CADTH

CADTH COMMON DRUG REVIEW

CADTH Canadian Drug Expert Committee Recommendation

(Final)

OFATUMUMAB (KESIMPTA — Novartis Pharmaceuticals Canada Inc.)
Indication: Multiple sclerosis, relapsing-remitting

RECOMMENDATION
The CADTH Canadian Drug Expert Committee (CDEC) recommends that ofatumumab should be reimbursed for the treatment of adult patients with an established diagnosis of relapsing-remitting multiple sclerosis (RRMS) only if the following conditions are met.

Conditions for Reimbursement
Initiation Criteria
1. Patients must have all of the following characteristics at the time of initiating treatment with ofatumumab:
   1.1. An Expanded Disability Status Scale (EDSS) score of less than 6.0
   1.2. Evidence of active disease defined as at least one of the following:
      1.2.1. One relapse during the previous year
      1.2.2. Two relapses during the previous 2 years
      1.2.3. A positive gadolinium (Gd)-enhancing MRI scan during the year before starting treatment with ofatumumab.
2. Ofatumumab should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis (MS).

Renewal Criteria
1. Ofatumumab may only be renewed for patients who do not exhibit evidence of disease progression since the previous assessment. Disease progression is defined in a manner similar to that for DMTs currently reimbursed for the treatment of RRMS.
2. Patients should be assessed for response to ofatumumab, as defined by Renewal Criteria 1, every 12 months.
3. Patients must not have experienced more than 1 relapse in the previous year.

Prescribing Conditions
1. Patients must be under the care of a specialist with experience in the diagnosis and management of MS.

Pricing Conditions
1. Price reduction.

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   1.2. Evidence of active disease defined as at least 1 of the following:
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      1.2.2. Two relapses during the previous 2 years
      1.2.3. A positive gadolinium (Gd)-enhancing magnetic resonance imaging (MRI) scan during the year before starting treatment with ofatumumab.
2. Ofatumumab should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis (MS).

Renewal Criteria

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1. Price reduction.

Reasons for the Recommendation

1. Two randomized, double-blind, active comparator–controlled trials (ASCLEPIOS I and ASCLEPIOS II) demonstrated that ofatumumab was superior to teriflunomide in reducing the annualized relapse rate (ARR) of MS, based on an ARR ratio of 0.50 (95% CI, 0.37 to 0.65; P < 0.001) in the ASCLEPIOS I study and an ARR ratio of 0.42 (95% CI, 0.31 to 0.56; P < 0.001) in the ASCLEPIOS II study. Patients in the ofatumumab groups also exhibited fewer Gd-enhancing T1 lesions per scan and fewer new or enlarging T2 lesions per year relative to baseline than patients in the teriflunomide groups in both trials. The number of Gd-enhancing lesions per scan corresponded to a rate reduction of 97.5% (rate ratio = 0.03; 95% CI, 0.01 to 0.05) and 93.8% (rate ratio = 0.06; 95% CI, 0.04 to 0.10) in the ASCLEPIOS I and II studies, respectively, for ofatumumab compared to teriflunomide (P < 0.001 in both studies). The difference between ofatumumab and teriflunomide in the mean rate of new or enlarging T2 lesions per year was 0.18 lesions (95% CI, 0.15 to 0.22; P < 0.001) in the ASCLEPIOS I study and 0.15 lesions (95% CI, 0.13 to 0.19; P < 0.001) in the ASCLEPIOS II study, both in favour of ofatumumab.
2. One indirect treatment comparison (ITC) provided by the sponsor showed that ofatumumab was likely as effective in reducing ARR as other monoclonal antibody DMTs (i.e., alemtuzumab, natalizumab, and ocrelizumab) and cladribine, and likely better than conventional DMTs (interferon beta [IFNB], teriflunomide, glatiramer, dimethyl fumarate, fingolimod) and placebo. For 6-month confirmed disability progression (CDP-6), ofatumumab was likely as effective as ocrelizumab, alemtuzumab, natalizumab, IFNB, dimethyl fumarate, cladribine, and fingolimod, and likely better than teriflunomide and placebo.

3. The CADTH re-analysis of the sponsor-submitted cost-utility analysis indicated that, at the submitted list price, ofatumumab would not be cost-effective at a $50,000 per quality-adjusted life-year (QALY) as other therapies provided additional benefit at a lower cost to the health system. As a first-line therapy, ofatumumab also would not be considered cost-effective at a $50,000 per QALY threshold compared with only interferons, dimethyl fumarate, glatiramer acetate, teriflunomide, ocrelizumab, and best supportive care (BSC).

Discussion Points

- There is no evidence to support a potential benefit of ofatumumab when used in combination with other DMTs for RRMS. Concomitant administration of such treatments was not permitted in patients enrolled in the ASCLEPIOS studies.
- CDEC discussed that patients in the ASCLEPIOS I and II trials were required to have documented disease activity at enrolment, and the trials excluded patients who had MS for more than 10 years with an EDSS score of 2 or less; therefore, results of the studies may not be generalizable to this patient population.
- CDEC discussed that although a change in EDSS score is an accepted measure of disability progression in patients with RRMS, there is no consensus on when to discontinue treatment with a DMT based on EDSS score.
- When considering negotiated list prices, there is no compelling evidence to support a price premium for ofatumumab over other monoclonal antibody DMTs. Therefore, to ensure it is cost-effective as a second-line therapy, it should not cost more than the lowest cost DMT with similar efficacy. As a first-line therapy, a price reduction would be required to ensure cost-effectiveness versus BSC and glatiramer acetate, as there is significant uncertainty that ofatumumab provides sufficient health gains to justify its cost at a $50,000 per QALY threshold.

Background

Ofatumumab has a Health Canada indication for the treatment of adult patients with RRMS with active disease defined by clinical and imaging features. Ofatumumab is a human monoclonal antibody. It is available as a solution for injection; the Health Canada–recommended dose is 20 mg administered by subcutaneous injection as follows:

- initial weekly dosing at weeks 0, 1, and 2, followed by
- subsequent monthly dosing starting at week 4.

Summary of Evidence Considered by CDEC

The committee considered the following information prepared by CADTH: a systematic review of randomized controlled trials of ofatumumab, 1 ITC submitted by the sponsor, and a critique of the sponsor's pharmacoeconomic evaluation. The committee also considered input from a clinical expert with experience in treating patients with RRMS, and patient group–submitted information about outcomes and issues important to patients.

Summary of Patient Input

One patient group submission was received for this review, which was authored by the Multiple Sclerosis Society of Canada. Patient perspectives were obtained from an online survey. The following is a summary of key input from the perspective of the patient group:

- Depending on the type and severity of the symptom, an individual's quality of life can be greatly impacted. Living with MS creates issues with employment due to relapses, symptoms, medication side effects, and disability progression. MS also creates a barrier to education, physical activity, family commitments, interpersonal relationships, and social and recreational life. MS symptoms that have a detrimental impact on patients' lives include fatigue, difficulty walking, visual impairment, cognitive difficulties, depression, bladder problems, pain, issues with balance, sexual dysfunction, spasticity, tremor, weakness, and difficulties with speaking and swallowing.
- The lives of caregivers are also greatly impacted by MS as they play an instrumental role in the overall care and management plan of the people living with the disease.
- There is a growing number of DMTs with varied forms of administration, dosing schedules, and decreased monitoring requirements — factors that are consistently identified as priorities for patients when selecting a DMT. Patients place high value

in having a choice to select the administration, dosing schedule, side-effect profile, and level of medication monitoring that best fit their lifestyle and personal preference and are looking for a treatment that would result in fewer relapses requiring hospitalization, decrease work absenteeism, and which allows them to remain active within their social networks.

Clinical Trials

The systematic review included 2 clinical studies, ASCLEPIOS I and II, which were identically designed. They were randomized, double-blind, double-dummy, active comparator–controlled, parallel-group, multi-centre trials with adaptive design features (flexible duration) of patients with relapsing MS (RMS).

Patients enrolled in the 2 studies had a diagnosis of RMS (95% with RRMS and 5% with secondary progressive MS), had mild to moderate disease (mean EDSS score was 2.9 to 3.0), were neurologically stable within 1 month before randomization, and had recent (1 year to 2 years) documentation of disease activity based on relapses and/or imaging features. The ASCLEPIOS I and II studies randomized a total of 927 and 955 patients, respectively, at a 1:1 ratio to 1 of 2 treatment groups: ofatumumab or teriflunomide. The ofatumumab group received subcutaneous injections of ofatumumab (20 mg) administered on study day 1, 7, 14, and month 1, then every 4 weeks until the end of the study. Patients in the teriflunomide group were treated with oral teriflunomide (14 mg) once daily. Between 58.9% and 61.8% of patients in the 2 studies had prior experience with any MS DMT at baseline. Overall, 10.3% and 17.5% of patients randomized to the ofatumumab and teriflunomide groups, respectively, withdrew from the ASCLEPIOS I study. In the ASCLEPIOS II study, 17.3% and 17.7% of patients randomized to the ofatumumab and teriflunomide groups, respectively, withdrew from study.

Overall, the ASCLEPIOS studies were well conducted, although subject to certain limitations. Key limitations to the internal validity of the 2 studies include differential frequencies of adverse events and discontinuation rates, missing data for health-related quality of life (HRQoL) outcomes and the Work Productivity and Activity Impairment Questionnaire: Multiple Sclerosis (WPAI:MS), and high concomitant use of systemic steroids, which might have contributed to the uncertainty and inconsistency of findings between the 2 trials. The duration of the trials also was likely too short to obtain meaningful results in changes in mobility, cognitive function, and even disability, as well as long-term safety as the treatment of MS is life-long.

Outcomes

Outcomes were defined a priori in CADTH's systematic review protocol. Of these, the committee discussed the following:

- Relapses: ARR was defined as the number of confirmed MS relapses in a year. A confirmed relapse was defined as the appearance of a new neurological abnormality or worsening of previously stable or improving pre-existing neurological abnormality, separated by at least 30 days from onset of a preceding clinical demyelinating event, present for at least 24 hours, must have occurred in the absence of fever or infection, and be accompanied by a clinically relevant change in the EDSS score (increase of ≥ 0.5 points on the EDSS score or an increase of 1 point on 2 functional system scores or 2 points on 1 functional system score, excluding changes involving the bowel and bladder or cerebral functional systems, compared to the previous available rating). Confirmation of MS relapse and severity grading was based on the EDSS score (provided by the Independent EDSS rater). A minimally important difference (MID) for the ARR was not identified.
- MRI outcomes (number of Gd-enhancing T1 lesions per scan, number of new or enlarging T2 lesions per year): Gd-enhancing lesions are useful for identifying active inflammation, whereas the occurrence of T2 lesions requires interpretation based on a comparison with the number of T2 lesions observed in previous scans. MRI criteria to predict treatment response have been reported with sensitivity ranging from 24% to 71% and specificity of 71% to 97%. A MID has not been identified for these outcomes.
- [redacted]

- Disability-related outcomes (time to 3-month confirmed disability worsening [3mCDW], 6-month CDW [6mCDW], and 6-month confirmed disability improvement (6mCDI). The disability worsening outcomes were defined as an EDSS score increase from baseline for at least 3 months or 6 months. Criteria for disability worsening differed based on total EDSS score at baseline. To be considered as disability worsening, an EDSS score of 0, 1 to 5, or 5.5 or greater at baseline needed to increase by at least 1.5, 1.0, or 0.5, respectively.

The primary outcome in both ASCLEPIOS trials was ARR, defined as the number of confirmed MS relapses in a year. The following imaging outcomes were key secondary outcomes in the 2 trials: number of Gd-enhancing T1 lesions per scan, number of new or enlarging T2 lesions per year relative to baseline.

Efficacy

The primary analysis evaluated the superiority of ofatumumab 20 mg over teriflunomide 14 mg in terms of ARR, which was met in both trials. In the ASCLEPIOS I trial, the adjusted ARR in patients in the ofatumumab and teriflunomide treatment groups was 0.11 (95% CI, 0.09 to 0.14) and 0.22 (95% CI, 0.18 to 0.26), respectively. This corresponded to a relative rate reduction of 50.5% based on an ARR ratio of 0.50 (95% CI, 0.37 to 0.65; P < 0.001), in favour of ofatumumab. Similarly, in the ASCLEPIOS II trial, the adjusted ARR in patients in the ofatumumab and teriflunomide treatment groups was 0.10 (95% CI, 0.08 to 0.13) and 0.25 (95% CI, 0.21 to 0.30), respectively. This corresponded to a relative rate reduction of 58.5% based on an ARR ratio of 0.42 (95% CI, 0.31 to 0.56; P < 0.001), in favour of ofatumumab.

Ofatumumab demonstrated superiority to teriflunomide for the measures of T1 and T2 lesions. Patients in the ofatumumab groups exhibited fewer Gd-enhancing T1 lesions per scan and fewer new or enlarging T2 lesions per year relative to baseline than patients in the teriflunomide treatment groups in both trials. In the ASCLEPIOS I trial, the adjusted mean number of Gd-enhancing T1 lesions per scan was 0.01 lesions (95% CI, 0.01 to 0.02) for the ofatumumab group, and 0.45 lesions (95% CI, 0.36 to 0.58) for the teriflunomide group. The results were similar in the ACLEPIOS II trial, in which 0.03 lesions (95% CI, 0.02 to 0.05) were reported in the ofatumumab group and 0.51 lesions (95% CI, 0.40 to 0.66) in the teriflunomide group. The treatment group difference corresponded to a relative rate reduction of 97.5% (rate ratio = 0.03; 95% CI, 0.01 to 0.05) and 93.8% (rate ratio = 0.06; 95% CI, 0.04 to 0.10) in the ASCLEPIOS I and II trials, respectively, in favour of ofatumumab in both studies (P < 0.001). The difference between the ofatumumab and teriflunomide groups for the mean rate of new or enlarging T2 lesions per year was 0.18 lesions (95% CI, 0.15 to 0.22; P < 0.001) in the ASCLEPIOS I trial and 0.15 lesions (95% CI, 0.13 to 0.19; P < 0.001) in the ASCLEPIOS II trial, both in favour of ofatumumab.

[redacted]

The 3mCDW, 6mCDW, and 6mCDI outcomes were analyzed in a pooled dataset including all patients in the ASCLEPIOS I and II trials. The between-treatment comparison of ofatumumab and teriflunomide (pooled analysis) in time to 3mCDW corresponded to a risk reduction of 34.4% or a hazard ratio of 0.66 (95% CI, 0.50 to 0.86; P = 0.002), in favour of ofatumumab. This was consistent with the results in the individual studies. Similarly, time to 6mCDW corresponded to a risk reduction of 32.5% or a hazard ratio of 0.68 (95% CI, 0.50 to 0.92; P = 0.012) in favour of ofatumumab in the pooled analysis. However, for the individual studies, a statistically significant difference was found in the ASCLEPIOS I trial (hazard ratio = 0.61; 95% CI, 0.40 to 0.93) but not in the ASCLEPIOS II trial (hazard ratio = 0.76; 95% CI, 0.49 to 1.17), due perhaps to a relatively smaller effect size (24% reduction) and lack of precision as a

result of high proportion of earlier discontinuations (17%) in this trial. No difference between groups was observed for 6mCDI in the pooled analysis (hazard ratio = 1.35; 95% CI, 0.95 to 1.92; P = 0.094), which was consistent with the results of the individual trials.

Subgroup analyses conducted in the 2 pivotal studies that were of interest to the CADTH review included age (≤ 40 years or > 40 years), number of relapses in the previous 2 years (< 2 or ≥ 2), prior treatment experience (treatment experience versus naive), RMS subtype (RRMS versus secondary progressive MS), and disease severity (EDSS > 3.5 or ≤ 3.5). The effect on ARR was generally consistent across all the subgroups in both trials. For the effect on CDW (3mCDW and 6mCDW), the subgroup results revealed that the treatment effect was potentially more evident in younger patients (≤ 40 years old) or patients free of Gd-enhanced T1 lesions at baseline. The treatment effect on CDW appeared to be similar regardless of disease severity, number of relapses in the previous 2 years (< 2 or ≥ 2), or prior treatment experience.

Harms (Safety)

No deaths were reported during the treatment period of the ASCLEPIOS I and II trials. The majority of patients reported at least 1 treatment-emergent adverse event (82.2% versus 82.3% in the ASCLEPIOS I trial and 85.0% versus 86.1% in the ASCLEPIOS II trial, for the ofatumumab versus teriflunomide treatment groups, respectively). The most commonly reported adverse events were injection-related reactions, nasopharyngitis, headache, and upper respiratory tract infections. In both studies, injection site reactions and a decrease in blood immunoglobulin M were reported in a greater proportion of patients in the ofatumumab treatment groups than the teriflunomide groups. Alopecia and diarrhea were more common in patients in the teriflunomide than ofatumumab groups. Additionally, injection-related reactions were reported by a greater proportion of patients in the ofatumumab treatment group than teriflunomide group in the ASCLEPIOS II trial, as were upper respiratory tract infections in the ASCLEPIOS I trial.

Serious adverse events were reported by 7.6% to 10.3% of patients in the treatment groups of both studies, but the frequency of individual serious adverse events was low. The proportion of patients who stopped treatment due to adverse events was low, ranging from 5.2% and 5.8% of patients across the 2 pivotal trials. The most common adverse events leading to treatment discontinuation was a decrease in blood immunoglobulin M, which occurred in 2.2% and 1.9% of patients in the ofatumumab groups and 0.6% and 0.6% in the teriflunomide groups of the ASCLEPIOS I and II trials, respectively.

Regarding notable harms identified in the CADTH review protocol, injection-related reactions were reported among 13.9% to 24.7% of patients and reductions in serum immunoglobulins (specifically, decrease in blood immunoglobulin M) were reported in 1.7% to 6.2% of patients in the ASCLEPIOS I and II trials. Both these events were more common among patients in the ofatumumab treatment groups than the teriflunomide treatment groups. Other notable harms reported in the 2 studies included malignancies, neutropenia, decreased blood immunoglobulin G, and lymphopenia. Each of these events was reported in 2.4% or less of patients in any treatment group, with no major differences between treatment groups.

Indirect Treatment Comparisons

One sponsor-submitted ITC was included in this review. The ITC consisted of a network meta-analysis (NMA) of ofatumumab and other DMTs for the treatment of adult patients (≥ 18 years) with relapsing forms of MS. The following outcomes were included: ARR, 3-month CDP (CDP-3), and CDP-6. The NMA approach used by the authors of the ITC was based on the evidence synthesis techniques described by the NICE Decision Support Unit Technical Support Document 2.

The results from the indirect comparisons showed that ofatumumab, administered subcutaneously, is likely to be as effective as the other monoclonal antibody DMTs (i.e., alemtuzumab, natalizumab, cladribine, and ocrelizumab) for ARR, and appears to be associated with an improvement when compared to IFNB, teriflunomide, glatiramer, dimethyl fumarate, and fingolimod. For CDP-3, ofatumumab is likely as effective as ocrelizumab, alemtuzumab, natalizumab, IFNB, dimethyl fumarate, and cladribine, and superior to teriflunomide, IFNB, glatiramer acetate, fingolimod, and placebo. For CDP-6, ofatumumab is likely as effective as ocrelizumab, alemtuzumab, natalizumab, IFNB, dimethyl fumarate, cladribine, and fingolimod, and superior to teriflunomide and placebo.

Limitations of the ITC stemmed from the heterogeneity in trial designs, including the varied definition of relapse, time to CDW or progression (CDP-3 or CDP-6), different study durations, and the relatively sparse network compared to the total number of included treatments. As with any Bayesian NMA that uses non-informative priors, the effect estimates might be less precise, especially when there is between study heterogeneity in a sparse network for each of the 3 study outcomes; this is more apparent when considering

the node for ofatumumab, which only has its comparison against teriflunomide in the 2 ASCLEPIOS studies. Although sensitivity analyses alleviate concerns of bias in this area, some older trials were included and might have elevated placebo-arm relapse rates (i.e., elevated baseline risk), which also creates issues in the heterogeneity and applicability of the results.

Cost and Cost-Effectiveness

Ofatumumab is available as a 20 mg/0.4 mL subcutaneous injection. Based on the recommended dosing at the start of treatment, a 20 mg dose of ofatumumab is given at initiation and then again at weeks 1, 2, and 4. Within the economic model, the sponsor assumed that ofatumumab is subsequently given monthly, although it was given every 4 weeks within the ASCLEPIOS clinical trials. The cost for ofatumumab is $2,333.33 per 20 mg injection. Based on monthly administration, the annual cost is between $32,667 and $35,000 in year 1, depending on when the first maintenance dose is taken, and $28,000 in subsequent years.

The sponsor submitted a cost-utility analysis based on a cohort multi-state Markov model that was developed in Microsoft Excel to simulate the disease course of RRMS patients receiving treatment with ofatumumab versus other DMTs including ocrelizumab, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), peginterferon beta-1a (Plegridy), glatiramer acetate (Copaxone, Glatect), teriflunomide (Aubagio), dimethyl fumarate (Tecfidera), natalizumab (Tysabri), cladribine (Mavenclad), fingolimod (Gilenya), and alemtuzumab (Lemtrada). BSC was also included as a comparator. The model was based on patients transitioning across EDSS states 0 to 9 and death. Patients with relapsing forms of MS entered the model in a state between EDSS 0 and 6 inclusive, based on the pooled patient population of the ASCLEPIOS I and II trials. In each cycle, patients could transition between EDSS states or enter the absorbing death state. Relative treatment effects for ARRs and CDP for ofatumumab versus other DMTs and BSC were derived from a sponsor-conducted ITC. Cycle length was 1 year, with half-cycle correction applied.

CADTH identified the following key limitations with the sponsor's pharmacoeconomic analysis:

- The sponsor assumed ARRs were dependent on a patient's EDSS state. Based on the input from the clinical expert consulted for the review, the CADTH base case assumed that ARRs were independent of EDSS as per the sponsor's scenario analysis.
- The sponsor assumed the relative effectiveness from short-term clinical trials would be maintained for the full time horizon of the model (65 years).
- The sponsor assumed that a significant proportion of patients would improve each year in terms of their EDSS state, with a higher proportion of patients receiving ofatumumab improving.
- The sponsor outlined 2 definitions of CDP when analyzing treatment efficacy in their NMA. One definition was based on the predefined criteria from the ASCLEPIOS trials. The other was a post hoc analysis. The predefined criteria definition was considered more relevant.

In the CADTH base case, ARRs were based on disease duration rather than EDSS score; a treatment waning effect was applied; all first-line, second-line, and third-line therapies were included; improvement in EDSS was removed; and effect estimates based on predefined CDP definitions were used. When compared to first-line therapies only, ofatumumab was extendedly dominated by ocrelizumab and glatiramer acetate (i.e. more QALYs would be generated at lower costs by a mix of ocrelizumab and glatiramer use). A 45.2% price reduction is required for ofatumumab to be cost-effective at a $50,000 per QALY threshold. When compared to first-line, second-line, and third-line therapies, ofatumumab was also dominated by alemtuzumab and cladribine. In this scenario, a 45.4% price reduction is required for ofatumumab to be cost-effective at a $50,000 per QALY threshold.

CDEC Members

Dr. James Silvius (Chair), Dr. Ahmed Bayoumi, Dr. Sally Bean, Dr. Bruce Carleton, Dr. Alun Edwards, Mr. Bob Gagne, Dr. Ran Goldman, Dr. Allan Grill, Mr. Allen Lefebvre, Dr. Kerry Mansell, Ms. Heather Neville, Dr. Danyaal Raza, Dr. Emily Reynen, Dr. Yvonne Shevchuk, and Dr. Adil Virani.

January 20, 2021, Meeting

Regrets

None

Conflicts of Interest

None