressing efficacy versus the current SOC in practice in Canada. However, CDEC also noted that as the treatment landscape for gMG now also includes the use of advanced targeted biologics, these are also relevant comparators for the review. Currently, these advanced targeted biologics may include B-cell–targeting therapies (e.g., rituximab), complement inhibitors (e.g., ravulizumab, zilucoplan, and eculizumab), and FcRn blockers (e.g., efgartigimod alfa and rozanolixizumab).

- **Efficacy versus conventional therapies:** One randomized placebo-controlled trial (the MINT trial; N = 238) evaluated a change from baseline in MG-ADL scores as a primary efficacy outcome in the overall population. At week 26 in the overall population, the LS mean change from baseline in MG-ADL scores was −4.2 in the inebilizumab group and −2.2 in the placebo group. The adjusted between-group difference was −1.9 (95% CI, −2.9 to −1.0; P < 0.0001).

  Change from baseline in MG-ADL scores in patients with AChR or MuSK antibody–positive gMG was a key secondary efficacy outcome in the MINT trial. In patients with AChR antibody–positive gMG, the LS mean change from baseline to week 26 in the MG-ADL score was −4.2 in the inebilizumab group and −2.4 in the placebo group. The between-group difference was −1.8 (95% CI, −2.9 to −0.7; P = 0.0015). At week 52, the LS mean change from baseline in the MG-ADL score was −4.8 in the inebilizumab group and −1.8 in the placebo group. The between-group difference was −3.0 (95% CI, −4.1 to −1.8; P < 0.0001).

  In the subpopulation with MuSK antibody–positive gMG, the LS mean change from baseline to week 26 in MG-ADL score was −3.9 in the inebilizumab group and −1.7 in the placebo group. The between-group difference was −2.2 (95% CI, −4.2 to −0.2; P = 0.0297).

  At week 26, the between-group differences in the proportion of patients with a 3-point or greater improvement in MG-ADL score with no rescue therapy use (between day 28 and week 26) were 19.8% (nominal P value = 0.0019) for the overall study population, 18.5% (nominal P value = 0.0104) for the subpopulation with AChR antibody–positive gMG, and 23.4% (nominal P value = 0.1072) for the subpopulation with MuSK antibody–positive gMG, favouring inebilizumab.
- **Clinical importance of treatment effects:** Patient input emphasized the need for treatments that achieve adequate disease control, minimize side effects of current treatments, restore physical function, improve quality of life, and reduce reliance on systemic corticosteroids and long-term NSISTs. In the MINT trial, outcomes related to disease severity, muscle strength, and HRQoL addressed several of these goals of treatment, and these are all relevant assessment tools for patients with gMG. However, literature-based between-group minimal importance difference estimates for MG-ADL scores and Myasthenia Gravis Quality of Life 15-item scale – Revised (MG-QoL15r) scores were not established in the study population. The review team acknowledged that these minimal importance differences are estimated for within-group changes, leaving some uncertainty in applying them to between-group differences. Despite these limitations, CDEC considered the totality of the improvements in the MG-ADL scale scores with inebilizumab compared to placebo at different time points and for the different subpopulations to be clinically important.
- **Certainty of the evidence:** In patients with AChR antibody–positive gMG, the assessments of efficacy, HRQoL, and harms were rated as having moderate to low certainty (compared to placebo) using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. In patients with MuSK antibody–positive gMG, these assessments were rated as having low to very low certainty. The main reasons for the low level of certainty were serious imprecision and serious risk of bias in the results of the MINT trial. The subpopulation with MuSK antibody–positive

gMG had a much smaller sample size than the subpopulation with AChR antibody–positive gMG, causing more uncertainty in the study findings and challenges in result interpretation.

- **Efficacy versus active treatments:** Based on the NMA submitted for this review, the results of the base-case analysis suggested that inebilizumab is similar to many comparator treatments for gMG in terms of efficacy (assessed by changes from baseline in MG-ADL, QMG, and MG-QoL15r scores). These comparators include conventional treatments and targeted biologics that include rituximab, other complement inhibitors, and FcRn antagonists. Although the NMA results suggested that inebilizumab may be favoured over efgartigimod (an FcRn blocker) for changes from baseline in MG-ADL scores, there is potential for small differences that may not meet the threshold for a clinically meaningful effect.

  The ability to draw firm conclusions from the NMA was limited by differences in patient characteristics, uncertainty in the distribution of some effect modifiers, sparse evidence networks, and the inability to assess the consistency assumption.
- **Potential disease-modifying properties:** CDEC also heard from clinical experts that as a B-cell–depleting therapy, inebilizumab can reduce B-cell production that is responsible for autoantibodies targeting the neuromuscular junction. The clinical experts indicated that depletion of B cells has the potential to provide durable control of disease activity and may support long-term remission in some patients.
- **Clinical value:** Based on all the preceding considerations, the committee determined inebilizumab demonstrates acceptable clinical value when compared to conventional treatments or all active treatments.

Unmet Clinical Need

- **Input on unmet clinical need:** CDEC noted that patients have identified some key unmet clinical needs that include goals to reduce disease exacerbations, prevent myasthenic crises, and improve disease stability. Patients would like to have effective treatments that can improve their muscle strength and reduce fatigue. Patients also face challenges in maintaining daily function and independence. For the management of gMG, there still exists a challenge to reduce reliance on the long-term use of corticosteroids and immunosuppressive therapies.
- **Severity of the disease:** CDEC acknowledges input from patients and clinicians that gMG is a rare, chronic autoimmune disorder characterized by fluctuating skeletal muscle weakness that commonly affects ocular, bulbar, and respiratory muscles, which in turn can impair vision, swallowing, breathing, speech, and mobility. gMG markedly reduces patients' quality of life, independence, and functional capacity.
- **Availability of treatment options:** CDEC noted that there are currently alternative treatments available for gMG. According to clinical practice guidelines, conventional therapy for gMG may consist of AChE inhibitors (e.g., pyridostigmine), systemic corticosteroids (e.g., prednisone), and NSISTs (e.g., azathioprine, mycophenolate mofetil, cyclosporine, and tacrolimus). Conventional therapies

in MG induce remission in 70% to 80% of patients, but very few patients achieve sustained stable remission while not receiving therapy. Emerging targeted immunotherapies, such as complement inhibitors (e.g., ravulizumab, zilucoplan, and eculizumab), FcRn blockers (e.g., efgartigimod alfa and rozanolixizumab), B-cell–targeting therapies (e.g., rituximab), and hematopoietic stem cell transplantation have been developed over the past decade. Many of these treatments target the specific pathophysiology of gMG, and they are intended to be used as add-on therapy to conventional treatment for patients with refractory gMG.

- **Place in therapy of advanced biologics:** CDEC also heard from clinical experts that treatments for patients with gMG should be individualized, including when advanced add-on therapy is clinically necessary following conventional treatments with corticosteroids alone, NSISTs alone, or corticosteroids in combination with NSISTs. In patients who present with moderate to severe gMG, earlier use of an advanced biologic may be indicated to rapidly control and stabilize the disease. In some circumstances, it may not be appropriate to initiate or continue NSISTs if an adequate disease response is not expected or has not been achieved, and patients may instead benefit from earlier escalation to an advanced biologic. Patients may have contraindications to, previous intolerance of, or adverse effects with NSISTs; for such patients, the next lines of treatment may require advanced biologics, following an adequate trial of corticosteroid therapy alone. Consequently, the clinical experts emphasized that access to advanced therapies should remain sufficiently flexible to accommodate differences in disease severity, disease presentation, and individual patient circumstances.
- **Significant unmet clinical need:** Despite available treatments providing symptom relief, CDEC heard from the clinical experts that many patients continue to experience residual fatigue and muscle weakness that significantly affect their quality of life. Many patients remain dependent on corticosteroids, leading to long-term safety concerns and treatment burden. Rituximab is an off-label treatment option for gMG in Canada, but access varies across jurisdictions. CDEC also acknowledged that there remains a significant unmet clinical need for adults with MuSK antibody–positive gMG due to challenges with evidence generation related to this rare disease subtype, limited treatment options, and the potential for more severe complications compared with other gMG subtypes.

Distinct Social and Ethical Considerations

- **Input on unmet nonclinical need and equity considerations:** CDEC noted some unmet nonclinical needs as identified by patients. These include inconsistent and inequitable access to targeted biologic therapies in Canada, logistical burden associated with treatment delivery, as well as caregiver and financial burdens associated with helping patients manage with gMG. CDEC has noted that inebilizumab therapy requires maintenance infusion every 6 months following an initial dosing regimen. This infrequent dosing has the potential to reduce treatment burden for patients and caregivers compared with several currently available therapies that require substantially more

frequent administration. CDEC also heard from patients that there are systemic barriers to timely access to appropriate care, especially for equity-deserving groups.

- **Ethical implications:** Some CDEC members highlighted that there may be ethical implications related to variable access to rituximab in Canada. Currently, rituximab is the only off-label B-cell therapy available, and its variable access for patients with gMG may introduce inequity concerns, especially if this treatment may address significant unmet needs for patients.

Economic Considerations

- **Health impacts of inebilizumab versus relevant comparators:** In patients with AChR antibody–positive gMG, inebilizumab plus SOC was associated with more quality-adjusted life-years (QALYs) gained over a lifetime horizon compared to SOC alone, efgartigimod plus SOC, IVIg plus SOC, plasma exchange (PLEX) plus SOC, and rituximab plus SOC. However, inebilizumab plus SOC generated fewer QALYs compared to rozanolixizumab plus SOC, zilucoplan plus SOC, and ravulizumab plus SOC. In patients with MuSK antibody–positive gMG, inebilizumab plus SOC is predicted to produce more QALYs than SOC alone, rituximab plus SOC, PLEX plus SOC, and IVIg plus SOC. However, inebilizumab plus SOC is predicted to produce fewer QALYs compared to rozanolixizumab plus SOC.
- **Cost of inebilizumab versus relevant comparators:** In patients with AChR antibody–positive gMG, inebilizumab plus SOC is predicted to be associated with higher costs to health care systems versus some comparators (range, $498,419 versus PLEX plus SOC to $1,408,439 versus rituximab plus SOC) and cost savings versus others (range, $326,463 versus rozanolixizumab plus SOC to $2,237,751 versus zilucoplan plus SOC). In patients with MuSK antibody–positive gMG, inebilizumab plus SOC is predicted to be associated with higher costs versus some comparators (range, $553,248 versus PLEX plus SOC alone to $1,467,927 versus rituximab plus SOC) and cost savings versus rozanolixizumab plus SOC ($228,677).
- **Key findings of the economic evaluation:** In each of the subpopulations with different serotypes, inebilizumab plus SOC was less effective and more costly than the combination of some patients within the population receiving rituximab plus SOC and the rest receiving rozanolixizumab plus SOC (i.e., it was extendedly dominated through these comparators). Based on this analysis, a price reduction would be required for inebilizumab plus SOC to be considered cost-effective at any given willingness-to-pay threshold. Differences in health impacts between inebilizumab plus SOC and other comparators added on to SOC were small and uncertain. If equal efficacy and safety are assumed between inebilizumab and add-on comparators, then the cost of inebilizumab should not exceed the cost of the least expensive add-on therapy reimbursed for the treatment of gMG that is inadequately controlled with SOC alone.
- **Certainty of the evidence:** The CDA-AMC analysis was informed by the sponsor-submitted NMA, which was deemed to be uncertain.

Impacts on Health Systems

- **Anticipated budget impact:** CDA-AMC estimated that by year 3 of reimbursement, a total of 1,111 patients would be eligible for inebilizumab; of them, 333 patients would be expected to receive it. The estimated incremental budget impact of reimbursing inebilizumab is predicted to be a savings of approximately $82.5 million over the first 3 years, with an expected expenditure of $124 million on inebilizumab. The actual budgetary impact of reimbursing inebilizumab will depend on its uptake, the comparators displaced, and the proportion of the population whose symptoms persist despite treatment with SOC.
- **Equity considerations:** CDEC noted that inebilizumab is an IV medication that requires pretreatment planning including immunization, hepatitis B and tuberculosis screening, and other treatment-related coordination to access a specialized infusion centre typically situated in urban cities; hence, patients living in remote areas may face additional challenge in accessing this treatment if there is no established infrastructure supporting this therapy within the proximity of their homes.

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 web page):

- the CDA-AMC review of the clinical and pharmacoeconomic evidence submitted by the sponsor, as well as relevant ethical issues related to inebilizumab (refer to the Main Report and the Supplemental Material document)
- the sponsor's comments on the draft report and the CDA-AMC responses
- patients' perspectives gathered by 2 patient groups, Muscular Dystrophy Canada and the Sumaira Foundation (refer to the Patient and Clinician Group Input document)
- input from 1 clinician group (the Neuromuscular Disease Network for Canada) (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 from Ontario and the Prairies with expertise in the management of myasthenia gravis 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, 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: July 22, 2026

Regrets: Two expert committee members did not attend.

Conflicts of interest: None

Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

ISSN: 2563-6596

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